As filed with the United States Securities and Exchange Commission on May 13, 2020

**Registration No. 333-**

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM F-1 REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

# **LEGEND BIOTECH CORPORATION**

(Exact name of Registrant as specified in its charter)

Cayman Islands (State or other jurisdiction of incorporation or organization) 2834 (Primary Standard Industrial Classification Code Number) Legend Biotech Corporation 2101 Cottontail Lane

Not Applicable (I.R.S. Employer Identification Number)

Somerset, NJ 08873 (732) 317-5050 (Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Yuan Xu, Ph.D. Chief Executive Officer Legend Biotech Corporation 2101 Cottontail Lane Somerset, NJ 08873 (732) 317-5050

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Divakar Gupta, Esq. Richard C. Segal, Esq. Mark Ballantyne, Esq. Cooley LLP 55 Hudson Yards New York, NY 10001 (212) 479-6000 Copies to: Robert W. Phillips, Esq. Will H. Cai, Esq. Michael Yu, Esq. Patrick Loofbourrow, Esq. Cooley LLP c/o 3501 35/F, Two Exchange Square 8 Connaught Place Central, Hong Kong +852 3758 1200

Richard D. Truesdell, Jr., Esq. Yasin Keshvargar, Esq. Davis Polk & Wardwell LLP 450 Lexington Avenue New York, NY 10017 (212) 450-4000

Approximate date of commencement of proposed sale to the public: as soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. 🗆

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards<sup>+</sup> provided pursuant to Section 7(a)(2)(B) of the Securities Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

#### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(2)(3)	Amount of Registration Fee	
Ordinary shares, par value \$0.0001 per share(1)	\$100,000,000	\$12,980	
(1) American denocitary shares or ADSs issuable upon denosit of ordinary shares registered hereby will be registered under a separate registration statement on Form F-6 (Registration			

(1) American depositary shares, or ADSs, issuable upon deposit of ordinary shares registered hereby will be registered under a separate registration statement on Form F-6 (Registration No. 333- ). Each ADS represents ordinary shares.

(2) Includes the aggregate offering price of additional ordinary shares represented by ADSs that the underwriters have the option to purchase solely to cover over-allotments, if any. Also includes ordinary shares initially offered and sold outside the United States that may be resold from time to time in the United States either as part of their distribution or within 40 days after the later of the effective date of this registration statement and the date the shares are first bona fide offered to the public. These ordinary shares are not being registered for the purpose of sales outside the United States.

(3) Estimated solely for the purpose of determining the amount of registration fee in accordance with Rule 457(o) under the Securities Act of 1933.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS (Subject to Completion) Issued May 13, 2020

# American Depositary Shares

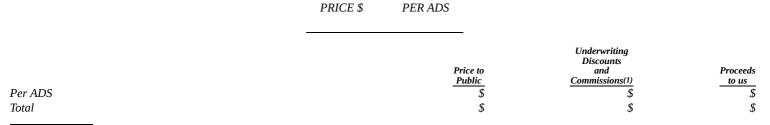


This is an initial public offering of American depositary shares, or ADSs, representing ordinary shares of Legend Biotech Corporation.

We are offeringADSs. Each ADS representsordinary shares, \$0.0001 par value per share. We anticipate the initial public offeringprice per ADS will be between \$and \$.

Prior to this offering, there has been no public market for the ADSs or our ordinary shares. We have applied to list the ADSs on the Nasdaq Global Market, or Nasdaq, under the symbol "LEGN."

We are an "emerging growth company" and a "foreign private issuer" under applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company" and "Prospectus Summary—Implications of Being a Foreign Private Issuer and a Controlled Company" for additional information.



(1) See "Underwriters" for a description of the compensation payable to the underwriters.

We have granted the underwriters the right to purchase up to an additional underwriting discounts and commissions.

ADSs to cover over-allotments at the initial public offering price, less

# Investing in the ADSs involves risks. See "Risk Factors" beginning on page 13.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Upon the completion of this offering, we will be a "controlled company" as defined under the Nasdaq Stock Market Rules because our parent, GenScript Biotech Corporation, or GenScript, will beneficially own % of our ordinary shares representing % of the voting power of our total issued and outstanding share capital immediately after the completion of this offering, assuming the underwriters do not exercise their over-allotment option to purchase additional ADSs.

The underwriters expect to deliver the ADSs against payment in New York, New York on , 2020.

# MORGAN STANLEY

J.P. MORGAN

**JEFFERIES** 

, 2020

# TABLE OF CONTENTS

PROSPECTUS SUMMARY	1	PRINCIPAL SHAREHOLDERS	176
RISK FACTORS	13	CERTAIN RELATIONSHIPS AND RELATED PARTY	
SPECIAL NOTE REGARDING FORWARD-LOOKING		TRANSACTIONS	177
STATEMENTS	89	DESCRIPTION OF SHARE CAPITAL	181
MARKET, INDUSTRY AND OTHER DATA	91	DESCRIPTION OF AMERICAN DEPOSITARY SHARES	191
USE OF PROCEEDS	92	SHARES AND ADSS ELIGIBLE FOR FUTURE SALE	207
DIVIDEND POLICY	94	TAXATION	209
CAPITALIZATION	95	<u>UNDERWRITERS</u>	215
DILUTION	96	EXPENSES RELATED TO THIS OFFERING	227
ENFORCEABILITY OF CIVIL LIABILITIES	98	LEGAL MATTERS	228
SELECTED CONSOLIDATED FINANCIAL DATA	99	EXPERTS	229
MANAGEMENT'S DISCUSSION AND ANALYSIS OF		WHERE YOU CAN FIND ADDITIONAL INFORMATION	230
FINANCIAL CONDITION AND RESULTS OF		INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1
<u>OPERATIONS</u>	100		
BUSINESS	112		
MANAGEMENT	168		

No dealer, salesperson or other person is authorized to give any information or to represent as to anything not contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell, and we are seeking offers to buy, only the ADSs offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or any sale of the ADSs.

Neither we nor the underwriters have done anything that would permit this offering or the possession or distribution of this prospectus or any filed free writing prospectus in any jurisdiction where other action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus filed with the U.S. Securities and Exchange Commission, or SEC, must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus or any filed free writing prospectus outside of the United States.

Until , 2020 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

i

## PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements appearing elsewhere in this prospectus. This summary does not contain all of the information that may be important to you in making your investment decision. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks of investing in the ADSs discussed under "Risk Factors," before deciding whether to invest in the ADSs.

#### Overview

We are a global, clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 650 employees in the United States, China and Europe, our differentiated technology, global development and manufacturing strategy and expertise provide us with the ability to generate, test and manufacture next-generation cell therapies targeting indications with high unmet needs.

Our lead product candidate, LCAR-B38M/JNJ-4528, is a chimeric antigen receptor, or CAR, T cell therapy we are jointly developing with our strategic partner, Janssen Biotech, Inc., or Janssen, for the treatment of multiple myeloma, or MM. We are developing LCAR-B38M/JNJ-4528 as a potentially improved therapy for MM. LCAR-B38M refers to the product candidate being studied in China, and JNJ-68284528, or JNJ-4528, refers to the product candidate being studied in the rest of the world. Our clinical results achieved to date demonstrate that LCAR-B38M/JNJ-4528 has the potential to deliver deep and durable anti-tumor responses in relapsed and refractory multiple myeloma, or RRMM, patients with a manageable safety profile.

In December 2019, we reported updated data from a Phase 1 clinical trial, which we refer to as LEGEND-2, of LCAR-B38M in China, in 74 patients with RRMM across four independent sites. For LEGEND-2, the primary endpoint was the occurrence of treatment-related adverse events and the secondary endpoint was anti-myeloma responses to LCAR-B38M cell treatment. Patients treated with LCAR-B38M had at least 24 months of median follow-up and achieved an overall response rate, or ORR, of 88 percent, with a complete response, or CR, rate ranging from 74 to 82 percent, depending on the site. In the largest site of 57 patients, median overall survival, or mOS, was 36.1 months as of July 31, 2019. Expected adverse events were reported in all patients in LEGEND-2 with over 90 percent reporting fever and cytokine release syndrome, or CRS. Over 82 percent of patients had Grade 1 or Grade 2 CRS which was managed with standard treatments and, in all but two of the 74 patients, CRS was resolved. One patient died of a CAR-T related toxicity as a result of CRS and tumor lysis syndrome. A second patient died from a potential pulmonary embolism and acute coronary syndrome, which was considered unrelated to treatment by the investigator.

The Phase 1b/2 registrational trial of JNJ-4528 in RRMM patients in the United States and Japan, which we refer to as CARTITUDE-1, has completed enrollment of the Phase 2 portion in the United States. For the Phase 1b portion of the CARTITUDE-1 trial, the primary endpoint was the incidence and severity of adverse events and secondary endpoints included efficacy results as measured with the International Myeloma Working Group uniform response criteria for MM, duration of and timing to response, progression-free survival, overall survival, pharmacokinetic and pharmacodynamic markers, and presence of anti-JNJ-4528 antibodies. All 29 patients treated with JNJ-4528 from the Phase 1b portion achieved a response, with an ORR of 100 percent. As of April 20, 2020, with a median follow-up of 11.5 months, 25 of 29 patients, or 86 percent, achieved a stringent complete response, or sCR. The 9-month progression free survival rate was 86 percent and 22 of the 29 patients remained alive and progression free at the time of data cut-off. The most common adverse events reported in CARTITUDE-1 have been CRS and cytopenias, which have been manageable with standard interventions used by hematologists. As of April 29, 2020, CRS was reported in 93 percent of patients, most of which were mild and only 7 percent of which were clinically considered to be Grade 3 or higher. One patient in CARTITUDE-1 died as a result of CRS, one patient died due to acute myeloid leukemia that occurred during the trial, which was

considered unrelated to treatment by the investigator, and one patient died due to progressive disease. Overall, the safety profile of LCAR-B38M/JNJ-4528 has been consistent with the safety profile of other CAR-T cell therapies in hematologic malignancies. We anticipate that data from the Phase 2 portion of CARTITUDE-1 will be presented at a major medical conference in the second half of 2020. JNJ-4528 has been granted breakthrough therapy designation and orphan drug designation by the U.S. Food and Drug Administration, or FDA, and Priority Medicines, or PRIME, designation, enabling accelerated assessment, by the European Medicines Agency, or EMA. We anticipate that a biologics license application, or BLA, will be submitted to the FDA, and a market authorization application, or MAA, will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020.

We believe that our fully integrated approach will enable us to rapidly expand the use of CAR-T cell therapies. We are leveraging our in-house antibody generation, coupled with our CAR-T specific functional screening capability, to add one or multiple tumor antigen binding sites on T cells. We seek to bridge the gap between discovery research and patients by leveraging our relationships with clinicians and their ability to conduct investigator-initiated clinical trials in top-tier hospitals in China without a formal Investigational New Drug, or IND, process as part of the encouragement of innovation by the National Medical Products Administration, or NMPA. We work with the clinicians and hospitals to conduct these trials in accordance with international standards to support future global regulatory filings and partnerships. This strategy enables us to rapidly advance product candidates to patient populations with large unmet needs. To satisfy anticipated commercial demand in various geographies, we are building manufacturing facilities in the United States, Europe and China. Furthermore, we will seek to make our product candidates, if approved, widely available to cancer patients throughout the United States, Europe and Asia independently or through partnerships.

We have established a global collaboration with Janssen for LCAR-B38M/JNJ-4528, pursuant to which we share equally the development, production and commercialization costs and profits or losses in all areas other than mainland China, Hong Kong, Macau and Taiwan, or Greater China, where we assume 70 percent of development, production and commercialization costs and retain or bear 70 percent of pre-tax profits or losses. We received an upfront payment of \$350.0 million from Janssen in 2018, and to date, we have received four milestone payments totaling \$110.0 million.

# **Our Pipeline**

We have built our company around overcoming the challenges associated with CAR-T cell therapy development through deploying our fullyintegrated, global cell therapy capabilities including in-house expertise on early-stage discovery, efficient clinical translation, manufacturing and commercialization to bring our pipeline of next-generation CAR-T product candidates to patients.



"AML= acute myeloid leukemia, BCMA= B-cell maturation antigen, DLBCL= diffuse large B-cell lymphoma, FL= follicular lymphoma, HIV= human immunodeficiency virus, MCL= mantle cell lymphoma, NHL= non-Hodgkin lymphomas, R/R MM= relapsed or refractory multiple myeloma, RoW= Rest of World, SLL=small lymphocytic lymphoma, TCL=T-cell lymphoma

# **Background of CAR-T Cell Therapies**

CAR-T cell therapy is a form of cancer immunotherapy, whereby a patient's T cells are engineered to express a CAR that recognizes and binds to tumor cell surface antigens, resulting in their activation to target cancer cells for destruction. CAR-T cell therapy has emerged as a revolutionary and potentially curative therapy for patients with certain hematologic cancers. In 2017, the FDA approved the first two CAR-T cell therapies, Kymriah and Yescarta, after these products demonstrated strong efficacy in select relapsed or refractory B cell malignancies.

The development of CAR-T cell therapies has required notable advancements across the spectrum to overcome several challenges, including selecting the ideal tumor antigen target, engineering a CAR construct that will lead to potent and selective killing of tumor cells, the lack of validated preclinical models that are predictive of safety and efficacy in humans and the ability to manufacture cell therapies with the high quality and reproducibility required for pharmaceutical products. In addition, meeting commercial demand at both a regional and global scale remains a challenge.

# **Our Programs**

Our lead product candidate, LCAR-B38M/JNJ-4528, is an autologous CAR-T cell therapy that targets the B-cell maturation antigen, or BCMA, which is a highly expressed protein in a number of hematologic malignancies including MM. MM is a highly aggressive disease representing approximately 10 percent of all hematologic malignancies and 20 percent of deaths of hematologic malignancies worldwide. Despite the fact that there are multiple existing therapies, MM remains incurable and patients eventually relapse and become refractory to treatment.

LCAR-B38M/JNJ-4528 is a structurally differentiated autologous CAR-T cell therapy that targets BCMA and we believe that LCAR-B38M/JNJ-4528 has the potential to transform the treatment of MM. We used single-domain antibodies against BCMA that we isolated from llamas to design the LCARB38M/JNJ-4528 CAR construct. Two BCMA binding domains, VHH1 and VHH2, were then linked to a T cell costimulatory domain from the 4-1BB protein, also known as CD137, and the CD3 zeta-chain to form the CAR construct. Anti-tumor activity of LCAR-B38M/JNJ-4528 has been observed in non-clinical studies.

We are enrolling up to 60 patients in a Phase 2 registrational trial of LCAR-B38M in RRMM patients in China, which we refer to as CARTIFAN-1, and conducting CARTITUDE-1 Phase 1b/2 registrational trial of JNJ-4528 in RRMM patients in the United States and Japan. Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, we anticipate that a BLA will be submitted to the FDA and an MAA will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020. We also intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China and the data from CARTITUDE-1 in support of a regulatory submission in Japan in 2021.

In addition to the trials we are conducting to support our BLA submission, we are conducting multiple clinical trials to evaluate LCAR-B38M/JNJ-4528 as an earlier line of therapy for MM as well as a comparison of the treatment with standard triplet therapy in Revlimid-refractory MM.

In addition to LCAR-B38M/JNJ-4528, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including Non-Hodgkins Lymphoma, or NHL, Acute Myeloid Leukemia, or AML, and T cell Lymphoma, or TCL, of which the first two are currently in investigator-initiated Phase 1 clinical trials in China. We are also developing an allogeneic CAR-T product candidate targeting CD20 for the treatment of NHL, which is currently in an investigator-initiated Phase 1 clinical trial in China. Furthermore, we have several product candidates in early preclinical and clinical development for the treatment of solid tumors as well as infectious diseases.

# **Our Strategy**

Our goal is to become a worldwide leader for CAR-T and related cell therapies in treating hematologic malignancies, solid tumors and infectious diseases. Our strategy to achieve this goal is as follows:

- Advance LCAR-B38M/JNJ-4528 through registrational trials and obtain approval for the treatment of RRMM globally
- Rapidly advance our pipeline by leveraging our global clinical development strategy
- Maintain and expand our global leadership in the cell therapy field
- Expand our manufacturing capabilities
- Establish ourselves as a preferred global partner

# Our Team

We have assembled a team of over 650 employees across the United States, China and Europe with broad experience in biopharmaceutical drug discovery, development and commercialization. We are led by Yuan Xu, Ph.D., our Chief Executive Officer, who previously served in senior roles in discovery, development and commercialization at Merck, Gilead, Novartis, Amgen, Chiron, GlaxoSmithKline and Genentech. Ying Huang, Ph.D., our Chief Financial Officer, was most recently a Managing Director and Head of Biotech Equity Research at BofA Securities, Inc., and earlier in his career, he was a Principal Scientist at Schering-Plough (now Merck).

## **Risk Factors**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. Some of these risks are:

- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will need additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.
- If we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of the ADSs may be materially and adversely affected.
- All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our proprietary, next-generation CAR-T cell preparation technologies, our modular approach for CAR-T and our manufacturing platform for our CAR-T product candidates, represent emerging approaches to cancer treatment that face significant challenges and hurdles.
- Our future success is highly dependent on the regulatory approval of LCAR-B38M/JNJ-4528 and our other pipeline programs. All of our product candidates will require significant preclinical study and clinical trial before we can seek regulatory approval for and launch a product commercially.
- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining clinical trial and marketing approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when, or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.
- The COVID-19 coronavirus could adversely impact our business, including our clinical trials.
- As a company partly based outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.
- We depend upon our existing collaboration partner, Janssen, and other third parties, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our product candidates.
- If we are unable to obtain and maintain patent protection for our technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

# Implications of Being an Emerging Growth Company

As a company with less than \$1.07 billion in revenue for the last fiscal year, we qualify as an "emerging growth company" pursuant to the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation

requirement under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, related to the assessment of the effectiveness of the emerging growth company's internal control over financial reporting. We have elected to take advantage of such exemptions.

We will remain an emerging growth company until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our ADSs that are held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

# Implications of Being a Foreign Private Issuer and a Controlled Company

Upon completion of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

Upon the completion of this offering, we will be a "controlled company" as defined under the Nasdaq Stock Market Rules because our parent, GenScript will beneficially own % of our ordinary shares representing % of the voting power of our total issued and outstanding shares immediately after the completion of this offering, assuming the underwriters do not exercise their over-allotment option to purchase additional ADSs. Under the Nasdaq Stock Market Rules, a "controlled company" may elect not to comply with certain corporate governance requirements, including the Nasdaq corporate governance rules requiring a board of directors to have:

- a majority of independent directors;
- an independent compensation committee; and
- an independent nominations/corporate governance committees.

Currently, we plan to utilize the "controlled company" exemptions with respect to our corporate governance practice after we complete this offering.

### **Corporate History and Information**

We are an exempted company incorporated in the Cayman Islands with limited liability. We commenced our operations in China in November 2014 as a wholly owned subsidiary of GenScript. In May 2015, we

incorporated Legend Biotech Corporation under the laws of the Cayman Islands, which became our ultimate holding company through a series of transactions.

Our principal executive offices are located at 2101 Cottontail Lane, Somerset, New Jersey 08873. Our telephone number at this address is (732) 317-5050. Our registered office in the Cayman Islands is located at 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands. Investors should submit any inquiries to the address and telephone number of our principal executive offices set forth above.

Our main website is www.legendbiotech.com. The information contained on this website is not a part of this prospectus.

"Legend Biotech," the Legend logo and other trademarks or service marks of Legend Biotech Corporation appearing in this prospectus are the property of Legend Biotech Corporation. Trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders.

## Hong Kong Stock Exchange Matters of GenScript

Under Practice Note 15 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited, this offering is deemed a "spin-off" transaction by GenScript for which GenScript requires approval by the Hong Kong Stock Exchange. On March 6, 2020, the Hong Kong Stock Exchange confirmed that GenScript may proceed with the "spin-off" transaction. Pursuant to Practice Note 15, GenScript must make available to its shareholders an "assured entitlement" to a certain portion of our ordinary shares.

As our ordinary shares are not expected to be listed on any stock exchange, GenScript intends to effect its assured entitlement distribution by providing to its shareholders a "distribution in specie," or distribution of the ADSs in kind, at a ratio of one ADS for a certain number of ordinary shares of GenScript held at the applicable record date for the distribution. The distribution will be made without any consideration being paid by GenScript's shareholders. GenScript's shareholders who are entitled to fractional ADSs, who elect to receive cash in lieu of ADSs or who are located in the United States or are U.S. persons, or who are otherwise ineligible holders, will only receive a cash alternative in the assured entitlement distribution.

GenScript currently intends to provide an assured entitlement with an aggregate value of approximately \$ million. The assured entitlement distribution will only be made if this offering is completed. The distribution in specie of ADSs by GenScript is not part of this offering and these shares will not be subject to a lock-up agreement.

# **Conventions that Apply to this Prospectus**

Unless otherwise indicated or the context otherwise requires, references in this prospectus to:

- "ADSs" are to the American depositary shares, each of which represents of our ordinary shares;
- "ADRs" are to the American depositary receipts that evidence the ADSs;
- "China" or "PRC" refers to the People's Republic of China, excluding, for the purpose of this prospectus only, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan; "Greater China" does not exclude Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan;
- "ordinary shares" are to ordinary shares of our company, par value \$0.0001 per share;
- "Renminbi" or "RMB" refers to the legal currency of the PRC;
- "Series A Preference Shares" are to the Series A preference shares, par value \$0.0001 per share; and
- "US\$," "U.S. dollars," "\$," or "dollars" are to the legal currency of the United States.



# THE OFFERING

ADSs offered by us	ADSs.
ADSs outstanding immediately after this offering	ADSs (or ADSs if the underwriters exercise their over- allotment option in full).
Ordinary shares outstanding immediately after this offering	
	ordinary shares (or ordinary shares if the underwriters exercise their over-allotment option in full).
The ADSs	Each ADS represents ordinary shares.
	The depositary will hold ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement among us, the depositary and owners and holders of ADSs from time to time.
	We do not expect to pay dividends in the foreseeable future. If, however, we declare dividends on our ordinary shares, the depositary will distribute the cash dividends and other distributions it receives on our ordinary shares after deducting its fees and expenses in accordance with the terms set forth in the deposit agreement.
	You may surrender your ADSs to the depositary for cancellation in exchange for ordinary shares. The depositary will charge you fees for any cancellation.
	We may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended.
	To better understand the terms of the ADSs, you should carefully read the "Description of American Depositary Shares" section of this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement that includes this prospectus.
Over-allotment option	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an aggregate of additional ADSs.
Use of proceeds	We expect that we will receive net proceeds of approximately million from this offering, assuming an initial public offering price of per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the clinical development of LCAR-B38M/JNJ-4528, to fund the construction of our manufacturing facilities, to fund the commercial launch, if approved, of LCAR-B38M/JNJ-4528 and the remaining amounts to fund the development of our pipeline programs, as well as for working capital and other general corporate purposes. See "Use of Proceeds" for additional information.
Lock-up	We, our officers and directors and substantially all of our existing securityholders have agreed with the underwriters not to sell, transfer or dispose of any ADSs, ordinary shares or similar securities for a period of 180 days after the date of this prospectus, subject to certain exceptions. See "Shares and ADSs Eligible for Future Sale" and "Underwriters."
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of the risks relating to investing in our ADSs. You should carefully consider these risks before deciding to invest in our ADSs.
Listing	We have applied to have the ADSs listed on The Nasdaq Global Market. The ADSs and shares will not be listed on any other stock exchange or traded on any automated quotation system.
Proposed Nasdaq Symbol	"LEGN"
Payment and settlement	The underwriters expect to deliver the ADSs against payment therefor through the facilities of the Depositary Trust Company on , 2020.
Depositary	JPMorgan Chase Bank, N.A.

The number of ordinary shares that will be issued and outstanding immediately after this offering is based on the 220,591,629 ordinary shares outstanding prior to giving effect to this offering, which consists of 200,000,000 ordinary shares outstanding as of March 31, 2020 and the conversion of all of our Series A Preference Shares into 20,591,629 ordinary shares immediately prior to the closing of this offering, and excludes:

- ordinary shares issuable upon the exercise of options outstanding as of March 31, 2020, with a weighted average exercise price of \$ per ordinary share;
- ordinary shares available for future issuance under our Share Option Scheme; and
- ordinary shares available for future issuance under our Restricted Share Unit Incentive Plan.

Except as otherwise indicated, all information in this prospectus reflects and assumes:

- no exercise of the outstanding options described above;
- no exercise of the underwriters' over-allotment option to purchase additional ADSs representing ordinary shares;
- the automatic conversion of all our Series A Preference Shares into 20,591,629 ordinary shares, which will occur automatically immediately prior to the closing of this offering, and without giving effect to any potential conversion price adjustment relating to our Series A Preference Shares described in "Description of Share Capital";

•	the	ADSs (assuming an initial public offering price of \$	per ADS, which is the midpoint of the price range set forth
	on the cover Stock Excha		e to its shareholders pursuant to the rules of the Hong Kong

• the filing and effectiveness of our Amended and Restated Memorandum and Articles of Association, which will occur immediately prior to the completion of this offering.

# SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data for the period indicated. We have derived the consolidated statement of profit or loss data for the years ended December 31, 2018 and 2019 and the consolidated statement of financial position data as of December 31, 2019 from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated financial statements are prepared and presented in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. IFRS differ in certain significant respects from U.S. generally accepted accounting principles, or U.S. GAAP. Our historical results are not necessarily indicative of results expected for future periods. You should read this section together with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

# Summary consolidated statement of profit or loss data

		Ended ıber 31,
	<u>2018</u>	2019 ls, except per
		e data)
Revenue	\$ 49,133	\$ 57,264
Other income and gains	13,901	7,125
Research and development expenses	(60,637)	(161,943)
Administrative expenses	(2,769)	(6,752)
Selling and distribution expenses	(1,160)	(25,620)
Other expenses	(2)	(221)
Finance costs	(82)	(223)
Loss before tax	(1,616)	(130,370)
Income tax expense	(1,168)	(2,602)
Loss for the year	\$ (2,784)	\$(132,972)
Attributable to:		
Equity holders of the parent	\$ (2,784)	\$(132,972)
Loss per share attributable to ordinary equity holders of the parent		
Basic	<u>\$ (0.01)</u>	\$ (0.66)
Diluted	\$ (0.01)	\$ (0.66)

#### Summary consolidated statement of financial position data

		As of December 31, 2019 (in thousands)	
		Pro Forma As	
	Actual Pro For	rma(1) Adjusted(2)	
Cash and cash equivalents	\$ 83,364	\$	
Working capital <sup>(3)</sup>	79,343		
Total assets	287,715		
Total liabilities	410,584		
Share capital	20		
Total ordinary shareholders' deficit	(122,869)		

- Gives effect to the issuance and sale of an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020 at a purchase price of \$7.792 per share for aggregate (1) gross proceeds of approximately \$160.5 million and the conversion of such shares into an aggregate of 20,591,629 ordinary shares, which will occur immediately prior to the closing of this offering.
- Gives effect to the sale of ADSs in this offering at the assumed initial public offering price of \$ per ADS, which is the midpoint of t cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Working capital is defined as total current assets minus total current liabilities. per ADS, which is the midpoint of the price range set forth on the (2)

(3)

The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, \$ each of cash and cash equivalents, working capital, total assets and total ordinary shareholders' equity (deficit) by \$ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable to us. Similarly, each increase or decrease of 1.0 million ADSs offered by us at the assumed initial public offering price would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets and total ordinary shareholders' equity (deficit) by \$ million, assuming the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

# **RISK FACTORS**

Investing in our ADSs involves a high degree of risk. Before you invest in our ADSs, you should carefully consider the risks described below together with all of the other information contained in this prospectus, including our financial statements and the related notes included elsewhere in this prospectus. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our ADSs could decline, which would cause you to lose all or part of your investment. Please also see "Special Note Regarding Forward-Looking Statements."

### Risks Related to Our Financial Position and Need for Additional Capital

# We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history and we have incurred significant net losses since our inception. Our net loss was \$133.0 million for the year ended December 31, 2019. We have funded our operations to date primarily with capital contributions from GenScript and from upfront and milestone payments from Janssen.

While we had revenue of \$57.3 million for the year ended December 31, 2019, this was attributable to our recognition of upfront and milestone payments we received from Janssen in connection with our collaboration and license agreement with Janssen, or the Janssen Agreement. We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of LCAR-B38M/JNJ-4528 and our other CAR-T cell therapy product candidates as well as to building out our manufacturing platform, cell therapy technologies and management team. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate could fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

None of our product candidates have received marketing approval, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our shareholders' deficit and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned research and development of LCAR-B38M/JNJ-4528 for the treatment of MM;
- conduct preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including ongoing and planned development of additional therapies for the treatment of TCL, NHL, AML, gastric cancer, pancreatic cancer, ovarian cancer and HIV;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;

- hire additional clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States, China, Europe and other geographies; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development, delivery and commercialization of complex autologous and allogeneic cell therapies, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our ADSs and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our ADSs could also cause you to lose all or part of your investment.

## Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. As an organization, we have not demonstrated an ability to successfully complete late-stage clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will be materially harmed.

## We will need additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.

We will require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next development and commercialization of LCAR-B38M/JNJ-4528 and our other product candidates and in connection with our

continuing operations and other planned activities. Our future capital requirements will depend on many factors, including:

- the progress, results and costs of laboratory testing, manufacturing, and preclinical and clinical development for our current product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- the development requirements of other product candidates that we may pursue;
- the timing and amounts of any milestone or royalty payments we may be required to make under future license agreements;
- the costs of building out our infrastructure, including hiring additional clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue we receive pursuant to the Janssen Agreement and the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. To date, we have not generated any revenue from product sales. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

## If we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of the ADSs may be materially and adversely affected.

Prior to the completion of this offering, as a subsidiary of Genscript, we only had limited accounting personnel and other resources with which to address internal control over financial reporting. In connection with the audits of our consolidated financial statements as of and for the year ended December 31, 2019, we and our independent registered public accounting firm identified two material weaknesses in our internal control over

financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, or PCAOB, a "material weakness" is a deficiency, or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that have been identified relate to our lack of sufficient accounting and financial reporting personnel with requisite knowledge of and experience in application of IFRS and SEC rules, and lack of financial reporting policies and procedures that are commensurate with IFRS and SEC reporting and compliance requirements. We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Internal Control Over Financial Reporting." However, we cannot assure you that these measures may fully address the material weaknesses and deficiencies in our internal control over financial reporting or that we may conclude that they have been fully remediated.

Upon completion of this offering, we will become subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404 will require that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report in our second annual report on Form 20-F after becoming a public company. In addition, once we cease to be an "emerging growth company" as such term is defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse opinion on the effectiveness of internal control over financial reporting because of the existence of a material weakness if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, after we become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. Generally speaking, if we fail to achieve and maintain an effective internal control environment, it could result in material misstatements in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our businesses, financial condition, results of operations and prospects, as well as the trading price of the ADSs, may be materially and adversely affected. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

### **Risks Related to the Development of Our Product Candidates**

# All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our lead product candidate, LCAR-B38M/JNJ-4528, is in clinical development for the treatment of MM. In collaboration with Janssen, we are currently conducting a Phase 2 trial of LCAR-B38M in RRMM patients in

China (CARTIFAN-1) and a Phase 1b/2 trial of JNJ-4528 in RRMM patients in the United States and Japan (CARTITUDE-1). In November 2019, we and our strategic partner Janssen began enrolling an aggregate of 80 patients in a Phase 2 multicohort trial of JNJ-4528 in the United States and Europe (CARTITUDE-2) in patients with MM in various clinical settings such as in early relapse patients or as a front-line therapy. In addition, the Phase 3 CARTITUDE-4 clinical trial, enrolling approximately 400 patients in the United States, Europe and Japan has been initiated. This clinical trial is comparing treatment with JNJ-4528 to treatment of standard triplet therapy in Revlimid-refractory MM. In addition to LCAR-B38M/JNJ-4528, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including NHL, AML and TCL, of which the first two are currently in investigator-initiated Phase 1 clinical trials in China. We are also developing an allogeneic CAR-T product candidate targeting CD20 for the treatment of NHL, which is currently in an investigator-initiated Phase 1 clinical trial in China. We also have several product candidates in early preclinical and clinical development for the treatment of solid tumors as well as infectious diseases. There is no assurance that these or any other future clinical trials of our product candidates will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA, the NMPA, the EMA, and the Japanese Pharmaceutical and Medical Device Agency, or PMDA, or other regulatory agencies, for any of our product candidates, with the exception of LCAR-B38M/JNJ-4528, we have not submitted an IND application to the FDA for our other current clinical-stage product candidates, which must be in effect before commencing clinical trials in the United States. There can be no assurance that the FDA will permit the IND applications for our other product candidates to go into effect in a timely manner or at all. Without an IND,

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- completing preclinical studies and receiving regulatory approvals or clearance for conducting clinical trials for our preclinical-stage programs;
- obtaining positive results in our clinical trials demonstrating efficacy, safety and durability of effect of our product candidates;
- receiving approvals for commercialization of our product candidates from regulatory authorities;
- manufacturing our product candidates at an acceptable quality and cost; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our products and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which would materially harm our business.

# Our proprietary, next-generation CAR-T cell preparation technologies, our modular approach for CAR-T and our manufacturing platform for our CAR-T product candidates, represent emerging approaches to cancer treatment that face significant challenges and hurdles.

We have concentrated our primary research and development efforts on our CAR-T cell therapies using our expertise in tumor biology and cell programming, and our future success is highly dependent on the successful development and manufacture of our CAR-T product candidates. We do not currently have any approved or commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay

development or require us to reengineer or abandon a particular product candidate. Because CAR-T cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA, the NMPA, the EMA, the PMDA and other regulatory authorities have limited experience with CAR-T therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's T cells *ex vivo* and infusing the engineered T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our product candidates;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent vector and cell manufacturing process;
- establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;
- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our CAR-T technologies and the potential side effect profile of each of our product candidates, such as potential adverse side effects related to CRS;
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of a novel therapy if we receive approval; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our CAR-T product candidates, our technology or our other product candidates in a manner that will yield products that are safe, effective, scalable or profitable.

Additionally, because our technology involves the genetic modification of patient cells *ex vivo*, we are subject to additional regulatory challenges and risks, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, only two CAR-T cell therapy products that involve the genetic modification of patient cells have been approved in the United States and the European Union, and none have been approved in China;
- genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells;
- although our viral vectors are not able to replicate, there is a risk with the use of retroviral or lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and



the FDA recommends a 15-year follow-up observation period for all patients who receive treatment using gene therapies, and we may need to adopt such an observation period for our product candidates.

Moreover, public perception and awareness of cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR-T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

# Our future success is highly dependent on the regulatory approval of LCAR-B38M/JNJ-4528 and our other pipeline programs. All of our product candidates will require significant preclinical study and clinical trial before we can seek regulatory approval for and launch a product commercially.

We do not have any products that have gained regulatory approval for marketing. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our LCAR-B38M/JNJ-4528 product candidate and our other pipeline programs. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates in countries outside the United States without obtaining regulatory approval for momercialize product candidates in countries outside the United States without obtaining regulatory approval from comparable regulatory authorities in relevant jurisdictions, such as the NMPA in China, the EMA in the European Union and the PMDA in Japan. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls comply with regulatory requirements with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA, the NMPA, the EMA, the PMDA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates.

The time required to obtain marketing approval by the FDA, the NMPA, the EMA, the PMDA and other regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's research and development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive marketing regulatory approval from the FDA, the NMPA, the PMDA or other regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes of our facilities;

- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

The FDA, the NMPA, the EMA, the PMDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional preclinical studies, clinical trials, or both, or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may impose warnings and restrictions on prescription and distribution, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

While LCAR-B38M/JNJ-4528 has received orphan drug designation and breakthrough therapy designation from the FDA and has received the PRIME designation from the EMA, our development strategy may also include the use of additional expedited pathways, such as through the accelerated or contingent approval pathway. Depending on results of the preclinical and clinical trials in our other product candidates, we may also pursue such status for those candidates. There is no certainty that our product candidates will qualify for breakthrough therapy, orphan drug or PRIME designations, nor can we assume that the clinical data obtained from trials of our product candidates will be sufficient to qualify for any expedited approval program.

Even if a product candidate were to successfully obtain marketing approval from the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenue attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

# We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to use our expertise in tumor biology and cell programming and our proprietary and modular CAR-T cell programming technologies to develop what we believe are safer and more effective CAR-T cell therapies. Our initial focus is on the development of a pipeline of product candidates for the treatment of hematological cancers and the progression of these product candidates through clinical development. We also intend to develop follow-on, or next-generation, product candidates with additional elements of programming built into the programmed CAR-T cell product candidate to offer enhanced characteristics as compared to the earlier product generation, as well as developing additional cell therapy product candidates. However, we may not be able to develop product candidates that are safe and effective, or which compare favorably with other commercially available alternatives. Even if we are successful in continuing to build our pipeline and developing next-generation product candidates or expanding into solid tumor indications, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, lack of anti-tumor activity, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research



programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Even if we receive FDA or other regulatory approval to market our product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Further, because of our limited financial and managerial resources, we are required to focus our research programs on certain product candidates and on specific diseases. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our ADSs.

# Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

Some of our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications in the United States and clinical trial applications, or CTAs, in China and the European Union. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further

development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities allowing clinical trials to begin.

## Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful.

Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product candidate and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute clinical trials to support regulatory approval. There is a high failure rate for biologic products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient-by-patient basis. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

## Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. While we have received some positive data in a clinical trial of LCAR-B38M/JNJ-4528 in RRMM, we are still in the process of producing and gathering the final data for LEGEND-2 and are still conducting additional clinical trials in the United States, China and Japan in order to seek regulatory approvals. Our other product candidates are in earlier stages of development. For that reason, we do not know whether these candidates will be effective and safe for the intended indications in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

# We depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with the protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the understanding of risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population who meet inclusion criteria;

- the proximity of patients to study sites;
- the design of the clinical trial;
- clinical trial investigators' ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell-based immunotherapy;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment.

In particular, some of our clinical trials are designed to enroll patients with characteristics that are found in a very small population. For example, our planned Phase 1 clinical trial for LB1901 will seek to enroll patients with relapsed or refractory TCL, a rare and heterogeneous form of NHL. Other companies are conducting clinical trials with their redirected T cell therapies in MM, pediatric relapsed or refractory acute B lymphocytic leukemia and relapsed or refractory diffuse large B-cell lymphoma, or DLBCL, and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical programs. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participating in our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

# We have studied our product candidates and plan to continue to study our product candidates in investigator-initiated clinical trials, which means we do not have full control over the conduct of such trials.

We are currently evaluating our product candidates in investigator-initiated clinical trials. In addition, part of our strategy is to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China, where such trials are initiated and conducted under the oversight of the China National Health Commission (NHC) as a medical practice technology, rather than the NMPA as a medical product. The NMPA, generally speaking, will accept, review, and reject or approve a CTA only from the manufacturer of the investigational product as the sponsor of the CTA, rather than from a physician who intends to be the investigator and sponsor of the CTA. The NMPA distinguishes the former as registrational clinical trial, and the latter as non-registrational clinical trial, and normally will not consider the data generated from investigator-initiated non-registrational clinical trials, when it reviews the application for registrational clinical trial from the manufacturer.

In the case of CAR-T therapy, however, the NMPA is aware of the large number of investigator-initiated non-registrational clinical trials in China and the United States, and some reviewers from its Center for Drug Evaluation have published two articles on its website in February 2018 and October 2018, expressing the view that (1) the mainstream regulatory oversight is to follow the pathway of registrational clinical trial, but that (2) data from investigator-initiated non-registrational clinical trials may be considered if the non-registrational clinical trials otherwise fully comply with the same requirements applicable to registrational clinical trials, in particularly the requirements related to manufacturing quality control, informed consent, data integrity, data management, and all GCP requirements.

Accordingly, there is risk to part of our strategy to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China that the NMPA may refuse to consider the data from the investigator-initiated clinical trials of our product candidates due to concerns that (1) this does not follow the mainstream regulatory pathway of relying on registrational clinical trial, or that (2) the non-registrational clinical trials of our product candidates may not otherwise fully comply with the same requirements applicable to registrational clinical trials, as further explained below.

Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this section relating to clinical trials initiated by us. While investigator-initiated trials may provide us with clinical data that can inform our future development strategy, we do not have full control over the protocols, administration, or conduct of the trials. As a result, we are subject to risks associated with the way investigator-initiated trials are conducted and there is no assurance the clinical data from any of our investigator-initiated clinical trials in China will be accepted by the FDA, EMA, PMDA or other comparable regulatory authorities outside of China, for any of our product candidates. Third parties in such investigator-initiated clinical trials may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with clinical trial protocols or applicable regulations. Further, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our product candidates. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. Third-party investigators may design clinical trials that we may design on our own. As a result, our lack of control over the design, conduct and timing of, and communications with the FDA, NMPA, EMA and PMDA regarding investigator-initiated trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the prospects for our product candidates.

Furthermore, there is no assurance the clinical data from any of our investigator-initiated clinical trials in China, where the patients are predominately of Chinese descent, will produce similar results in patients of different races, ethnicities or those of non-Chinese descent.

# The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for last line use. When blood cancers are detected, they are treated with first line of therapy with the intention of curing the cancer. This generally consists of chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. In addition, sometimes a bone marrow transplantation can be added to the first line therapy after the combination chemotherapy is given. If the patient's cancer relapses, then they are given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these, or a combination of these, or bone marrow transplant. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy in the treatment of lymphoma and myeloma is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

While we are initially developing LCAR-B38M/JNJ-4528 as a last line therapy for patients with MM, there is no guarantee that it, or any of our product candidates, even if approved, would be approved for earlier line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to or post gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth

line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, in our planned Phase 1 clinical trial for LB1901, we will seek to enroll patients with relapsed or refractory TCL, a rare and heterogeneous form of NHL. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenue without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

# Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label or result in significant negative consequences following any potential marketing approval.

In clinical trials conducted by other companies involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures and speech impairment. Adverse events with the worst grades and attributed to CAR-T cells were severe and life threatening in some patients. The life threatening events were related to kidney dysfunction and neurotoxicity. Severe and life threatening in our clinical trials. In our LEGEND-2 clinical trial, CRS was observed in over 90 percent of patients. Low grade CRS, experienced by 82 percent of patients, was managed with standard therapies and resolved. One patient died of a CAR-T related toxicity as a result of CRS and tumor lysis syndrome. A second patient died from a potential pulmonary embolism and acute coronary syndrome, which was considered unrelated to treatment by the investigator. In our CARTITUDE-1 clinical trial, as of April 29, 2020, CRS was reported in 93 percent of patients. One patient died as a result of CRS, one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator. In our CARTITUDE-1 clinical trial, as of April 29, 2020, CRS was reported in 93 percent of patients. One patient died as a result of CRS, one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator. In our CARTITUDE-1 clinical trial, as of April 29, 2020, CRS was reported in 93 percent of patients. One patient died as a result of CRS, one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator, and one patient died due to progressive disease.

Our clinical trials include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of our other product candidates will include similar patients with deteriorating health. It is possible that some of these patients may experience similar adverse side effects as were observed in clinical trials conducted by other companies and academic institutions involving CAR-T cells, and that additional patients may die during our clinical trials for various reasons, including as a result of receiving our product candidates, because the patient's disease is too advanced, or because the patient experiences medical problems that may not be related to our product candidate. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of clinical trials by us, ethics committee, the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenue from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation

period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, or similar risk management plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

# If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict accurately when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each proposed indication. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of clinical development.

We may experience numerous unforeseen events prior to, during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit eligible patients to participate in a trial;
  - 26

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, such as cytokine-induced toxicity and T cell aplasia, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA, the NMPA, the EMA, the PMDA or regulatory authorities in other countries or jurisdictions to approve our BLA, MAA, new drug application, or NDA, or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

# We may not be able to successfully create our own manufacturing infrastructure for supply of our requirements of programmed CAR-T cell product candidates for use in clinical trials and for commercial sale.

We currently have manufacturing facilities in China and the United States supplying clinical materials for our trials. We intend to expand the capacities at these sites as we begin to commercialize our products. We are also in the process of establishing manufacturing capability in Europe, which will provide a regional product supply as well as add to our global manufacturing ability. We will be conducting the manufacturing of LCAR B38M/JNJ-4528 globally.

Our manufacturing and commercialization strategy is based on establishing a fully integrated vein-to-vein product delivery cycle. Over time, we expect to establish regional or zonal manufacturing hubs to service major markets to meet projected needs for commercial sale quantities. However, we are still in the process of constructing manufacturing facilities that will allow us to meet commercial sale quantities.

We expect to expand our cell manufacturing capacity in 2022 by taking occupancy of a specialized manufacturing facility in Zhenjiang, China. Our long-term plan is to establish additional manufacturing capacity in the United States and in Europe. The implementation of this plan is subject to many risks. For example, the establishment of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals. Expanding our internal manufacturing infrastructure will rely upon finding personnel with an appropriate background and training to staff and operate the facility. Should we be unable to find these individuals, we may need to rely on external contractors or train additional personnel to fill the needed roles. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

We expect that operating our own commercial cell manufacturing facilities will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid

implementation of process changes, and allow for better long-term cost margins. However, we have limited experience as a company in designing and operating a commercial manufacturing facility and may never be successful in developing our own manufacturing capability. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

# We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin.

We believe that our current, robust manufacturing processes are fit for commercial scale and we anticipate they will enable commercial supply at an economical cost. However, we have not yet established manufacturing capacity at sufficient commercial scale and may underestimate the cost and time required to do so, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our product candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those product candidates are commercialized.

# Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.

We have developed a robust process for manufacturing CAR-T cells with desired quality, and we have improved the viral transduction process to help eliminate processing inconsistencies. We believe that our current processes are suitable for commercialization. While we have established a process which we believe is scalable for commercial production, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. We have not yet manufactured or processed most of our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

We, like other manufacturers of biologic products, may encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems include delays or breakdowns in logistics and shipping, difficulties with production costs and yields, quality control, and product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations.

Furthermore, if microbial, viral or other contaminations are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any of these or other issues relating to the manufacture of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

The manufacture and delivery of CAR-T cell therapies to patients involves complex, integrated processes, including harvesting T cells from patients, programming the T cells *ex vivo*, multiplying the CAR-T cells to obtain the desired dose, and ultimately infusing the CAR-T cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics in general, and our CAR-T cell product candidates in particular,

is generally higher than traditional small molecule chemical compounds, and the manufacturing process is more variable and is more difficult and costly to reproduce. In addition, our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of white blood cells from the patient, shipping such patient material to the manufacturing site, storing and processing such patient material, shipping the patient material with the CAR-T cells back to the patient, and infusing the patient with the final product. Other manufacturing issues include the differences in patient starting materials, inconsistency in cell growth, variability in product characteristics, interruptions in the manufacturing process, equipment or reagent failure, improper installation or operation of equipment, and vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If we lose, destroy or otherwise impair the patient materials at any point in the vein-to-vein supply chain, the manufacturing process for that patient may need to be restarted and the resulting delay may adversely affect that patient's outcome due to the risk of disease progression. In addition, because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Our manufacturing facilities also require commissioning and validation activities to demonstrate that they operate as designed, and are subject to government inspections by the FDA, the NMPA, the EMA, the PMDA and other comparable regulatory authorities. If we are unable to reliably produce products to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to manufacture our products. Further, our facilities may fail to pass government inspections prior to or after the commercial launch of our product candidates, which would cause significant delays and additional costs required to remediate any deficiencies identified by the regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

#### The process for treating cancer patients using T cell therapy is subject to human and systemic risks.

The "vein-to-vein" cycle for treating cancer patients using T cell therapy typically takes approximately four to six weeks and involves a large number of steps and human participants. First, the patient's lymphocytes are isolated by apheresis at the clinical site and shipped to the manufacturing site. Under current good manufacturing practices, or cGMP, conditions at the manufacturing site, the patient's lymphocytes are thawed and washed, and then enriched for CD3-positive T cells using specialized reagents. After overnight culture and T cell activation, the T cells are transduced using lentiviral vector transduction technology to introduce the CAR genetic construct into the enriched T cell population. At the completion of T cell transduction, the T cells are expanded for several days, harvested, formulated into the final drug product and then cryopreserved for delivery to patients. In both the United States and China, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of a T cell therapy treatment process. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated.

## Prior treatments can alter the cancer and negatively impact chances for achieving clinical activity with our CAR-T cells.

Patients with hematological cancers typically receive highly toxic chemotherapy as their initial treatments that can impact the viability of the T cells collected from the patient and may contribute to highly variable responses to CAR-T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed CAR-T cell product candidate and thereby these patients may have cancer cells with low or no expression of the target. As a result, our CAR-T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. Our lead product candidate, LCAR-B38M/JNJ-4528, may face this challenge. For example, MM patients could have received a BCMA-targeting antibody drug conjugate BCMA-ADC like GSK2857916, BCMA targeting T cell engagers like AMG-420 (Amgen) and CC-93269 (Bristol-Myers Squibb), or similar products or product candidates prior to receiving LCAR-B38M/JNJ-4528. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could have an adverse effect on the value of our ADSs.

# We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

## **Risks Related to our Business Operations**

# As a company partly based outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with substantial operations in China, our business is subject to risks associated with conducting business outside the United States. Many of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the Renminbi, or RMB, U.S. dollar, euro and currency controls;

- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our Share Option Scheme or Restricted Share Unit Incentive Plan;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

See "—Risks Related to Doing Business in China" for additional risks related to our operations in China.

### We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2019, we had 645 full-time employees. As our development and commercialization plans and strategies to expand and develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, NMPA, EMA and PMDA review processes for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in cell therapy and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

In addition to expanding our organization, we are increasing the size of our facilities and building out our development and manufacturing capabilities, which requires significant capital expenditures. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the increase in the size of our facilities is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

### Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel, including Dr. Yuan Xu, our Chief Executive Officer, and Dr. Frank Fan, our Chief Scientific Officer and one of our founders. Although we intend to enter into new employment arrangements with the members of our senior management after the closing of this offering, each of them may currently terminate their employment with us at any time and will continue to be able to do so after the closing of this offering. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

# If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

# Our internal information technology systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs, give rise to significant liability, subject us to costly and protracted litigation, cause significant reputational harm and our ability to operate our business effectively.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants may be vulnerable to a variety of disruptive elements, including cyber-attacks by malicious third parties (including the deployment of computer viruses, harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or a loss of, or damage to, our data or applications, or those of our third-party vendors and other collaborators, contractors and consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed. In addition, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party vendors and other collaborators, contractors and consultants become subject to disruptions or security breaches, we may be exposed to material liability and have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

## We are or may become subject to a variety of privacy and data security laws, policies and contractual obligations, and our failure or failure of our third-party vendors, collaborators, contractors or consultants to comply with them could harm our business.

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, sensitive information, including confidential business and personal information, including health information in connection with our preclinical and clinical studies and our employees, and are subject to laws and regulations governing the privacy and security of such information. Failure by us, our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA, into which we may expand our business. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. For example, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. The U.S. Department of Health and Human Services, or HHS, has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how

their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and can include any of our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country and our operations or business practices may not comply with these regulations in each country.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face regulatory investigations, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations.

#### The COVID-19 coronavirus could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread globally, including to the United States, Europe and Japan, which are countries in which we have planned or ongoing clinical trials. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked. As a result, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

For our clinical trials that are being conducted at sites outside the United States, particularly in countries which are experiencing heightened impact from the COVID-19 coronavirus, in addition to the risks listed above, we may also experience the following adverse impacts:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which
  our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

The extent to which the COVID-19 coronavirus may impact our business and clinical trials is highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak and social distancing regulations, travel restrictions, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

#### Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

#### **Risks Related to Our Dependence on Third Parties**

# We depend upon our existing collaboration partner, Janssen, and other third parties, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our product candidates.

We have a significant collaboration with Janssen for the development and commercialization of LCAR-B38M/JNJ-4528. We may enter into additional collaborations for our other product candidates or technologies in

development. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development, manufacturing or marketing of our products. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, including material breach of agreement and unforeseen material safety event. If the Janssen Agreement were to be terminated, we could encounter significant delays in developing LCAR-B38M/JNJ-4528, lose the opportunity to earn any future revenue we expected to generate under the agreement, incur unforeseen costs, and suffer damage to the reputation of our products, product candidates and as a company generally.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party contract research organizations, or CROs, to assist us in this process. In addition, to optimize the launch and market penetration of certain of our future product candidates, we may enter into distribution and marketing agreements with pharmaceutical industry leaders. For these future potentially partnered product candidates, we would not market our products alone once they have obtained marketing authorization. The risks inherent in entry into these contracts are as follows:

- the negotiation and execution of these agreements is a long process that may not result in an agreement being signed or that can delay the development or commercialization of the product candidate concerned;
- these agreements are subject to cancellation or nonrenewal by our collaborators, or may not be fully complied with by our collaborators;
- in the case of a license granted by us, we lose control of the development of the product candidate licensed;
- in such cases we would have only limited control over the means and resources allocated by our partner for the commercialization of our product; and
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

Should any of these risks materialize, or should we fail to find suitable collaborators, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

# The revenue generated from the Janssen Agreement has contributed and is expected to contribute a large portion of our revenue for the foreseeable future.

We have entered into the Janssen Agreement in respect of the development of LCAR-B38M/JNJ-4528. We received an upfront payment of \$350.0 million from Janssen in 2018, and to date, we have received four milestone payments from Janssen totaling \$110.0 million. Janssen may not execute its obligations as planned or may refuse to honor their commitments under the Janssen Agreement. The non-performance of Janssen, early termination of the Janssen Agreement, or our inability to find new or replacement partners may negatively impact our revenue and research and development activities and funding therefor. Should any of these risks materialize, this would have an adverse effect on our business, prospects, financial condition and results of operations.

# If we or Janssen do not achieve our product development or commercialization objectives in the time frames we expect, we may not receive milestone or royalty payments, and we may not be able to conduct our operations as planned.

We have received and expect to continue to receive payments from Janssen when we satisfy certain pre-specified milestones in the Janssen Agreement. We currently depend to a large degree on these milestone payments from Janssen in order to fund our operations. We may enter into new collaboration agreements that

also provide for milestone payments. The milestone payments in the Janssen Agreement are generally dependent on the accomplishment of various clinical, regulatory, sales and other product development objectives. The successful or timely achievement of many of these milestones is outside of our control, in part because some of these activities are being or will be conducted by Janssen. If we or Janssen fail to achieve the applicable milestones, we will not receive such milestone payments. A failure to receive any such milestone payment may cause us to:

- delay, reduce or terminate certain research and development programs or otherwise find ways to reduce short-term expenses that may not be in our long-term best interest;
- raise funds through additional equity or convertible debt financings that could be dilutive to our shareholders and holders of our ordinary shares and ADSs;
- obtain funds through collaboration agreements that may require us to assign rights to technologies or products that we would have otherwise retained;
- sign new collaboration or license agreements that may be less favorable than those we would have obtained under different circumstances; and
- consider strategic transactions or engaging in a joint venture with a third party.

Any potential royalty payments are also dependent on the successful product development and commercialization of our drug candidates, which may never occur. Our failure to receive milestone or royalty payments and the occurrence of any of the events above may have a material adverse impact on our business, prospects, financial condition and results of operations.

#### We rely on GenScript to provide various services.

We rely on the services provided by GenScript pursuant to the agreements described in "Certain Relationships and Related Party Transactions— Transactions with GenScript." We do not expect personnel and support staff who provide services to us under these agreements will have as their primary responsibility the management and administration of our business or act exclusively for us. In addition, GenScript may prioritize its own needs ahead of the services GenScript has agreed to provide us, or GenScript employees who conduct services for us may prioritize GenScript's interests over our interests. As a result, such individuals will not allocate all of their time and resources to us.

If GenScript fails to perform its obligations in accordance with the terms of these agreements, it could be difficult for us to operate our business, including compliance with SEC reporting requirements. Any failure by GenScript to effectively manage the services that they provide to us could harm our business, financial condition and results of operations. In addition, the termination of our relationships with GenScript could make it difficult for us to operate our business. For instance, GenScript may terminate our human resources services agreement with them with one-month written notice.

Additionally, over time we will need to transition from receiving the services that GenScript is currently providing to performing such activities internally. If we do not have adequate financial resources or personnel and systems in place at the time that we assume responsibilities for such services, we may not be successful in effectively or efficiently transitioning these services from GenScript, which could disrupt our business and have a material adverse effect on our financial condition and results of operations. Even if we are able to successfully transition these services, they may be more expensive or less efficient than the services we are receiving from GenScript during the transition period.

## We have entered, and may in the future enter into, partnership agreements with third parties for the development and commercialization of our product candidates, which may adversely affect our ability to generate revenue.

We have entered into and may seek to enter into additional collaborations or partnerships with third parties for the development and potential commercialization of our product candidates. Should we seek to collaborate with a third party with respect to a prospective development program, we may not be able to locate a suitable partner or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing partners for the development and commercialization of our product candidates, such as the arrangement we have entered into related to the development and commercialization of LCAR-B38M/JNJ-4528 with Janssen, we have limited control over the time and resources that our partners may dedicate to the development and commercialization of our product candidates. These partnerships pose a number of risks, including the following:

- partners may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenue;
- partners may decide to pursue a competitive product developed outside of the collaboration arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- partners may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, partnership agreements may not lead to development, regulatory approval or successful commercialization of product candidates in the most efficient manner or at all. Some partnership agreements are terminable without cause on short notice. Once a partnership agreement is signed, it may not lead to regulatory approval and commercialization of a product candidate. We also face competition in seeking out partners. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenue.

# We rely, and expect to continue to rely, on independent investigators and other third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good laboratory practices and good clinical practices for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United

States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database within specified time frames. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidates or any future product candidates.

# Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for access to facilities and supply of certain materials and equipment used in the manufacture of our product candidates. For example, we currently use facilities and equipment at external contract manufacturing organizations, or CMOs, as well as supply sources internal to the collaboration for vector supply. Our use of CMOs increases the risk of delays in production or insufficient supplies as we transfer our manufacturing technology to these CMOs and as they gain experience with our supply requirements. In addition, we purchase equipment and reagents critical for the manufacture of our product candidates from Hemacare, Miltenyi, Leukapheresis Collection Center and other suppliers on a purchase order basis. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers, and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights

to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

#### Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

#### Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the NMPA, the EMA, the PMDA and other comparable regulatory authorities in other jurisdictions. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the NMPA, the EMA, the PMDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be impaired.

In order to market and sell our products in China, the European Union, Japan and any other international jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

## Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

# Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a REMS program or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved

labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements of the FDA, the NMPA, the EMA, the PMDA and other regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP and other comparable regulations and standards, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We or our suppliers could be subject to periodic unannounced inspections by the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our suppliers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability.

Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

# Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of products in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, or if other of our marketing claims are deemed false or misleading, we may be subject to enforcement action. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;

- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Noncompliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Noncompliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

### Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners, and vendors, could include failures to comply with regulations of the FDA, the NMPA, the EMA, the PMDA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement of profits, imprisonment, possible exclusion from participation

in Medicare, Medicaid and other federal healthcare programs, or other government supported healthcare in other jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

#### Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, customers and thirdparty payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable healthcare laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and privacy and security regulation by the U.S. federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated;
- U.S. federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, which, among other things, impose criminal and civil penalties, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false

claims laws. Further, pharmaceutical manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;

- HIPAA, which contains new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH also contains four new tiers of civil monetary penalties; amends HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and to seek attorneys' fees and costs associated with pursuing federal civil actions;
- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions), to report information related for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual

knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Efforts to ensure that our internal operations and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

#### Our product candidates are subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the United States, China, the European Union, Japan and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congressional leadership and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

# Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost for us to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which resulted in a number of changes to laws and regulations, and may

result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we obtain marketing approval. For a detailed discussion of healthcare reform initiatives of importance to the pharmaceutical industry, see the section titled "Business—Government Regulation—United States Regulation—Healthcare Reform."

For example, the ACA was enacted in the United States in March 2010 with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change healthcare delivery, increase the number of individuals with insurance, ensure access to certain basic healthcare services, and contain the rising cost of care. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. H.R. 1: An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, or the Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to repeal or replace elements of the ACA. These executive orders and legislative actions are expected to result in increased health insurance premiums and reduce the number of people with health insurance in the United States, and have other effects that adversely affect U.S. health insurance markets and the ability of patients to have access to therapies that our product candidates can provide.

In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year through 2029 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several

recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and, at the same time, has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020, This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency meas

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of or reimbursement and access to pharmaceutical products, may limit or delay our ability to generate revenue, attain profitability, or commercialize our products.

# We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

## If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials

and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, in connection with the construction of certain research and development facilities in China, we have not completed all required fire prevention and safety-related procedures and filings in a timely manner, which could subject us to fines and other administrative penalties.

Although we maintain insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

#### **Risks Related to the Commercialization of Our Product Candidates**

# If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We currently plan to work to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, other than the assistance required to be provided by Janssen under the Janssen Agreement, we currently have limited sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to expand our sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenue and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

# We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national

pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Due to their promising clinical therapeutic effect in clinical exploratory trials, engineered T cell therapies, redirected T cell therapies in general and antibody-drug conjugates are being pursued by multiple biotechnology and pharmaceutical companies. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates noncompetitive and obsolete.

Our potential CAR-T cell therapy competitors include companies developing cell therapies targeting BCMA for the treatment of MM, including Allogene, Autolus, bluebird, Bristol-Myers Squibb, Carsgen, Innovent, Poseida Therapeutics, Novartis and Precision Biosciences. Our potential competitors also include additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Regeneron, GSK and Pfizer. In addition, we may compete with cell therapies companies that are focused on development in Asia.

Our competitors with development-stage programs may obtain marketing approval from the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or noncompetitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA, NMPA, EMA, PMDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

#### Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, thirdparty payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory agencies and are able to initiate commercialization of our clinical-stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

• the clinical indications for which our product candidates are approved;

- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- hospitals and cancer treatment centers establishing the infrastructure required for the administration of redirected CAR-T cell therapies;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective, may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

## Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels.

Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. These pressures are further compounded by significant controversies and intense political debate and publicity about prices for pharmaceuticals that some consider excessive, including government regulatory efforts, funding restrictions, legislative proposals, policy interpretations, investigations and legal proceedings regarding pharmaceutical pricing practices. Global pressures on pricing may negatively impact, in parallel, both our product pricing and our market access. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program, or the PRDL, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to the affordability of the government's Basic Medical Insurance. If we were to successfully launch commercial sales of our products in China but fail in our efforts to have our products included in the NRDL or PRDL, our revenue from commercial sales in China will be highly dependent on patient self-payment, which can make our products less competitive. Additionally, even if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts accepts our application for the inclusion of products in the NRDL or PRDL, our potential revenue from the sales of these products in China

could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL or PRDL.

We cannot be sure that coverage and reimbursement in the United States, China, the European Union, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

#### Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold \$5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

#### **Risks Related to Our Intellectual Property**

#### If we are unable to obtain and maintain patent protection for our technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, China, the European Union, Japan and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including the United States, China, major countries in Europe and Japan. However, we do not own any issued patents covering our clinical and preclinical products and our patent portfolio for such products is currently comprised only of applications. If we are unable to obtain or maintain patent protection with respect to our proprietary product candidates and technology or do not otherwise adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary positions, we file patent applications in the United States and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive, complex and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications in all potential jurisdictions at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

Prosecution of our patent portfolio is at a very early stage. Much of our patent portfolio consists of pending priority applications that are not examined and pending applications under the Patent Cooperation Treaty, or PCT. Neither priority applications nor PCT applications can themselves give rise to issued patents. Rather, protection for the inventions disclosed in these applications must be further pursued by applicable deadlines via applications that are subject to examination. As applicable deadlines for the priority and PCT applications become due, we will need to decide whether and in which countries or jurisdictions to pursue patent protection for the various inventions claimed in these applications, and we will only have the opportunity to pursue and obtain patents in those jurisdictions where we pursue protection.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, may affect the scope, strength, validity and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.



We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own or in-license any patents or patent applications in the future, we may not be certain that we or the applicable licensor were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, post-grant, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, hold unenforceable or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any of the foregoing could have a material adverse effect on our business.

### Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary and modular CAR-T cell technology without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including relating to the modification of T cells and the production of CAR-T cells, and including patents held by our competitors.

Third parties, including our competitors, may allege that our product candidates, including LCAR-B38M/JNJ-4528, infringe certain of these patents. While we believe that we would have valid defenses against any assertion of such patents against us, such defenses may be unsuccessful. If any of our products is found to infringe any of these patents, we could be required to obtain a license from the respective patent owners, or, if

applicable, their licensees, to continue developing, manufacturing, marketing, selling and commercializing such products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving the licensor and other third parties the right to use the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease development, manufacturing, marketing and commercializing the applicable products. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willingly infringed any such patent. Even if we were ultimately to prevail, any litigation could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes, misappropriates or otherwise violates their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates. Moreover, we may fail to identify relevant third-party patents or patent applications, or we may increctly conclude that the claims of an issued patent are invalid or are not infringed by our activities. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result i

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity and enforceability. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required or may choose to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the otherwise infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could require us to make substantial licensing and royalty payments and it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Any of the foregoing could have a material adverse effect on our business.

# We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

## We may become involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, if issued, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement thas superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel for significant periods of time during such litigation could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

#### Changes in U.S. and Chinese patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents and may affect the scope, strength and enforceability of our patent rights or the nature of

proceedings that may be brought by or against us related to our patent rights. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, a Draft Amendment to the PRC Patent Law was released in January 2019 and proposes to introduce patent extensions to eligible innovative drug patents. If adopted, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. The adoption of this draft amendment may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to Chinese intellectual property laws would not have a negative impact on our intellectual property protection.

#### Even if we are able to obtain patent protection for our product candidates, the life of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. The pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in "Business—Intellectual Property." Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

#### Our product candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

There is a risk that any exclusivity we may be afforded if any of our product candidates are approved as a biologic product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to market it until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

### We may be subject to claims by third parties asserting that we or our employees, consultants or advisors have misappropriated, wrongfully used or disclosed their trade secrets or other intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused such individual to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

#### We may be subject to claims challenging the inventorship or ownership of our patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

#### Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.



#### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors or other third parties could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third parties, our competitive position would be harmed.

#### We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our

efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

# Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business.

#### Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we may own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

#### **Risks Related to Doing Business in China**

## The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

A material portion of our research and development operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See "Business—Government Regulation—PRC Regulation" for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. For example, under PRC law, before we enter into a clinical trial agreement with a PRC partner, the parties are required to obtain an approval for projects of international collaboration in respect of human genetic resources in order to collect any biological samples that contain the genetic material of Chinese human subjects. The relevant PRC partners in some of our collaboration projects have not obtained such approval in a timely manner. The failure to obtain such approval could cause relevant collaboration projects to be suspended by governing authorities, may result in fines and also may constitute a breach under our agreements with certain CROs. Furthermore, under relevant PRC laws, a license for use of laboratory animals is required for performing experimentation on animals. Any failure of fully comply with such requirement may result in the invalidation of our experimental data. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

## The Chinese economy differs from the economies of most developed countries in many respects, including a higher level of government involvement, the ongoing development of a market-oriented economy, a higher level of control over foreign exchange, and a less efficient allocation of resources.

While the PRC economy has experienced significant growth since the late 1970s, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. These measures are intended to benefit the overall PRC economy, but may also have a negative effect on us. For example, our business, financial condition and results of operations could be adversely affected by PRC government control over capital investments or changes in regulations that are applicable to us.

The PRC economy has been transitioning from a centrally planned economy to a more market-oriented economy. Although the PRC government has implemented measures since the late 1970s that emphasize the utilization of market forces for economic reform, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.



#### The PRC legal system contains uncertainties, which could limit the legal protections available to you and to us.

In 1979, the PRC government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. Our PRC subsidiary is subject to laws and regulations applicable to foreign-invested enterprises in China. In particular, they are subject to PRC laws, rules and regulations governing foreign companies' ownership and operation of pharmaceutical businesses. Such laws and regulations are subject to change, and their interpretation and enforcement involve uncertainties, which could limit the legal protections available to us and our investors. In addition, we cannot predict the effect of future developments in the PRC legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement of such laws, or the preemption of local regulations by PRC laws, rules and regulations.

Moreover, China has a civil law system based on written statutes, which, unlike common law systems, is a system in which decided judicial cases have little precedential value. Furthermore, interpretation of statutes and regulations may be subject to government policies reflecting domestic political changes. The relative inexperience of China's judiciary in many cases creates additional uncertainty as to the outcome of litigation. In addition, enforcement of existing laws or contracts based on existing laws may be uncertain and sporadic, and it may be difficult to obtain swift and equitable enforcement within China. All such uncertainties could materially and adversely affect our business, financial condition and results of operations.

## You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in China against us or our management named in the prospectus based on foreign laws.

We are an exempted company incorporated under the laws of the Cayman Islands. We conduct a material portion of our operations in China and a material portion of our assets are located in China. In addition, many of our senior executive officers and directors reside within China for a significant portion of the time and some of them are PRC nationals. As a result, it may be difficult for you to effect service of process upon us or those persons inside China. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, the PRC courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security or the public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

#### We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded, at least in part, by

the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Currently, as the term "state secret" is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to specific administrative penalties imposed by those government authorities.

#### Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. In March 2018, U.S. President Donald J. Trump announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018 announced further tariffs targeting goods imported from China. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

# Dividends we receive from our subsidiaries located in the PRC may be subject to PRC withholding tax, which could materially and adversely affect the amount of dividends, if any, we may pay our shareholders.

The PRC Enterprise Income Tax Law classifies enterprises as resident enterprises and non-resident enterprises. The PRC Enterprise Income Tax Law provides that an income tax rate of 20% may be applicable to dividends payable to non-resident investors, which (i) do not have an establishment or place of business in the PRC, or (ii) have an establishment or place of business in the PRC but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The State Council of the PRC reduced such rate to 10% through the implementation regulations of the PRC Enterprise Income Tax Law. Further, pursuant to the Double Tax Avoidance Arrangement between Hong Kong and Mainland China, or the Double Tax Avoidance Arrangement, and the Notice on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties issued in February 2009 by the State Administration of Taxation of the PRC, or the SAT, if a Hong Kong resident enterprise owns more than 25% of the equity interest in a company in China at all times during the 12-month period immediately prior to obtaining a dividend from such company, the 10% withholding tax on dividends is reduced to 5% provided that certain other conditions and requirements under the Double Tax Avoidance Arrangement and other applicable PRC laws are satisfied at the discretion of relevant PRC tax authority.

If our British Virgin Island subsidiary and our Hong Kong subsidiary are considered as non-resident enterprises and our Hong Kong subsidiary is considered as a Hong Kong resident enterprise under the Double Tax Avoidance Arrangement and is determined by the competent PRC tax authority to have satisfied relevant conditions and requirements, then the dividends paid to our Hong Kong subsidiary by its PRC subsidiary may be

subject to the reduced income tax rate of 5% under the Double Tax Avoidance Arrangement. However, based on the Notice on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. In addition, based on the Announcement of the State Administration of Taxation on Issues Relating to Beneficial Owner in Tax Treaties, effective from April 1, 2018, under certain conditions a company cannot be defined as a beneficial owner under the treaty and thus are not entitled to the abovementioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement. If we are required under the PRC Enterprise Income Tax Law to pay income tax for any dividends we receive from our subsidiaries in China, or if our Hong Kong subsidiary is determined by PRC government authority as receiving benefits from reduced income tax rate due to a structure or arrangement that is primarily tax-driven, it would materially and adversely affect the amount of dividends, if any, we may pay to our shareholders.

## If we are classified as a "resident enterprise" of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside the PRC with "de facto management body" within the PRC is considered a "resident enterprise" and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, SAT issued a circular, known as SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" in China and will be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in the PRC.

We believe that we are not a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, we may be required to withhold a 10% tax from dividends we pay to our shareholders that are non-resident enterprises, including the holders of the ADSs. In addition, non-resident enterprise shareholders, including our ADS holders, may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends paid to our non-PRC individual shareholders, including our ADS holders, and any gain realized on the transfer of ADSs or ordinary shares by such shareholders may be subject to PRC tax at a rate of 20%, which in the case of dividends may be withheld at source. Any PRC tax liability may be reduced by an applicable tax treaty. However, it is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on your investment in our ADSs or ordinary shares.

In addition to the uncertainty as to the application of the "resident enterprise" classification, we cannot assure you that the PRC government will not amend or revise the taxation laws, rules and regulations to impose stricter tax requirements or higher tax rates. Any of such changes could materially and adversely affect our financial condition and results of operations.

#### Governmental control of currency conversion may affect the value of your investment.

Currently, the RMB cannot be freely converted into any foreign currency. The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in the availability of foreign currency may restrict the ability of our PRC subsidiary to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency dominated obligations. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and expenditures from trade-related transactions, can be made in foreign currencies without prior approval from the PRC State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. However, for most capital account items, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of bank loans denominated in foreign currencies. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the ADSs.

#### Fluctuation in exchange rates could have a negative effect on our results of operations and the value of your investment.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions in China and by China's foreign exchange policies. Since June 2010, the RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. On November 30, 2015, the Executive Board of the International Monetary Fund, or IMF, completed the regular five-year review of the basket of currencies that make up the Special Drawing Right, or the SDR, and decided that with effect from October 1, 2016, the RMB is determined to be a freely usable currency and will be included in the SDR basket as a fifth currency, along with the U.S. dollar, the euro, the Japanese yen and the British pound. Since the fourth quarter of 2016, the RMB has depreciated significantly in the backdrop of a surging U.S. dollar and persistent capital outflows of China. With the development of the foreign exchange market and progress toward interest rate liberalization and RMB internationalization, the PRC government may in the future announce further changes to the exchange rate system, and we cannot assure you that the RMB will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

Significant revaluation of the RMB may have a negative effect on your investment. For example, to the extent that we need to convert U.S. dollars we receive from this offering into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount available to us.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. As of the date of this prospectus, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert RMB into foreign currency or to convert foreign currency into RMB.

# PRC regulations relating to offshore investment activities by PRC residents and enterprises may increase our administrative burden and restrict our overseas and cross-border investment activity. If our PRC resident and enterprise shareholders fail to make any required applications and filings under such regulations, we may be unable to distribute profits to such shareholders and may become subject to liability under PRC law.

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, which replaces the Notice on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Round-tripping Investment via Overseas Special Purpose, or SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China. In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or SAFE Notice 13. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound direct investments, including those required under SAFE Circular 37, shall be filed with qualified banks instead of SAFE. Qualified banks should examine the applications and accept registrations under the supervision of SAFE.

We may not be aware of the identities of all of our beneficial owners who are PRC residents. To our knowledge, some of our beneficial owners have not complied with SAFE registration requirements under SAFE Circular 37 and subsequent implementation rules on time or at all, sometimes due to reasons beyond their control. However, we do not have control over our beneficial owners and cannot compel them to comply with SAFE Circular 37 and subsequent implementation rules. Therefore, we cannot assure you that any required registration under SAFE Circular 37 and any amendment will be completed in a timely manner, or at all. The failure of our beneficial owners who are PRC residents to register or amend their foreign exchange registrations pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future beneficial owners of our company who are PRC residents to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiary to fines and legal sanctions. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiary and limit our PRC subsidiary's ability to distribute dividends to us. These risks may have a material adverse effect on our business, financial condition and results of operations.

Furthermore, as these foreign exchange and outbound investment related regulations and their interpretation and implementation have been constantly evolving, it is unclear how these regulations, and any future regulation concerning offshore or cross-border investments and transactions, will be interpreted, amended and implemented by the relevant government authorities. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign-currency-denominated borrowings, which may adversely affect our financial condition and results of operations. We cannot assure you that we have complied or will be able to comply with all applicable foreign exchange and outbound investment related regulations. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or the owners of such company, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange

regulations. This may restrict our ability to implement our acquisition strategy and could adversely affect our business and prospects.

# PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiary.

As an offshore holding company of our PRC operating subsidiary, we may make loans or additional capital contributions to our PRC subsidiary, subject to satisfaction of applicable governmental registration and approval requirements.

Any loans we extend to our PRC subsidiary, which is treated as a foreign-invested enterprise under PRC law, cannot exceed the statutory limit and must be registered with the local counterpart of the SAFE.

We may also decide to finance our PRC subsidiary by means of capital contributions. According to the relevant PRC regulations on foreign-invested enterprises in China, these capital contributions are subject to registration with State Administration for Market Regulation or its local counterparts. In addition, the PRC government also restricts the convertibility of foreign currencies into RMB and use of the proceeds. On March 30, 2015, SAFE promulgated the Notice on Reforming the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or SAFE Circular 19, which took effect and replaced certain previous SAFE regulations from June 1, 2015. SAFE further promulgated the Circular on Reforming and Regulating Policies on the Management of Foreign Exchange Settlement of Capital Accounts, or SAFE Circular 16, effective on June 9, 2016, which, among other things, amends certain provisions of SAFE Circular 19. According to SAFE Circular 19 and SAFE Circular 16, the flow and use of the RMB capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope. Violations of the applicable circulars and rules may result in severe penalties, including substantial fines as set forth in the Foreign Exchange Administration Regulations. These circulars may limit our ability and speed to transfer the net proceeds from this offering to our PRC subsidiary. On October 23, 2019, SAFE promulgated the Circular to Further Facilitating Cross-border Trade and Investment, or SAFE Circular 28, which took effect on the same day. SAFE Circular 28 cancels restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the "capital account - account for settled foreign exchange to be paid" to receive the corresponding funds according to relevant provisions. Despite the restrictions and procedural requirements under these SAFE circulars, our PRC subsidiary may use RMB funds converted from foreign currency registered capital to carry out any activities within their normal course of business and business scope, including to fund operational needs, and to make equity investments in domestic companies.

In light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC entities by offshore holding companies, we cannot assure you that we have completed or will be able to complete the necessary government registrations, meet the relevant government requirements or obtain the necessary government approvals on a timely basis, or at all, with respect to existing or future loans to our PRC subsidiary or future capital contributions by us to our PRC subsidiary. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds we expect to receive from this offering to fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

# Failure to comply with PRC regulations regarding the registration requirements for employee stock ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Under the applicable regulations and SAFE rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in an overseas publicly listed company are required to register with SAFE and complete certain other procedures. In February 2012, SAFE promulgated the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plan or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE in March 2007. Pursuant to the Stock Option Rules, if a PRC resident participates in any stock incentive plan of an overseas publicly listed company, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock options or stock such participant holds. Such participating PRC residents' foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents' foreign exchange income received from the sale of stock and dividends distributed by the overseas publicly listed company must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other share-based incentives of ours will be subject to the Stock Option Rules when our company becomes an overseas listed company upon the completion of this offering. If we or our PRC resident participants fail to comply with these regulations, we and/or our PRC resident participants may be subject to fines and legal sanctions.

### We may be required to obtain prior approval from the China Securities Regulatory Commission for the listing and trading of the ADSs on Nasdaq.

On August 8, 2006, six PRC regulatory agencies, including the China Securities Regulatory Commission, or the CSRC, promulgated the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors, or the M&A Rules, which became effective on September 8, 2006 and was amended on June 22, 2009. This regulation, among other things, requires offshore SPVs formed for the purpose of an overseas listing and controlled by PRC companies or individuals, to obtain the CSRC approval prior to listing their securities on an overseas stock exchange. The application of this regulation remains unclear. Our PRC legal counsel has advised us that, based on their understanding of the current PRC laws, the CSRC approval is not required under the M&A Rules in the context of this offering because the ownership structure of our PRC subsidiary was established by direct investment instead of through acquisition of equity interests or assets of any PRC domestic company by foreign entities as defined under the M&A Rules.

However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel. If it is determined that the CSRC approval is required for this offering, we may face sanctions by the CSRC or other PRC regulatory agencies for failure to seek the CSRC approval for this offering. These sanctions may include fines and penalties on our operations in the PRC although, to our knowledge, no definitive rules or interpretations have been issued to determine or quantify such fines or penalties, delays or restrictions on the repatriation of the proceeds from this offering into the PRC, restrictions on or prohibition of the payments or remittance of dividends by our PRC subsidiary, or other actions that may have a material adverse effect on our business and the trading price of the ADSs. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable to us, to halt this offering before the settlement and delivery of the ADSs that we are offering. Consequently, if you engage in market trading or other activities in anticipation of and prior to the settlement and delivery of the ADSs we are offering, you would be doing so at the risk that the settlement and delivery may not occur.

# The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

The M&A Rules and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. The M&A Rules require that the Ministry of Commerce, or the MOFCOM, be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

The Anti-Monopoly Law promulgated by the Standing Committee of the National People's Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with MOFCOM. Without the clearance from MOFCOM, no concentration of undertakings shall be implemented and effected. Mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold under the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules, issued by the State Council in August 2008 is triggered. If such prior notification is not obtained, MOFCOM may order the concentration to cease its operations, dispose of shares or assets, transfer the business of the concentration within a time limit, take any other necessary measures to restore the situation as it was before the concentration, and may impose administrative fines.

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises, issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors involved in "an industry related to national security" are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions.

We cannot preclude the possibility that the MOFCOM or other government agencies may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

# We and our shareholders face uncertainty with respect to indirect transfers of equity interests in PRC resident enterprises, assets attributed to a PRC establishment of a non-PRC company or immovable properties located in China owned by non-PRC companies.

In February 2015, SAT issued a Public Notice Regarding Certain Corporate Income Tax Matters on Indirect Transfer of Properties by Non-Tax Resident Enterprises, or SAT Public Notice 7. SAT Public Notice 7 extends its tax jurisdiction to transactions involving transfer of other taxable assets through offshore transfer of a foreign intermediate holding company. In addition, SAT Public Notice 7 provides clear criteria for assessment of reasonable commercial purposes and has introduced safe harbors for internal group restructurings and the purchase and sale of equity through a public securities market. SAT Public Notice 7 also brings challenges to

both foreign transferor and transferee (or other person who is obligated to pay for the transfer) of taxable assets. In October 2017, SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or SAT Bulletin 37, which came into effect on December 1, 2017. The Bulletin 37 further clarifies the practice and procedure of the withholding of nonresident enterprise income tax. Where a non-resident enterprise transfers taxable assets indirectly by disposing of the equity interests of an overseas holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such Indirect Transfer to the relevant tax authority. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer other than transfer of shares of ADSs acquired and sold on public markets may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes.

We face uncertainties as to the reporting and other implications of certain past and future transactions that involve PRC taxable assets, such as offshore restructuring, sale of the shares in our offshore subsidiaries and investments. Our company may be subject to filing obligations or taxed if our company is the transferor in such transactions, and may be subject to withholding obligations if our company is the transferee in such transactions, under SAT Public Notice 7 or Bulletin 37, or both.

# The audit report included in this prospectus is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, our investors are deprived of the benefits of such inspection.

Our independent registered public accounting firm that issues the audit report included in our prospectus filed with the SEC, as auditors of companies that are traded publicly in the United States and a firm registered with the PCAOB is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Because our auditors are located in the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditors are not currently inspected by the PCAOB. On December 7, 2018, the SEC and the PCAOB issued a joint statement highlighting continued challenges faced by the U.S. regulators in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. The joint statement reflects a heightened interest in this issue that U.S. regulators have focused on in recent years. However, it remains unclear whether the SEC and PCAOB will take any further actions to address the issue.

Inspections of other firms that the PCAOB has conducted outside of China have identified deficiencies in those firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections.

The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside China that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

# If additional remedial measures are imposed on the "big four" PRC-based accounting firms, including our independent registered public accounting firm, in administrative proceedings brought by the SEC alleging

# such firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, we could fail to timely file future financial statements in compliance with the requirements of the Securities Exchange Act of 1934, as amended.

Starting in 2011 the Chinese affiliates of the "big four" accounting firms, including our independent registered public accounting firm, were affected by a conflict between U.S. and Chinese law. Specifically, for certain U.S.-listed companies operating and audited in mainland China, the SEC and the PCAOB sought to obtain from the Chinese firms access to their audit work papers and related documents. The firms were, however, advised and directed that under China law they could not respond directly to the U.S. regulators on those requests, and that requests by foreign regulators for access to such papers in China had to be channeled through the CSRC.

In late 2012, this impasse led the SEC to commence administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act against the Chinese accounting firms, (including our independent registered public accounting firm). A first instance trial of the proceedings in July 2013 in the SEC's internal administrative court resulted in an adverse judgment against the firms. The administrative law judge proposed penalties on the firms including a temporary suspension of their right to practice before the SEC, although that proposed penalty was subject to the pending review of the SEC Commissioner. On February 6, 2015, prior to the SEC Commissioner's scheduled review, the firms reached a settlement with the SEC. Under the settlement, the SEC agreed that its future requests for the production of documents would normally be made to the CSRC. The firms would receive matching requests under Section 106 of the Sarbanes-Oxley Act, and are required to abide by a detailed set of procedures with respect to such requests, which in substance required them to facilitate production via the CSRC. If they fail to meet the specified criteria, the SEC retains the authority to impose a variety of additional remedial measures on the firm's performance of certain audit work, commencement of a new proceeding against the firm, or in extreme cases, the resumption of the current proceeding against all four "big four" accounting firms.

#### Our business may be significantly affected by the newly enacted Foreign Investment Law and the "negative list."

On March 15, 2019, the NPC promulgated the Foreign Investment Law, which took effect on January 1, 2020 and replaced three existing laws regulating foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperative Joint Venture Law and the Wholly Foreign-owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list" published by the State Council. We are a Cayman Islands company and our PRC subsidiary, Nanjing Legend Biotech Co., Ltd., or Legend Nanjing, is currently considered to be a foreign invested entity.

The latest version of the "negative list," namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2019), which became effective on July 30, 2019, provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies. As of the date of this prospectus, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" and the application of this regulation remains unclear. Legend Nanjing is engaged in the research and development of CAR-T cell therapies. We believe the CAR-T cell therapies, as they are currently being researched and developed by Legend Nanjing, do not involve the use of human stem cells or genetic diagnostic and treatment, and as such should not fall into the category of "human stem cell or gene diagnostic and therapeutic technologies." Moreover, relevant governmental authorities also confirmed the research and development of CAR-T cell therapies currently engaged in by Legend Nanjing complies with the requirements of foreign investment industrial policies. We have been advised by our PRC legal counsel, JunHe LLP, that Legend Nanjing has complied with PRC laws and regulations in all material respects

for, and obtained all material governmental approvals and permits from PRC regulatory agencies for, the research and development of CAR-T cell therapies. However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to our view and the opinion of our PRC legal counsel above. If our CAR-T cell therapies or other technologies that are being researched and developed by Legend Nanjing are deemed by relevant PRC regulatory agencies as falling into the category of "human stem cell or gene diagnostic and therapeutic technologies," Legend Nanjing would be prohibited from engaging in the research or development of such technologies. In that event, we may have to stop investing in Legend Nanjing or consider restructuring Legend Nanjing as a PRC domestic entity and our variable interest entity. Legend Nanjing may also have to forfeit its income derived from the research and development of such technologies. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

# Our leased property interest may be defective and our right to lease the properties may be challenged, which could cause significant disruption to our business.

In China, we lease certain premises used in our operations from third parties. Certain lessors have not provided us with valid ownership certificates or authorization of sublease for our leased properties. Under the relevant PRC laws and regulations, if the lessors are unable to obtain certificates of title because such properties were built illegally or failed to pass the inspection or other reasons, such lease contracts may be recognized as void and, as a result, we may be required to vacate the relevant properties. In addition, if our lessors are not the owners of the properties and they have not obtained consents from the owners or their lessors, our leases could be invalidated. If this occurs, we may have to renegotiate the leases with the owners or the parties who have the right to lease the properties, and the terms of the new leases may be less favorable to us, or we may be required to vacate the relevant properties if the terms of the new leases are not reached.

Under PRC laws, all lease agreements are required to be registered with the local housing authorities. We have not registered certain of our lease agreements with the relevant government authorities. Failure to complete these required registrations may expose our landlords, lessors and us to potential monetary fines.

#### Increases in labor costs and enforcement of stricter labor laws and regulations in the PRC may adversely affect our business and our profitability.

China's overall economy and the average wage level in China have increased in recent years and are expected to continue to grow. The average wage level for our employees has also increased in recent years. We expect that our labor costs, including wages and employee benefits, will continue to increase.

In addition, we have been subject to stricter regulatory requirements in terms of entering into labor contracts with our employees and paying various statutory employee benefits, including pensions, housing funds, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance to designated government agencies for the benefit of our employees. We cannot assure you that we have complied or will be able to comply with all labor-related laws and regulations including those relating to obligations to make social insurance payments and contribute to the housing provident funds. We have not fully paid the housing provident funds for all of our employees as required by applicable PRC regulations. We may be required to make up the contributions for our employees, resulting in financial conditions and results of operations to be adversely affected. Furthermore, certain overseas employee of our PRC subsidiary has not obtained required work permit, which may subject our PRC subsidiary to fines and penalty.

#### Risks Related to this Offering, Our Securities and Our Status as a Public Company

# An active trading market for our ADSs may not develop and you may not be able to resell your ADSs at or above the initial offering price, if at all.

This offering constitutes the initial public offering of our ADSs, and no public market has previously existed for our ADSs. We have applied to list our ADSs on Nasdaq. Any delay in receiving approval for the listing from the Nasdaq and in the commencement of trading of our ADSs on the Nasdaq would impair the liquidity of the market for the ADSs and make it more difficult for holders to sell the ADSs. There can be no assurance that an active trading market for the ADSs will develop or be sustained after this offering is completed. The lack of an active trading market may also reduce the fair market value of the ADSs. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial public offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that, following the completion of this offering, the ADSs will trade at a price equal to or greater than the initial public offering price.

### The trading price of our ADSs may be volatile, and you could lose all or part of your investment.

The trading price of our ADSs following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ADSs at or above the price paid for the ADSs. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, China and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure of healthcare payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates or CAR-T cells in general;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our ADSs on Nasdaq;

- sales of our ADSs or ordinary shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or China;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs at or above the price paid for the ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our ADSs.

# We will be a "controlled company" within the meaning of the applicable Nasdaq listing rules and, as a result, will qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to shareholders of companies that are subject to such requirements.

Upon the closing of this offering, GenScript will continue to control a majority of the voting power of our outstanding common shares. As a result, we will be a "controlled company" within the meaning of applicable Nasdaq listing rules. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company." For so long as we remain a "controlled company," we may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter;
- addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We intend to use these exemptions upon the closing of this offering and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to shareholders of companies that are subject to all of the Nasdaq corporate governance requirements.

# GenScript will continue to own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

GenScript is currently our majority shareholder, and after this offering is completed, we will continue to be controlled by GenScript. Upon the closing of this offering, GenScript will beneficially own approximately % of the voting power of our outstanding share capital, or approximately % if the underwriters exercise their option to purchase additional common shares in full. These ownership percentages do not reflect the potential purchase of ADSs in this offering by GenScript. Therefore, even after this offering, GenScript will have the ability to substantially influence us and exert significant control through this ownership position. For example, GenScript and its shareholders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. GenScript's interests may not always coincide with our corporate interests or the interests of other shareholders. Further, there may be changes to the management or ownership of GenScript that could impact GenScript's interests in a way that may not coincide with our corporate interests or the interests of other shareholders. So long as GenScript continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

#### Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our ADSs, on the one hand, and GenScript and its shareholders, on the other hand. Certain of our directors and employees have equity interests in GenScript and, accordingly, their interests may be aligned with GenScript's interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Further, our other shareholders may not have visibility into the GenScript ownership of any of our directors or officers, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors' or officers' GenScript ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with GenScript. GenScript and its shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common shares. Any material transaction between us and GenScript or any other subsidiary of GenScript will be subject to a related party transaction policy we intend to adopt, which will require prior approval of such transaction by our audit committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

### If you purchase ADSs in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our ADSs is substantially higher than the pro forma as adjusted net tangible book value per ADS. Therefore, if you purchase ADSs in this offering, you will pay a price per ADS that substantially exceeds our pro forma as adjusted net tangible book value per ADS after this offering. Based on the initial public offering price of \$ per ADS, you will experience immediate dilution of \$ per ADS, representing the difference between our pro forma as adjusted net tangible book value per ADS after this offering, we will also have outstanding options to purchase ordinary shares with exercise prices lower than the initial public offering price. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering. For further information regarding the dilution resulting from this offering, see the section titled "Dilution" in this prospectus.

# A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our ADSs to drop significantly, even if our business is doing well.

Sales of a substantial number of our ordinary shares or ADSs in the public market could occur at any time. If our shareholders sell, or the market perceives that our shareholders intend to sell, substantial amounts of our ordinary shares or ADSs in the public market following this offering, the market price of our ADSs could decline significantly.

Upon completion of this offering, we will have outstanding ordinary shares, including ordinary shares represented by ADSs, based on the number of shares outstanding as of March 31, 2020. Of these shares, the ADSs sold in this offering and currently outstanding ordinary shares will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements entered into by our shareholders in connection with the offering. The representatives of the underwriters may agree to release these shareholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our ADSs to fall or make it more difficult for you to sell your ADSs at a time and price that you deem appropriate.

In addition, promptly following the completion of this offering, we intend to file one or more registration statements registering the issuance of approximately ordinary shares (which may be in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

Additionally, after this offering, the holders of an aggregate of of our ordinary shares, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

# If we fail to implement and maintain effective internal controls over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

Upon becoming a public company, we will be subject to reporting obligations under U.S. securities laws, including the Sarbanes-Oxley Act. Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), will require that, beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. We expect our first Section 404(a) assessment will take place for our annual report for the fiscal year ending December 31, 2021. Although Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, which could require us to restate our operating results or result in our auditors issuing a qualified audit report. In order to establish and maintain effective disclosure controls and procedures and internal controls over financial reporting, we will need to expend

significant resources and provide significant management oversight. Developing, implementing and testing changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in establishing and maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on the Nasdaq.

# We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash and cash equivalents, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ADSs. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our ADSs to decline and delay the development of our product candidates and preclinical program. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that losses value. See the section titled "Use of Proceeds" for additional information.

# Raising additional capital may cause dilution to our holders, including purchasers of our ADSs in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to the holders of our ADSs or ordinary shares, including ADSs sold in this offering.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would

otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders, and may cause the market price of our ADSs to decline.

#### Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

# ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could augur less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement, our shares or the ADSs or the transactions contemplated thereby. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

# You may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Although we do not have any present plans to declare or pay any dividends, in the event we declare and pay any dividends, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to register under U.S. securities laws any offering of ADSs, ordinary shares or other securities received through such distributions. We also have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of your ADSs.

### Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

# Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our ADSs to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or out of the credit standing in our company's share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our shareholders may, subject to our memorandum and articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, received by us from our subsidiaries, our future results of operations and cash flow, our capital requirements and surplus, the amount of directors. As a result, capital appreciation, if any, on our ADSs will be your sole source of gains for the foreseeable future. Investors seeking cash dividends should not purchase our ADSs in this offering.

### If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive

income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business. We have not yet determined our expected PFIC status for the current taxable year or any future taxable year. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance that we will or will not be considered a PFIC in any taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2020, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

The tax consequences that would apply if we have classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

# If a United States person is treated as owning at least 10% of our ordinary shares, including ordinary shares represented by ADSs, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder (as defined below under "Material Income Tax Considerations—Material U.S. Federal Income Tax Considerations for U.S. Holders") is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, including ordinary shares represented by ADSs, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary, certain of our non-U.S. subsidiaries may be treated as controlled foreign corporations (regardless of whether Legend Biotech Corporation is treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries, if any, are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting.



#### Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

The tax treatment of the company is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organisation for Economic Co-operation and Development's, Base Erosion and Profit Shifting, Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

# Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

# We will incur significantly increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal controls over financial reporting. However, while we remain an emerging growth company, we will not be

required to include an attestation report on internal controls over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal controls over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal controls over financial reporting is effective as required by Section 404.

# We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our ADSs may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an emerging growth company, we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ordinary shares, including ordinary shares represented by ADSs, held by non-affiliates exceeds \$700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an emerging growth company as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

# We qualify as a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that permit less detailed and frequent reporting than that of a U.S. domestic public company.

Upon the closing of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year.

Foreign private issuers also are exempt from Regulation FD, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than

the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time-consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

# As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

We are entitled to rely on a provision in the Nasdaq's corporate governance rules that allows us to follow Cayman Island's corporate law with regard to certain corporate governance matters. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on the Nasdaq. The corporate governance practice in our home country, the Cayman Islands, does not require a majority of our board to consist of independent directors or the implementation of a nominating and corporate governance committee. Since a majority of our board of directors will not consist of independent directors as long as we rely on the foreign private issuer exemption, fewer board members will be exercising independent judgment and the level of board oversight on the management of our company may decrease as a result.

#### Since shareholder rights under Cayman Islands law differ from those under U.S. law, you may have difficulty protecting your shareholder rights.

We are an exempted company limited by shares incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our memorandum and articles of association, the Companies Law (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records, other than the memorandum and articles of association and any special resolutions passed by such companies, and the registers of mortgages and charges of such companies. The Registrar of Companies of the Cayman Islands shall make available the list of the names of the current directors of the Company (and where applicable the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. Our directors have discretion under our post-offering memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders.

This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. Currently, we do not plan to rely on home country practice with respect to any corporate governance matter. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by our management, members of our board of directors or our controlling shareholders than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Law of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, see "Description of Share Capital—Differences in Corporate Law."

# Our amended and restated memorandum and articles of association to be effective in connection with the closing of this offering will provide that the U.S. federal district courts will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Our amended and restated memorandum and articles of association to be effective in connection with the closing of this offering will provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. If a court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition.

# If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs could decline.

The trading market for our ADSs will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ADSs after the completion of this offering, and such lack of research coverage may adversely affect the market price of our ADSs. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our ADSs could decline if one or more equity research analysts downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline.

#### You may be subject to limitations on transfers of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when deemed necessary or advisable by it in good faith in connection with the performance of its duties or at our reasonable written request, subject in all cases to compliance with applicable U.S. securities laws. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

# We may be subject to securities litigation, which is expensive and could divert management's attention.

The market price of our ADSs may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled "Prospectus summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business." Known and unknown risks, uncertainties and other factors, including those listed under "Risk Factors," may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases, such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include statements relating to:

- the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- our ability to achieve milestones under our collaboration with Janssen for LCAR-B38M/JNJ-4528;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the

extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;

- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from this offering.

These forward-looking statements involve various risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," and other sections in this prospectus. You should read thoroughly this prospectus and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this prospectus and the documents that we refer to in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

# MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified this data. Further, while we believe that our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

# **USE OF PROCEEDS**

We estimate that we will receive net proceeds from this offering of approximately \$, or approximately \$ if the underwriters exercise their over-allotment option in full, after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. These estimates are based upon an assumed initial public offering price of \$ per ADS, which is the midpoint of the price range shown on the front page of this prospectus.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per ADS would increase or decrease, as applicable, the net proceeds to us from this offering by \$ , assuming the number of ADSs offered by us, as set forth on the front cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1.0 million in the number of ADSs we are offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our ADSs and facilitate our future access to the public capital markets.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$ million to \$ million to fund the clinical development of LCAR-B38M/JNJ-4528;
- approximately \$ million to \$ million to fund the construction of our manufacturing facilities;
- approximately \$ million to \$ million to fund the commercial launch, if approved, of LCAR-B38M/JNJ-4528; and
- the remaining amounts to fund the development of our pipeline programs, as well as for working capital and other general corporate purposes.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our planned operating expenses and capital expenditures through the next months. The net proceeds from this offering, together with our existing cash and cash equivalents, may be insufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. It is difficult to predict the cost and timing required to complete development and obtain regulatory approval of, and commercialize, our product candidates due to, among other factors, the relatively short history of our experience with initiating, conducting and completing clinical trials, obtaining regulatory approval and commercializing our product candidates, the rate of subject enrollment in our clinical trials, filing requirements with various regulatory agencies, clinical trial results and the actual costs of manufacturing and supplying our product candidates.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. We believe that opportunities may exist from time to time to expand our current business through licenses with or acquisitions of, or investments in, complementary businesses, products or technologies, and we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing, cost and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending any use described above, we intend to invest the net proceeds of this offering in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

### **DIVIDEND POLICY**

Our board of directors has discretion on whether to distribute dividends, subject to the amended and restated memorandum and articles of association of our company and certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. In either case, all dividends are subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or the credit standing in our company's share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid. Even if we decide to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant.

We do not have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future after this offering. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

If we pay any dividends on our ordinary shares, we will pay those dividends, which are payable in respect of the ordinary shares underlying the ADSs to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to our ADS holders in proportion to the ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. See "Description of American Depositary Shares." Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2019:

- on an actual basis;
- on a pro forma basis to reflect our issuance and sale of an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020 at a purchase price of \$7.792 per share for aggregate gross proceeds of \$160.5 million, and the conversion of such shares into an aggregate of 20,591,629 ordinary shares, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to reflect our issuance and sale of ordinary shares in the form of ADSs by us in this offering at an assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (assuming the underwriters do not exercise their over-allotment option to purchase additional ADSs).

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing elsewhere in this prospectus, as well as the sections of this prospectus titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	At December 31, 2019		
	Actual	Pro Forma (in thousands)	Pro Forma As Adjusted(1)
Cash and cash equivalents	\$ 83,364	<u> </u>	\$
Equity			
Share capital	20		
(Deficits)/reserves	(122,889)		
Total ordinary shareholders' (deficit)/equity	(122,869)		
Total capitalization	\$ (122,869)		\$

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of cash and cash equivalents, share capital, total ordinary shareholders' (deficit)/equity and total capitalization by \$ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase or decrease of 1.0 million in the number of ADSs offered by us would increase or decrease, as applicable, each of cash and cash equivalents, share capital, total ordinary shareholders' (deficit)/equity and total capitalization by \$ million, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and estimated offering expenses payable by us.

The number of ordinary shares issued and outstanding, as adjusted in the table above, is based on the 200,000,000 ordinary shares outstanding as of December 31, 2019, and excludes:

- ordinary shares issuable upon the exercise of options outstanding as of December 31, 2019, with a weighted average exercise price of per ordinary share;
- ordinary shares available for future issuance under our Share Option Scheme; and
- ordinary shares available for future issuance under our Restricted Share Unit Incentive Plan.

### DILUTION

If you invest in the ADSs, your interest will be diluted to the extent of the difference between the initial public offering price per ADS and our net tangible book value per ADS after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the book value per ordinary share attributable to the existing shareholders for our presently outstanding ordinary shares.

Our historical net tangible book value as of December 31, 2019 was \$, or \$ per ordinary share (equivalent to \$ per ADS). Historical net tangible book value represents the amount of our total consolidated tangible assets, less the amount of our total consolidated liabilities. Dilution is determined by subtracting historical net tangible book value per ordinary share, after giving effect to the additional proceeds we will receive from this offering, from the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus adjusted to reflect the ADS-to-ordinary share ratio, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our pro forma net tangible book value as of December 31, 2019 was \$ million, or \$ per ordinary share (equivalent to \$ per ADS). Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to our issuance and sale of an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020 at a purchase price of \$7.792 per share for aggregate gross proceeds of \$160.5 million, and the conversion of such shares into an aggregate of 20,591,629 ordinary shares, which will occur immediately prior to the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of ordinary shares outstanding as of December 31, 2019, after giving effect to the pro forma adjustments described above.

After giving further effect to our sale of the ADSs offered in this offering at the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (assuming the underwriters do not exercise their over-allotment option to purchase additional ADSs), our pro forma as adjusted net tangible book value as of December 31, 2019 would have been \$ , or \$ per ordinary share (equivalent to \$ per ADS). This represents an immediate increase in net tangible book value of \$ per ADS to our existing shareholders and an immediate dilution in net tangible book value of \$ per ADS in this offering. The following table illustrates such dilution:

Assumed initial public offering price	\$
Historical net tangible book value per ordinary share as of December 31, 2019	\$
Increase per ordinary share attributable to the issuance and sale of Series A Preference Shares and conversion of such shares	
into ordinary shares	
Pro forma net tangible book value per ordinary share as of December 31, 2019	
Pro forma increase in net tangible value per ordinary share attributable to new investors participating in this offering	
Pro forma as adjusted net tangible book per ordinary share following this offering	 
Dilution per ordinary share to new investors participating in this offering	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per ADS would increase or decrease, as applicable, our pro , the pro forma as adjusted net tangible book value after giving effect to this offering by \$ per ordinary share and the dilution in pro forma as adjusted net tangible book value per ADS to new investors in this offering by \$ per ADS, assuming no change to the number of ADSs offered by us as set forth on the front cover of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1.0 million in the

number of ADSs we are offering would increase our pro forma as adjusted net tangible book value as of December 31, 2019 after this offering by \$ per ADS, assuming the assumed initial public offering price per ADS remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1.0 million in the number of ADSs we are offering would decrease our pro forma as adjusted net tangible book value as of December 31, 2019 after this offering price per dominant of ADSs we are offering would decrease our pro forma as adjusted net tangible book value as of December 31, 2019 after this offering by \$ per ordinary share, and would increase dilution to investors in this offering by \$ per ADS, assuming the assumed initial public offering public offering price per ADS remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2019, the differences between existing shareholders and the new investors with respect to the number of ordinary shares (in the form of ADSs or ordinary shares) purchased from us, the total consideration paid and the average price per ordinary share and per ADS paid before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The total number of ordinary shares does not include ordinary shares underlying the ADSs issuable upon the exercise of the overallotment option granted to the underwriters.

		Ordinary Shares Purchased(1)		Total Consideration		Average Price Per
	Number	Percent	Amount	Percent	Ordinary Share	ADS
Existing shareholders		%	\$	%	\$	\$
New investors		%	\$	%	\$	\$
Total			\$	100%		

(1) Including ordinary shares underlying ADSs.

If the underwriters exercise the over-allotment option in full, the number of ordinary shares held by existing shareholders would be reduced to % of the total number of ordinary shares outstanding after this offering, and the number of ordinary shares held by new investors participating in the offering would be increased to % the total number of ordinary shares outstanding after this offering (in each case, including ordinary shares underlying ADSs).

The foregoing tables and calculations are based on the 200,000,000 ordinary shares outstanding as of December 31, 2019, and excludes:

- ordinary shares issuable upon the exercise of options outstanding as of December 31, 2019, with a weighted average exercise price of per ordinary share;
- ordinary shares available for future issuance under our Share Option Scheme; and
- ordinary shares available for future issuance under our Restricted Share Unit Incentive Plan.

To the extent that any outstanding options are exercised or new options are issued under the equity benefit plans, or we issue additional ordinary shares or other securities convertible into or exercisable or exchangeable for ordinary shares in the future, there will be further dilution to investors participating in this offering.

### ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. We are incorporated in the Cayman Islands to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

- political and economic stability;
- an effective judicial system;
- tax neutrality;
- the absence of exchange control or currency restrictions; and
- the availability of professional and support services.

However, certain disadvantages accompany incorporation in the Cayman Islands. These disadvantages include but are not limited to:

- the Cayman Islands has a less developed body of securities laws as compared to the United States and these securities laws provide significantly less protection to investors as compared to those of the United States; and
- Cayman Islands companies may not have standing to sue before the federal courts of the United States.

Our constituent documents do not contain provisions requiring that disputes, including those arising under the securities laws of the United States, between us, our officers, directors and shareholders, be arbitrated.

Certain of our directors are nationals or residents of jurisdictions other than the United States and most of their assets are located outside the United States. As a result, it may be difficult for a shareholder to effect service of process within the United States upon these individuals, or to bring an action against us or these individuals in the United States, or to enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

Harney Westwood & Riegels, our counsel as to Cayman Islands law, has advised us that there is uncertainty as to whether the courts of the Cayman Islands would (i) recognize or enforce judgments of U.S. courts obtained against us or our directors or officers that are predicated upon the civil liability provisions of the federal securities laws of the United States or the securities laws of any state in the United States, or (ii) entertain original actions brought in the Cayman Islands against us or our directors or officers that are predicated upon the securities laws of any state in the United States or the securities laws of any state in the United States.

Harney Westwood & Riegels has informed us that although there is no statutory enforcement in the Cayman Islands of judgments obtained in the federal or state courts of the United States (and the Cayman Islands are not a party to any treaties for the reciprocal enforcement or recognition of such judgments), the courts of the Cayman Islands will, at common law, recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without any re-examination of the merits of the underlying dispute based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the liquidated sum for which such judgment has been given, provided such judgment (i) is final and conclusive, (ii) is not in respect of taxes, a fine or a penalty or similar fiscal or revenue obligations, and (iii) was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands. However, the Cayman Islands courts are unlikely to enforce a judgment obtained from the U.S. courts under civil liability provisions of the U.S. federal securities law if such judgment is determined by the courts of the Cayman Islands to give rise to obligations to make payments that are penal or punitive in nature. A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

# SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present our selected consolidated financial data as of the dates and for the periods indicated. We have derived the consolidated statement of profit or loss data for the years ended December 31, 2018 and 2019 and the consolidated statement of financial position data as of December 31, 2018 and 2019 from our audited consolidated financial statements appearing at the end of this prospectus. Our consolidated financial statements are prepared and presented in accordance with IFRS, as issued by the IASB. IFRS differs in certain significant respects from U.S. GAAP.

Our historical results are not necessarily indicative of results expected for future periods. You should read this section together with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

### Selected consolidated statement of profit or loss data

		Ended nber 31,
	<u>2018</u>	2019
		ds, except per e data)
Revenue	\$ 49,133	\$ 57,264
Other income and gains	13,901	7,125
Research and development expenses	(60,637)	(161,943)
Administrative expenses	(2,769)	(6,752)
Selling and distribution expenses	(1,160)	(25,620)
Other expenses	(2)	(221)
Finance costs	(82)	(223)
Loss before tax	(1,616)	(130,370)
Income tax expense	(1,168)	(2,602)
Loss for the year	\$ (2,784)	\$ (132,972)
Attributable to:		
Equity holders of the parent	<u>\$ (2,784)</u>	<u>\$ (132,972)</u>
Loss per share attributable to ordinary equity holders of the parent		
Basic	<u>\$ (0.01</u> )	\$ (0.66)
Diluted	\$ (0.01)	\$ (0.66)

Selected consolidated statement of financial position data

	As of December 31,	
	2018	2019
	(in thousands)	
Cash and cash equivalents	\$210,166	\$ 83,364
Working capital <sup>(1)</sup>	167,771	79,343
Total assets	429,047	287,715
Total liabilities	420,398	410,584
Share capital	20	20
Total ordinary shareholders' equity/(deficit)	8,649	(122,869)

(1) Working capital is defined as total current assets minus total current liabilities.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### Overview

We are a global, clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 650 employees in the United States, China and Europe, our differentiated technology, global development and manufacturing strategy and expertise provide us with the ability to generate, test and manufacture next-generation cell therapies targeting indications with high unmet needs.

Our lead product candidate, LCAR-B38M/JNJ-4528, is a CAR-T cell therapy we are jointly developing with our strategic partner, Janssen, for the treatment of MM. LCAR-B38M refers to the product candidate being studied in China, and JNJ-4528 refers to the product candidate being studied in the rest of the world. Clinical results achieved to date demonstrate that LCAR-B38M/JNJ-4528 has the potential to deliver deep and durable anti-tumor responses in RRMM patients with a manageable safety profile.

Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with capital contributions from GenScript, with proceeds from the sale of our Series A Preference Shares and from upfront and milestone payments from Janssen. From inception through December 31, 2019, we received \$3.9 million in capital contributions and an aggregate of \$430.0 million from Janssen under the Janssen Agreement. As of December 31, 2019, we had \$158.9 million in cash and cash equivalents and time deposits. Subsequent to December 31, 2019, we received an additional \$30.0 million milestone payment from Janssen in January 2020 and aggregate gross proceeds of \$160.5 million from our sale of an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020.

Since inception, we have incurred significant operating losses. Our net losses were \$2.8 million and \$133.0 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had accumulated losses of \$127.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue our ongoing and planned research and development of our lead product candidate, LCAR-B38M/JNJ-4528, for the treatment of RRMM;
- continue our ongoing and planned clinical development for our other product candidates, including those we are developing for the treatment of AML, NHL, TCL, DLBCL, gastric cancer, ovarian cancer, pancreatic cancer and HIV;
- continue our ongoing and planned research and development activities;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- continue to scale up internal and external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- hire additional clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations globally; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company following the completion of this offering.

#### **Our Collaboration with Janssen**

In December 2017, we entered into a collaboration and license agreement with Janssen for the worldwide development and commercialization of LCAR-B38M/JNJ-4528.

Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize LCAR-B38M/JNJ-4528. We and Janssen will collaborate to develop and commercialize LCAR-B38M/JNJ-4528 for the treatment of MM worldwide pursuant to a global development plan and global commercialization plan. Janssen will be responsible for conducting all clinical trials worldwide with participation by our team in the United States and Greater China for LCAR-B38M/JNJ-4528. We will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for Greater China, while Janssen will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for the rest of the world. We and Janssen will share development, production and commercialization costs and pre-tax profits or losses equally in all countries of the world except for Greater China, for which the cost-sharing and profit/loss split will be 70% for us and 30% for Janssen.

In consideration for the licenses and other rights granted to Janssen, Janssen has paid us an upfront fee of \$350.0 million and milestone payments totaling \$110.0 million for the achievement of four development milestone events to date. Additionally, we are eligible to receive further milestone payments up to \$125.0 million for the achievement of specified manufacturing milestones and an additional \$1,115 million for the achievement of specified future development, regulatory and net trade sales milestones.

#### **Components of Our Results of Operations**

#### Revenue

To date, we have not generated any revenue from product sales. Our revenue to date has primarily consisted of the upfront payments and milestone payments received pursuant to the Janssen Agreement. Our ability to generate product revenue and to become profitable will depend upon our ability to successfully develop, obtain regulatory approval and commercialize LCAR-B38M/JNJ-4528 and our other product candidates. Because of the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount, timing or whether we will be able to obtain product revenue.

### **Operating Expenses**

### **Research and Development Expenses**

Research and development expenses consist primarily of costs incurred in connection with our research activities and include:

- personnel expenses, including salaries, benefits and share-based compensation expense;
- costs of funding research performed by third parties;
- costs of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing preclinical study and clinical trial materials;
- consultant fees;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies;
- facility costs including rent, depreciation and maintenance expenses; and
- fees for maintaining licenses under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by allocating these costs to either our BCMA program or to all our other non-BCMA programs, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or preclinical programs. For the years ended December 31, 2018 and 2019, our total research and development expenses were \$45.7 million and \$113.1 million, respectively, for our BCMA program and \$14.9 million and \$48.8 million, respectively, for all other non-BCMA programs.

From inception through December 31, 2019, we have incurred approximately \$231.7 million in research and development expenses to research and advance the development of our product candidates and preclinical programs. We expect our research and development expenses will increase for the foreseeable future as we seek to advance our preclinical programs and product candidates. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the product candidates, if approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- continued acceptable safety profiles of products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

### Administrative Expenses

Administrative expenses consist primarily of personnel expenses, including salaries, benefits and share-based compensation expense, for personnel in executive, finance, accounting, business development, legal and human resource functions. Administrative expenses also include corporate facility costs not otherwise included in research and development expenses, legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We anticipate that our administrative expenses will increase in the future to support continued research and development activities, including our ongoing and planned research and development of our lead product candidate, LCAR-B38M/JNJ-4528, for the treatment of RRMM and the initiation and continuation of our preclinical and clinical trials for our other product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses, associated with operating as a public company.

#### Selling and Distribution Expenses

Selling and distribution expenses consist primarily of costs incurred in connection with our commercial function's activities and include salaries and related costs for personnel, including stock-based compensation, travel expenses, recruiting expenses, costs of sponsorships and consulting fees paid to external parties related to the development of LCAR-B38M/JNJ-4528.

#### **Other Income and Gains**

Other income and gains consists of finance income, fair value gains on financial assets at fair value change through profit or loss, government grants, foreign exchange gain and loss and rental income.

### **Results of Operations**

### Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019:

	Year Ended December 31,		Increase
	2018	2019	Increase (Decrease)
		(in thousands)	
Consolidated Statement of Operations Data:			
Revenue	\$ 49,133	\$ 57,264	\$ 8,131
Operating expenses:			
Research and development expenses	(60,637)	(161,943)	(101,306)
Administrative expenses	(2,769)	(6,752)	(3,983)
Selling and distribution expenses	(1,160)	(25,620)	(24,460)
Other income and gains	13,901	7,125	(6,776)
Other expenses	(2)	(221)	(219)
Finance costs	(82)	(223)	(141)
Loss before tax	(1,616)	(130,370)	(128,754)
Income tax expense	(1,168)	(2,602)	(1,434)
Net loss	\$ (2,784)	\$ (132,972)	\$(130,188)

#### Revenue

Revenue for the year ended December 31, 2018 was \$49.1 million, compared to \$57.3 million for the year ended December 31, 2019. This increase of \$8.2 million was primarily due to recognition of additional milestone payments from Janssen. Revenue for the year ended December 31, 2018 consisted of recognition of upfront and milestone payments received pursuant to the Janssen Agreement and \$1.0 million in revenue earned from research and development services we provided to Nanjing Jinsirui Biotechnology Co., Ltd. in 2018. Revenue for the year ended December 31, 2019 consisted of recognition of upfront and milestone payments received pursuant to the Janssen Agreement. We have not generated any revenue from product sales to date.

#### **Operating Expenses**

#### **Research and Development Expenses**

Research and development expenses for the year ended December 31, 2018 were \$60.6 million, compared to \$161.9 million for the year ended December 31, 2019. This increase of \$101.3 million was primarily due to a higher number of clinical trials and a higher number of patients enrolled in those trials in 2019.

#### Administrative Expenses

Administrative expenses for the year ended December 31, 2018 were \$2.8 million, compared to \$6.8 million for the year ended December 31, 2019. This increase of \$4.0 million was primarily due to our expansion of supporting administrative functions to aid continued research and development activities in 2019.

#### Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2018 were \$1.2 million, compared to \$25.6 million for the year ended December 31, 2019. This increase of \$24.4 million was primarily due to increased costs in 2019 associated with commercial preparation activities for our BCMA program.

#### Other Income and Gains

Other income and gains for the year ended December 31, 2018 was \$13.9 million, compared to \$7.1 million for the year ended December 31, 2019. This decrease of \$6.8 million was primarily due to lower foreign currency exchange gain during 2019.

#### **Income Tax Expense**

Income tax expense for the year ended December 31, 2018 was \$1.2 million, compared to \$2.6 million for the year ended December 31, 2019.

#### Liquidity and Capital Resources

#### Sources of Liquidity

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our research programs and product candidates. We expect that our research and development and general and administrative expenses will increase in connection with conducting additional clinical trials and preclinical studies for our current and future research programs and product candidates, contracting with CMOs to support clinical trials and preclinical studies, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations to date primarily with capital contributions from GenScript, with proceeds from the sale of our Series A Preference Shares and from upfront and milestone payments from Janssen. From inception through December 31, 2019, we have received \$3.9 million in capital contributions and an aggregate of \$430 million from Janssen under the Janssen Agreement. As of December 31, 2019, we had \$158.9 million in cash, cash equivalents and time deposits, and accumulated losses of \$127.3 million. Subsequent to December 31, 2019, we received an additional \$30.0 million milestone payment from Janssen in January 2020 and aggregate gross proceeds of approximately \$160.5 million from our sale of an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020. We had no indebtedness as of December 31, 2019.

### **Cash Flows**

The following table shows a summary of our cash flows for the years ended December 31, 2018 and 2019:

		Year Ended December 31,	
	2018	2019	
	(in thou	isands)	
Net cash from/(used in) operating activities	\$ 307,682	\$ (83,065)	
Net cash used in investing activities	(102,256)	(58,652)	
Net cash from financing activities	2,501	14,666	
Net increase/(decrease) in cash and cash equivalents	\$ 207,927	\$(127,051)	

### **Operating Activities**

Net cash provided by operating activities for the year ended December 31, 2018 was \$307.7 million, consisting primarily of a net increase in operating assets and liabilities of \$318.7 million, offset by our net loss before tax of \$12.7 million adjusted for non-cash items. The increase in operating assets and liabilities was mainly driven by the upfront payment of \$350.0 million received from Janssen.

Net cash used in operating activities for the year ended December 31, 2019 was \$83.1 million, consisting primarily of our net loss before tax of \$128.9 million adjusted for non-cash items, primarily due to continued spending in research and development activities, partially offset by milestone payments received from Janssen.

### **Investing Activities**

Net cash used in investing activities for the year ended December 31, 2018 was \$102.3 million, consisting primarily of cash advances of \$75.0 million to affiliates of GenScript and \$21.0 million in purchases of property, plant and equipment.

Net cash used in investing activities for the year ended December 31, 2019 was \$58.7 million, consisting primarily of purchases of property, plant and equipment of \$38.6 million and purchases of short-term time deposits of \$75.6 million, partially offset by collection of cash advances from related parties of \$63.0 million.

### **Financing Activities**

Net cash provided by financing activities in the year ended December 31, 2018 was \$2.5 million, consisting primarily of cash advances from affiliates of GenScript of \$35.9 million, partially offset by repayment of cash advances to affiliates of GenScript of \$33.2 million.

Net cash provided by financing activities in the year ended December 31, 2019 was \$14.7 million, consisting primarily of proceeds from cash advances from related parties of \$38.9 million, partially offset by repayment of cash advances from related parties of \$19.2 million.

#### **Funding Requirements**

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our

product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under the Janssen Agreement and any other collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

# **Contractual Obligations & Commitments**

The following is our contractual obligations and commitments as of December 31, 2019:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	re than Years	Total
			(in thousands)		
Lease obligations(1)	\$ 1,073	\$3,994	\$988	\$ 875	\$6,930
Capital commitment	\$ 2,844			 	\$2,844
Total	\$ 3,917	\$3,994	\$988	\$ 875	\$9,774

(1) Amounts presented in the table represent payments due under operating leases for facilities in New Jersey, Ireland and China that in the aggregate total of \$6.9 million.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

We also enter into cancelable contracts in the normal course of business with CROs for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes.

### **Internal Control Over Financial Reporting**

During the audit of our financial statements for the year ended December 31, 2019, two material weaknesses were identified in our internal control over financial reporting. Under standards established by the PCAOB, a "material weakness" is a deficiency, or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that have been identified relate to our lack of sufficient accounting and financial reporting personnel with requisite knowledge of and experience in application of IFRS and SEC rules, and lack of financial reporting policies and procedures that are commensurate with IFRS and SEC reporting and compliance requirements.

We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified including: (i) hiring additional accounting and financial reporting personnel with IFRS and SEC reporting experience, (ii) expanding the capabilities of existing accounting and financial reporting personnel through continuous training and education in the accounting and reporting requirements under IFRS, and SEC rules and regulations, (iii) developing, communicating and implementing an accounting policy manual for our accounting and financial reporting personnel for recurring transactions and period-end closing processes, and (iv) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our company's consolidated financial statements and related disclosures.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2018 and 2019 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.

#### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

# **Critical Accounting Policies**

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. Our most critical accounting policies are summarized below. See note 2.3 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of our other significant accounting policies.

### **Revenue Recognition**

### Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If we perform by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

#### **Contract liabilities**

A contract liability is recognized when a payment is received or a payment is due (whichever is earlier) from a customer before we transfer the related goods or services. Contract liabilities are recognized as revenue when we perform under the contract (i.e., transfers control of the related goods or services to the customer).

#### **Upfront** fees

Upfront payment is allocated to the performance obligations based on our best estimate of their relative stand-alone selling prices. The upfront fees from Janssen of \$350 million were included in the transaction price upon contract inception in 2017 and fully received by us in 2018.

#### Milestone payments

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price. The milestone payments were allocated to the performance obligations based on our best estimate of their relative stand-alone selling prices unless the criteria under IFRS 15.85 are met, where the milestone payments are allocated entirely to the performance obligations which the milestone payments are specifically related to.

The initial two milestone payments from Janssen of \$50.0 million were included in the transaction price upon contract inception in 2017. Subsequently in 2019, an additional two milestone payments of \$60.0 million were included in the transaction price when the milestones triggered by dosing of a specified number of patients in the CARTITUDE-1 clinical trial were achieved. As of December 31, 2019, we were eligible to receive further milestone payments of up to \$125.0 million for the achievement of specified manufacturing milestones and an additional \$1,115.0 million, consisting of \$105.0 million for the achievement of specified future development milestones, \$800.0 million for the achievement of specified regulatory milestones and \$210.0 million for the achievement of specified net trade sales milestones. We assessed that achievement of the remaining milestones is still highly uncertain and cannot be included in the transaction price. The milestone is achieved when the triggering event described in the agreement occurs.

#### Licenses of intellectual property

In assessing whether a license is distinct from the other promises, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the counterparty can benefit from a license for its intended purpose without the receipt of the remaining promise(s) by considering whether the value of the license is dependent on the unsatisfied promise(s), whether there are other vendors that could provide the remaining promise(s), and whether it is separately identifiable from the remaining promise(s). We evaluate the nature of a promise to grant a license in order to determine whether the promise is satisfied over time or at a point in time. We evaluated that the licenses are separate performance obligations which represent a right to use our license as it exists at the point in time that the license is granted. Revenue from licenses is recognized when the control of the right to use of the license is transferred to the customer.

#### Steering committee services

In assessing whether the preparation and participation in a Joint Steering Committee which leads to the commercialization of new drug, or the JSC service, is a promised service in the arrangement with Janssen, we concluded that the services are capable of being distinct from the intellectual property licenses and distinct within the context of the contract based on a careful evaluation of the specific facts and circumstances. The performance obligation is satisfied over time as services are rendered. Revenue from JSC service is recognized on a straight-line basis over the period when the JSC service is provided.

#### Research and development costs

All research costs are charged to profit or loss as incurred.

Expenditures incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

#### **Share-Based** Compensation

We operate a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our operations. Our employees and directors can receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments, or equity-settled transactions.

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model. See note 23 to our consolidated financial statements beginning on page F-1 of this prospectus for further details.

The cost of equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefit expense. The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the

grant date fair value. Any other conditions attached to an award, but without an associated service requirement,

are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

The following table lists the inputs to the model used:

	Year Ended December 31,		
	2018	2019	
Expected life of options (years)	10	10	
Expected volatility	64.2%-66.4%	66.4%-80.3%	
Risk-free interest rate	2.48%-2.87%	1.98%-2.69%	
Dividend yield	0%	0%	
Weighted average share price	\$0.609-\$0.615	\$0.590-\$0.615	

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options that include performance vesting conditions and are subject to forfeiture if the participants cannot meet certain performance targets set by our board of directors.

We estimate the fair value of each stock option grant using the Binomial option-pricing model, which uses as inputs the fair value of our common stock, exercise price of our stock options, expected volatility of our common stock based on historical volatility of comparable companies, the expected terms of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, the post-vesting forfeit rate and our expected dividend yield.

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by reference to our most recently available third-party valuations of common stock which are close to the grant date. We have periodically determined the estimated fair value of our common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the IFRS2 *Sharebased Payment* and IFRS 13 *Fair Value Measurement*.

Our common stock valuations were performed solely on the income approach in the form of a discounted cashflow, or DCF, methodology to estimate our enterprise value. The market approach was not utilized as our Company is still in development stage and its products are yet to be commercialized.

We performed these contemporaneous valuations, with the assistance of a third-party valuation specialist, as of December 26, 2017, August 30, 2018, December 31, 2018, July 2, 2019 and November 29, 2019. In addition to these valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the progress of our research and development programs, including the status of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results; and
- the lack of an active public market for our common stock.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes

change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2019, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject To Options Granted	Exe	er Share rcise Price Options	C St Sl Opti	r Value of ommon ock per hare on ion Grant Date	Estin V	er Share mated Fair /alue of Options
January 14, 2019	10,000	\$	1.0	\$	0.615	\$	0.362
January 28, 2019	10,000	\$	1.0	\$	0.615	\$	0.362
July 2, 2019	2,233,000	\$	1.5	\$	0.590	\$	0.286
July 8, 2019	2,000	\$	1.5	\$	0.590	\$	0.286
July 22, 2019	1,000,000	\$	1.5	\$	0.590	\$	0.286
November 29, 2019	472,000	\$	1.5	\$	0.610	\$	0.345
December 9, 2019	30,000	\$	1.5	\$	0.610	\$	0.345

#### **Issued But Not Yet Effective Reporting Standards**

See note 2.2 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

### Qualitative and Quantitative Disclosures about Market Risk

Our cash is held in readily available checking accounts. These securities are generally not dependent on interest rate fluctuations that may cause the principal amount of these assets to fluctuate. As a result, a change in market interest rates would not have any significant impact on our financial position or results of operations. As of December 31, 2019, we have no material interest rate risk exposure.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2018 and 2019. We also do not believe that we are exposed to any material foreign currency exchange rate risk.

### **Emerging Growth Company Status**

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more, (2) the last day of the fiscal year in which the fifth anniversary of the completion of this initial public offering occurs, (3) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (4) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when we have more than \$700.0 million in market value of our stock held by non-affiliates as of the prior June 30th and we have been a public company for at least 12 months and have filed one annual report.

### BUSINESS

### Overview

We are a global, clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 650 employees in the United States, China and Europe, our differentiated technology, global development and manufacturing strategy and expertise provide us with the ability to generate, test and manufacture next-generation cell therapies targeting indications with high unmet needs. Our lead product candidate, LCAR-B38M/JNJ-4528, is a chimeric antigen receptor, or CAR, T cell therapy we are jointly developing with our strategic partner, Janssen Biotech, Inc., or Janssen, for the treatment of multiple myeloma, or MM. LCAR-B38M refers to the product candidate being studied in China, and JNJ-68284528, or JNJ-4528, refers to the product candidate being studied in the rest of the world. Clinical results achieved to date demonstrate that LCAR-B38M/JNJ-4528 has the potential to deliver deep and durable anti-tumor responses in relapsed and refractory multiple myeloma, or RRMM, patients with a manageable safety profile.

In December 2019, we reported updated data from a Phase 1 clinical trial of LCAR-B38M in China, in 74 patients with RRMM across four independent sites. Patients treated with LCAR-B38M had at least 24 months of median follow-up and achieved an overall response rate, or ORR, of 88 percent, with a complete response, or CR, rate ranging from 74 to 82 percent, depending on the site. In the largest site of 57 patients, median overall survival, or mOS, was 36.1 months as of July 31, 2019. The Phase 1b/2 registrational trial of JNJ-4528 in RRMM patients in the United States and Japan, which we refer to as CARTITUDE-1, has complete enrollment of the Phase 2 portion in the United States. All 29 patients treated with JNJ-4528 from the Phase 1b portion achieved a response, with an ORR of 100 percent. As of April 20, 2020, with a median follow-up of 11.5 months, 25 of 29 patients, or 86 percent, achieved a stringent complete response, or sCR. The 9-month progression free survival rate was 86 percent and 22 of the 29 patients remained alive and progression free at the time of data cut-off. We anticipate that data from the Phase 2 portion of CARTITUDE-1 will be presented at a major medical conference in the second half of 2020. JNJ-4528 has been granted breakthrough therapy designation and orphan drug designation by the U.S. Food and Drug Administration, or FDA, and Priority Medicines, or PRIME, designation, enabling accelerated assessment, by the European Medicines Agency, or EMA. We anticipate that a biologics license application, or BLA, will be submitted to the FDA and a market authorization application, or MAA, will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020.

CAR-T cell therapy is a form of cancer immunotherapy, whereby a patient's T cells are engineered to express a CAR that recognizes and binds to tumor cell surface antigens, resulting in their activation to target cancer cells for destruction. CAR-T cell therapy has emerged as a revolutionary and potentially curative therapy for patients with certain hematologic cancers. In 2017, the FDA approved the first two CAR-T cell therapies, Kymriah and Yescarta, after these products demonstrated strong efficacy in select relapsed or refractory B cell malignancies.

The development of CAR-T cell therapies has required notable advancements across the spectrum to overcome several challenges, including selecting the ideal tumor antigen target, engineering a CAR construct that will lead to potent and selective killing of tumor cells, the lack of validated preclinical models that are predictive of safety and efficacy in humans, and the ability to manufacture cell therapies with the high quality and reproducibility required for pharmaceutical products. In addition, meeting commercial demand at both a regional and global scale remains a challenge.

We have built our company around overcoming the challenges associated with CAR-T cell therapy development through deploying our fullyintegrated, global cell therapy capabilities including in-house expertise on early-stage discovery, efficient clinical translation, manufacturing and commercialization to bring our pipeline of next-generation CAR-T product candidates to patients. We are leveraging our in-house antibody generation, coupled with our CAR-T specific functional screening capability, to add one or multiple tumor antigen binding sites on T cells. We seek to bridge the gap between discovery research and patients by leveraging our relationships with clinicians and their ability to conduct investigator-initiated clinical trials in top-tier hospitals in

China without a formal investigational new drug, or IND, process as part of the encouragement of innovation by the National Medical Products Administration, or NMPA. We work with the clinicians and hospitals to conduct these trials in accordance with international standards to support future global regulatory filings and partnerships. This strategy enables us to rapidly advance product candidates to patient populations with large unmet needs. To satisfy anticipated commercial demand in various geographies, we are building manufacturing facilities in the United States, Europe and China. Furthermore, we will seek to make our products, if approved, widely available to cancer patients throughout the United States, Europe and Asia independently or through partnerships. Taken together, we believe that our fully integrated approach will enable us to rapidly expand the use of CAR-T cell therapies.

Our lead product candidate, LCAR-B38M/JNJ-4528, is an autologous CAR-T cell therapy that targets the B-cell maturation antigen, or BCMA, which is a highly expressed protein in a number of hematologic malignancies including MM. Autologous cells refer to the patient's own cells. We are developing LCAR-B38M/JNJ-4528 as a potentially improved therapy for MM. MM is a highly aggressive disease representing approximately 10 percent of all hematologic malignancies and 20 percent of deaths of hematologic malignancies worldwide. In 2020, the American Cancer Society projects that 32,270 new cases of MM and 12,830 deaths will occur in the United States. Worldwide, there were an estimated 159,985 new cases of MM in 2018. Existing therapies include monoclonal antibodies, proteasome inhibitors and immunomodulatory agents, which generated aggregate sales of approximately \$18 billion in 2018. Nevertheless, MM remains incurable and patients eventually relapse and become refractory to treatment. For example, mOS in patients who have received at least three prior lines of therapy and are refractory to both an immunomodulatory drug and a proteasome inhibitor is only 13 months. The reported ORR for approved therapies for the population of heavily pre-treated and refractory patients with MM is 30% or less. Therefore, we believe there is a high unmet need for a therapy that provides an improved efficacy profile for a prolonged period of time.

We believe that LCAR-B38M/JNJ-4528 has the potential to transform the treatment of MM. Following the results from our Phase 1 clinical trial in China, which we refer to as LEGEND-2, we are enrolling up to 60 patients in a Phase 2 registrational trial of LCAR-B38M in RRMM patients in China, which we refer to as CARTIFAN-1, and conducting CARTITUDE-1 Phase 1b/2 registrational trial of JNJ-4528 in RRMM patients in the United States and Japan. Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, we anticipate that a BLA will be submitted to the FDA and an MAA will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020. We also intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China and the data from CARTITUDE-1 in support of a regulatory submission in Japan in 2021.

In addition to the trials we are conducting to support our initial regulatory submissions, we are conducting multiple clinical trials to evaluate LCAR-B38M/JNJ-4528 as an earlier line of therapy for MM. In November 2019, we and our strategic partner Janssen began enrolling an aggregate of 80 patients in a Phase 2 multicohort trial of JNJ-4528 in the United States and Europe, which we refer to as CARTITUDE-2, in patients with MM in various clinical settings such as in early relapse patients or as a front-line therapy. Based on those results, we intend to explore expanding our investigation in those patient populations to potentially support regulatory approval submissions upon the agreement of regulatory agencies. In addition the Phase 3 CARTITUDE-4 clinical trial, enrolling approximately 400 patients in the United States, Europe and Japan has been initiated. This clinical trial is comparing treatment with JNJ-4528 to treatment of standard triplet therapy in Revlimid-refractory MM.

We have established a global collaboration with Janssen for LCAR-B38M/JNJ-4528, pursuant to which we share equally the development, production and commercialization costs and profits or losses in all areas other than mainland China, Hong Kong, Macau and Taiwan, or Greater China, where we assume 70 percent of development, production and commercialization costs and retain or bear 70 percent of pre-tax profits or losses. We received an upfront payment of \$350.0 million from Janssen in 2018, and to date, we have received four milestone payments totaling \$110.0 million.

In addition to LCAR-B38M/JNJ-4528, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including Non-Hodgkins Lymphoma, or NHL, Acute Myeloid Leukemia, or AML, and T cell Lymphoma, or TCL, of which the first two are currently in investigator-initiated Phase 1 clinical trials in China. We are also developing an allogeneic CAR-T product candidate targeting CD20 for the treatment of NHL, which is currently in an investigator-initiated Phase 1 clinical trial in China. Allogeneic cells are cells from a donor. Furthermore, we have several product candidates in early preclinical and clinical development for the treatment of solid tumors as well as infectious diseases. Our pipeline of product candidates is summarized in the table below.



"AML= acute myeloid leukemia, BCMA= B-cell maturation antigen, DLBCL= diffuse large B-cell lymphoma, FL= follicular lymphoma, HIV= human immunodeficiency virus, MCL= mantle cell lymphoma, NHL= non-Hodgkin lymphomas, R/R MM= relapsed or refractory multiple myeloma, RoW= Rest of World, SLL=small lymphocytic lymphoma, TCL=T-cell lymphoma

We have assembled a team with broad experience in biopharmaceutical drug discovery, development and commercialization. We are led by Yuan Xu, Ph.D., our Chief Executive Officer, who previously served in senior roles in discovery, development and commercialization at Merck, Gilead, Novartis, Amgen, Chiron, GlaxoSmithKline and Genentech. Ying Huang, Ph.D., our Chief Financial Officer, was most recently a Managing Director and Head of Biotech Equity Research at BofA Securities, Inc., and earlier in his career, he was a Principal Scientist at Schering-Plough (now Merck).

# **Our Strategy**

Our goal is to become a worldwide leader for CAR-T and related cell therapies in treating hematologic malignancies, solid tumors and infectious diseases. Our strategy to achieve this goal is as follows:

- Advance LCAR-B38M/JNJ-4528 through registrational trials and obtain approval for the treatment of RRMM globally. We believe
  we have demonstrated that LCAR-B38M/JNJ-4528 can deliver deep and durable anti-tumor responses, resulting in increased survival in
  RRMM patients. Based on the results of CARTITUDE-1, we anticipate that a BLA will be submitted to the FDA for JNJ-4528 for the
  treatment of RRMM in the second half of 2020. We also plan to seek regulatory approval of LCAR-B38M/JNJ-4528 in other key
  geographies, including in Europe, China and Japan. Furthermore, we intend to aggressively pursue clinical development of
  LCAR-B38M/JNJ-4528 in MM including in earlier-stage patients and potentially as front-line therapy.
- **Rapidly advance our pipeline by leveraging our global clinical development strategy.** We plan to continue to leverage our technical know-how, discovery and clinical expertise, and deep relationships

with clinical investigators and treatment centers to explore new opportunities for cell therapy. We plan to continue to leverage our access to investigator-initiated clinical trials that are conducted in accordance with international standards to advance our product candidates in China and to select product candidates for IND applications in the United States. Our global clinical development strategy enables us to quickly assess the therapeutic potential of these individual product candidates in patients in an efficient and cost-effective manner. We believe this will allow us to rapidly advance product candidates that we find most promising into global registrational clinical trials. We can also refine and optimize product candidates that do not achieve sufficient results in the investigator-initiated trials, and potentially mitigate certain clinical development risks in our target markets.

- **Maintain and expand our global leadership in the cell therapy field.** We believe we are a leading company in the cell therapy field, and we intend to continue to expand our global presence in order to provide access to our products, if approved, to patients around the world. We plan to continue to recruit leading talent across regions to be able to leverage our efficient and cost-effective clinical development strategy in China and to expand our suite of technologies that we believe enables us to take a systematic approach to rapidly developing improved cell therapies. We are conducting clinical pivotal trials for LCAR-B38M/JNJ-4528 designed to support regulatory submissions for approval in the major markets of the United States, Europe, China and Japan. We also intend to establish a global commercial team to support all aspects of our product sales including market access, healthcare provider education, hospital certification, reimbursement, manufacturing and patient and provider support.
- **Expand our manufacturing capabilities.** We currently have manufacturing facilities in China and the United States supplying clinical materials for our trials. As we prepare to potentially commercialize our products, we intend to further expand the commercial-scale manufacturing capacities at these facilities and establish a manufacturing facility in Europe. We expect these facilities will enable rapid scale-up capabilities and provide product supply at both a regional and global scale.
- Establish ourselves as a preferred global partner. Our global network and strategy facilitates accelerated clinical proof-of-concept for pipeline candidates. Further, through our strong presence in China, deep relationships with Chinese key opinion leaders, health policy experts, leading healthcare institutions, local world-class manufacturing and strong understanding of and experience with Chinese regulations, we are well positioned to be the partner of choice to help foreign companies navigate the lucrative yet complex Chinese market. We believe our global collaboration with Janssen, for the development and potential commercialization of LCAR-B38M/JNJ-4528 is a testament to our potential as a preferred global partner.

### Background on Cancer and CAR-T Cell Therapy

Cancer is the second leading cause of death worldwide. Cancers originate when individual cells develop mutations in essential cellular functions that drive increased cell division and growth. T cells, a key component of the immune system, are responsible for defending the body against infectious pathogens and cancerous cells. Through their T cell receptor, T cells are able to recognize and eliminate cancerous cells. However, cancer cells can evolve mechanisms to evade recognition by and establish other escape mechanisms from T cell surveillance. Cancer immunotherapy is a treatment strategy designed to enhance and manipulate immune responses to work more effectively against cancer.

Adoptive cell therapy, or ACT, is a cancer immunotherapy that involves the infusion of immune cells into a patient with the intent of having these cells attack and destroy cancer cells. In most cases these immune cells are autologous, or isolated from the same patient to which they are re-administered. These isolated cells are expanded in number and can be stimulated with specific growth factors, cytokines, chemokines or antigens, or can be genetically modified to recognize and destroy certain tumors.

The two most common engineered ACTs, CAR-T cells and TCR T cells, are genetically modified cells that express either chimeric receptors or naturally occurring T cell receptors, or TCRs, that recognize antigens on a

patient's tumors. Synthetic CAR receptors combine the specificity of a monoclonal antibody with cytotoxic and immune surveillance functions of a T cell and bind to extracellular antigens of cell-surface proteins overexpressed by cancer cells, thus enabling major histocompatibility complex-independent T cell activation. CD19 is an antigen overexpressed on lymphoma cancer cells. Anti-CD19 CAR-T cell therapies have demonstrated strong efficacy and in some cases curative potential in select relapsed or refractory B cell malignancies, ultimately leading to the FDA approvals of the first CAR-T therapies, Kymriah and Yescarta in 2017.

# Challenges in Developing CAR-T Cell Therapies

Despite the advancements in the field, there are a number of key challenges in developing CAR-T cell therapies.

- Selecting an appropriate tumor antigen target: The antigen targets that are recognized by CAR-T cells are membrane-bound cell surface proteins. Limited distribution in normal tissue, over or homogeneous expression in tumors, and lack of shedding or internalization are critical factors related to the target antigen that need to be considered for target selection for developing CAR-T therapies. While expression of target antigens on normal tissues increases the risk of on-target/off-tumor toxicity, reduced or loss of expression due to shedding or internalization on tumor cells can decrease the treatment efficacy.
- **Designing an optimal CAR construct:** The properties of the CAR construct are crucial to the overall success of CAR-T therapy. The affinity and flexibility of the antigen binding domain(s) are important in enhanced tumor-specific recognition, and co-stimulation during CAR-T cell activation regulates metabolism, survival and functions of T cells. A common side effect with CAR-T therapy is excessive T cell activation when encountering its target antigen. Such over activation can result in cytokine release syndrome, or CRS, a life threatening condition caused by high levels of inflammatory cytokines. Therefore, designing an optimal CAR construct requires a balance between efficacy and safety.
- **Preclinical to clinical translation:** The lack of validated preclinical models that are predictive of safety and efficacy in humans presents a considerable barrier for efficient development of CAR-T products. Currently, few preclinical animal models can recapitulate the human immune system, tumor microenvironment and normal tissue distribution of target antigens. Although several animal models have been used in prior CAR-T studies, most of them do not reflect the obstacles to achieve clinical efficacy and fail to predict potentially life-threatening toxicities.
- **Manufacturing complexities:** Manufacturing of CAR-T cell therapies is difficult due to the variability of collected cells from individual patients. Limited economies of scale can be realized given the bespoke nature of autologous CAR-T manufacturing. These factors have contributed to limited clinical translation and patient access. Furthermore, high costs and, in certain instances, high failure rates during the manufacturing process, continue to limit the scalability of CAR-T therapies. The difference in regulations governing the manufacturing of CAR-T therapies from region to region presents an additional layer of complexity for drug developers looking to expand their capabilities globally.

# **Our Approach**

We have built our company around overcoming the challenges associated with CAR-T cell therapy development through deploying our fullyintegrated, global cell therapy capabilities including in-house expertise on early-stage discovery, efficient clinical translation, manufacturing and commercialization to bring our pipeline of next-generation CAR-T product candidates to patients. We are leveraging our in-house antibody generation, coupled with our CAR-T specific functional screening capability, to add one or multiple binding sites on T cells. We seek to bridge the gap between discovery research and patient treatments by leveraging our long-term relationships with clinicians in China and their expertise to conduct investigatorinitiated clinical trials in top-tier

hospitals in China to rapidly advance product candidates to patient populations with large unmet needs. To satisfy anticipated commercial demand in various geographies, we are building manufacturing facilities in the United States, Europe and China. Furthermore, we will seek to make our products, if approved, widely available to cancer patients globally, including in the United States, Europe and Asia. Taken together, we believe that our fully integrated approach will enable us to rapidly expand the use of CAR-T cell therapies to meet the significant unmet need among patients.

# **Technology Capabilities**

From the commencement of our operations in 2014, we recognized the transformational potential of CAR-T cells. We have assembled a team of experts and a suite of technologies that we believe enables us to take a systematic approach to rapidly develop improved cell therapies.

A number of technical areas underpin our approach to CAR-T cell therapy and related fields.

### In-house antibody and CAR screening capability

There is considerable variability in CAR-T cell therapies' ability to specifically recognize and kill tumor cells. Many earlier product candidates developed by others have relied on in-licensed antibodies, which may not be specifically designed for CAR-T application. In contrast, we have developed a high-throughput screening technology that allows us to identify antibody fragments that have the most desirable properties and thus allowing us to optimize antigen-binding domains and linkers for specific CAR constructs. This allows us to repeatedly select and prioritize CAR constructs that are most likely to target the tumor cells of interest with high potency while sparing normal cells. We have demonstrated in our preclinical research and early clinical investigations that appropriate selection of the antigen-binding domain is an important determinant of overall anti-tumor activity. We also believe that our in-house antibody generation, coupled with our CAR-T specific functional screening capability, helps us expand our internal pipeline programs and keep pace with the rapidly evolving cell therapy development landscape.

### Multiple antibody development platforms and multi-specific binding approaches

To maximize the possibility of identifying the best binder for a given target in a CAR-T application, we have multiple in-house antibody development platforms, including single domain antibodies derived from llama and mice and fully human antibodies.

For our lead product candidate, LCAR-B38M/JNJ-4528, we have chosen to generate and characterize our own antigen-binding domains isolated from llamas. Llamas produce highly diverse antibodies including a unique class of single-domain antibodies that can have high antigen-binding potency compared to that of more conventional antibodies which are composed of heavy and light chain domains. These smaller, single-domain antibodies are also able to access antigenic sites that are close to the cell membrane, which may not be physically accessible to larger, conventional antibodies.

Our technology has the potential to efficiently generate multi-epitope antibodies targeting the same antigen or multi-antigen specific CAR constructs. The small size of llama single-domain antibody allows us to efficiently construct CARs with two or more antigen binding domains targeting the same antigen or different antigens simultaneously. Using this technology, we successfully generated llama single-domain antibodies targeting two epitopes on BCMA, which were applied to the CAR construct in LCAR-B38M/JNJ-4528.

# **Global Clinical Development Strategy**

We employ a global clinical development strategy designed to progress our product candidates rapidly through the clinic. In particular, we utilize our deep relationships with thought leaders in China to conduct

proof-of-concept studies, from which we believe we can more efficiently inform the design of our clinical development programs and potentially mitigate certain clinical development risks. Through initially testing product candidates in humans in investigator-initiated trials in China, we can quickly assess the therapeutic potential of and improve individual product candidates in an efficient and cost-effective manner, which allows us to quickly identify promising product candidates and advance them into registrational clinical trials across China, the United States, Europe and Japan. We also intend to establish global manufacturing facilities and a global commercial team to support all aspects of our product sales including market access, healthcare provider education, hospital certification, reimbursement, manufacturing and patient and provider support.

Given our expertise and understanding of the significant differences in the regulatory environment for cell therapies in China compared to the United States, we have the potential to be a preferred partner for companies outside of China or those that are founded or controlled by entities outside of China to conduct scientific research using genetically modified cells in China. Following consultation, and subject to oversight by scientific advisory boards and ethical committees, clinicians in China can initiate clinical testing for experimental cell therapies at their hospitals without the requirement for clearance of a formal IND application by the NMPA as part of the NMPA's encouragement of innovation. We work with the clinicians and hospitals to conduct investigator-initiated trials in accordance with international standards to support future global regulatory filings and partnerships. This approach enables us to rapidly test our product candidates directly in patients. We also have established relationships with China-based key opinion leaders, regulatory bodies, institutional review boards, ethics committees and related entities involved in accelerating and monitoring clinical development of cell therapies.

We are one of the most advanced companies in developing CAR-T cell therapies in China, having received clearance for the first CAR-T cell therapy IND application by the NMPA. We are also the first to conduct a registrational CAR-T clinical trial in China. We have built a strong, global research team of over 300 researchers who identify potential cellular targets and create and assess a broad portfolio of product candidates. Establishing this expertise has attracted the leading investigators and partners within China.

Our LEGEND-2 trial was conducted at four top-tier large-scale hospitals that treat millions of patients annually and are associated with universities with integrated operations in medical treatment and medical education. In China alone, there were an estimated 4.3 million new cancer cases and 2.9 million cancer deaths in 2018. Eighty percent of these patients are treated in regional and provincial hospitals, many of which we collaborate with. We believe the clinical experience at these hospitals in treating patients with these therapies with regard to dosing, conditioning regimens and management of adverse events, such as CRS, represent an invaluable resource for first-in-human testing of potential clinical candidates.

Patients who are enrolled in investigator-initiated clinical trials typically have failed multiple lines of previous therapies and lack any alternatives. From these clinical trials clinicians collect detailed biomarker data, profiles of cellular responses, and clinical responses which are used to help refine treatment protocols and are shared with us to understand the strengths and weaknesses of our product candidates. We use the data from these early clinical trials to advance promising product candidates and, when appropriate, improve other product candidates. We also use the data to identify product candidates or biological hypotheses that are not effective, enabling us to narrow our focus and avoid unnecessary expense and time.

## Clinical- and Commercial-Stage Manufacturing Expertise

We have assembled a clinical, manufacturing and commercial, or CMC, team with extensive CAR-T process development and commercialization experience, many of who have direct experience with commercial launch and manufacturing supply of marketed CAR-T products. We have current good manufacturing practices, or cGMP, compliant manufacturing facilities in the United States and China that supply the clinical material for our trials. These facilities have been designed for rapid scale-up, and we intend to source our global commercial supply and distribution from these facilities, if any of our product candidates are approved. We are also in the process of selecting a European site and facility for future supply for Europe.

In establishing these facilities, we have taken significant efforts to establish defined procedures regarding manufacturing robustness, facility design, employing quality personnel and designing cell therapies taking into account manufacturability. We believe these efforts, along with our rigorous manufacturing infrastructure and deep industry expertise have enabled the development of our robust manufacturing process and can potentially drive further cycle time improvement and cost reductions in developing cell therapy product candidates.

# **Our Programs**

# LCAR-B38M/JNJ-4528 for the Treatment of Multiple Myeloma

LCAR-B38M/JNJ-4528 is a CAR-T cell therapy that we are developing for the treatment of MM. LCAR-B38M refers to the product candidate in the rest of the world. Both product candidates express an identical CAR protein. In a Phase 1 first-in-human clinical trial (LEGEND-2), treatment of 57 RRMM patients with LCAR-B38M resulted in an ORR of 88 percent including a CR rate of 74 percent in the patients treated at the Second Affiliated Hospital of Xi'an Jiaotong University, or Xi'an, clinical site as of July 31, 2019 with a median follow-up time of 25 months, and treatment of 17 RRMM patients at three other sites resulted in an ORR of 88 percent with a CR rate of 82 percent as of October 31, 2019 with a median follow-up time of 26 months. The other three sites were Jiangsu Province Hospital, or Jiangsu, Shanghai Changzheng Hospital, or Changzheng, and Shanghai Ruijin Hospital, or Ruijin. ORR includes patients that achieved a CR, very good partial response, or VGPR, or a partial response, or PR. Expected adverse events were reported in all patients in LEGEND-2 with over 90 percent reporting fever and cytokine release syndrome, or CRS. Over 82 percent of patients had Grade 1 or Grade 2 CRS which was managed with standard treatments and, in all but two of the 74 patients, CRS was resolved. One patient died of a CAR-T related toxicity as a result of CRS and tumor lysis syndrome. A second patient died from a potential pulmonary embolism and acute coronary syndrome, which was considered unrelated to treatment by the investigator.

Patients are measured for whether they achieved a CR, VGPR or a PR in accordance with the International Myeloma Working Group, or the IMWG, uniform response criteria for MM. The IMWG uniform response criteria has been utilized in registration studies of approved myeloma drugs. The IMWG uniform response criteria assesses efficacy of treatment options for myeloma and allows for a comparison of efficacy between treatment strategies in clinical trials, strict definitions for responses, as shown in the table below, and classifications to improve detail and clarify inconsistent interpretations across clinical trials.

The IMWG criteria for CR, VGPR, PR and stable disease, or SD, is summarized below.

- CR Negative immunofixation in the serum and urine and
  - Disappearance of any soft tissue plasmacytomas and
- <5% plasma cells in bone marrow aspirates</li>
- VGPR Serum and urine monoclonal protein, or M-protein, detectable by immunofixation but not on electrophoresis or
- <sup>3</sup>90% reduction in serum M-protein plus urine M-protein level <100 mg/24 h</li>
- PR 350% reduction of serum M-protein plus reduction in 24-hour urinary M-protein by 390% or to <200 mg/24 h
  - If the serum and urine M-protein are unmeasurable, a <sup>3</sup>50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria and if serum-free light assay is also unmeasurable, <sup>3</sup>50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma-cell percentage was <sup>3</sup>30%
  - In addition to these criteria, if present at baseline, a 350% reduction in the size (SPD) of soft tissue plasmacytomas is also required
- SD Not meeting criteria for CR, VGPR, PR, or progressive disease

In collaboration with Janssen, we are currently conducting a Phase 2 trial of LCAR-B38M in RRMM patients in China (CARTIFAN-1) and a Phase 1b/2 trial of JNJ-4528 in RRMM patients in the United States and Japan (CARTITUDE-1). All 29 patients treated with JNJ-4528 from the Phase 1b portion achieved a response, with an ORR of 100 percent. As of April 20, 2020, with a median follow-up of 11.5 months, 25 of 29 patients, or 86 percent, achieved a sCR. The 9-month progression free survival rate was 86 percent and 22 of the 29 patients remained alive and progression free at the time of data cut-off. The most common adverse events reported in CARTITUDE-1 have been CRS and cytopenias, which have been manageable with standard interventions used by hematologists. As of April 29, 2020, CRS was reported in 93 percent of patients, most of which were mild and only 7 percent of which were clinically considered to be Grade 3 or higher. One patient in CARTITUDE-1 died as a result of CRS, one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator, and one patient died due to progressive disease. Overall, the safety profile of LCAR-B38M/JNJ-4528 has been consistent with the safety profile of other CAR-T cell therapies in hematologic malignancies. We anticipate that data from the Phase 2 portion of CARTITUDE-1 will be presented at a major medical conference in the second half of 2020. JNJ-4528 has been granted breakthrough therapy designation and orphan drug designation by the FDA and PRIME designation, enabling accelerated assessment, by the EMA. Clinical results received to date demonstrate that LCAR-B38M/JNJ-4528 has the potential to deliver deep and durable anti-tumor responses in RRMM patients with a manageable safety profile. Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, we anticipate that a BLA will be submitted to the FDA and an MAA will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020. We also intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China and the data from CARTITUDE-1 in support of a regulatory submission in Japan in 2021.

In 2017, we entered into a global collaboration with Janssen for LCAR-B38M/JNJ-4528, pursuant to which we share equally the development, production and commercialization costs and profits or losses in all areas other than Greater China, where we assume 70 percent of development, production and commercialization costs and retain or bear 70 percent of pre-tax profits or losses. We received an upfront payment of \$350.0 million from Janssen in 2018, and to date, we have received four milestone payments totaling \$110.0 million.

#### **Background on Multiple Myeloma**

MM is currently an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of a type of antibodyproducing white blood cell called plasma cells. MM is the third most common blood cancer and represents approximately ten percent of all cases and twenty percent of deaths of hematological malignancies. In 2018, there were 25,962 new cases of MM and 13,648 deaths in the United States, 48,297 new cases of MM and 30,860 deaths in Europe and 20,066 new cases of MM and 14,655 deaths in China. In 2020, the American Cancer Society projects that 32,270 new cases of MM and 12,830 deaths will occur in the United States. Worldwide, there were an estimated 160,000 new cases of MM in 2018, accounting for one percent of worldwide new cancer cases.

Most people in the United States who are diagnosed with MM are 65 years old or older, with less than one percent of cases diagnosed in people younger than 35 years old. With currently available treatments, MM has a five-year survival rate of approximately 52 percent.

Treatment choices for MM vary with the aggressiveness of the disease and overall health of the patients. Newly diagnosed patients in good physical health with active disease generally receive high-dose chemotherapy followed by autologous hematopoietic stem cell transplantation, or HSCT. When transplantation is not an option or if HSCT patients fail to achieve a CR, standard of care consists of systemic chemotherapy. The therapeutic landscape of MM has changed significantly in the past decade with the introduction of novel immunomodulatory agents, such as lenalidomide, marketed as Revlimid by Bristol-Myers Squibb, as well as monoclonal antibodies, such as daratumumab, marketed as Darzalex by Janssen, and proteasome inhibitors, including bortezomib, marketed as Velcade by Takeda and Janssen, and carfilzomib, marketed as Kyprolis by Amgen. Worldwide sales of drugs to treat MM were approximately \$18 billion in 2018 with 63 percent of these sales in the United States.

Despite these major advances, MM remains incurable even when patients receive one or more treatment agents. Patients typically receive between three and five lines of therapy but then ultimately experience a final tumor relapse having exhausted all effective treatment options. mOS in patients who have received at least three prior lines of therapy, and are refractory to both an immunomodulatory drug and a proteasome inhibitor, is only 13 months, with an mOS of less than 12 months in patients that are refractory to CD38-targeting monoclonal antibodies and one or more proteasome inhibitors and/or one or more immunomodulatory drugs. The reported ORR for approved therapies for the population of heavily pre-treated and refractory patients with MM is 30 percent or less.

Emerging therapeutic approaches include an array of product candidates that target specific antigens on MM cells, and includes antibody-drug conjugates and redirected T cell therapies such as T cell engagers and CAR-T cell therapies. Despite recent progress, we believe there is a high unmet need for a therapy that provides an improved and durable efficacy profile.

# BCMA

BCMA is a protein normally expressed on B cells, where it functions as a pro-survival receptor. High levels of BCMA are found in plasma cells, which are specialized B cells that produce and secrete large quantities of antibodies. BCMA is overexpressed in a number of hematologic malignancies, including MM.

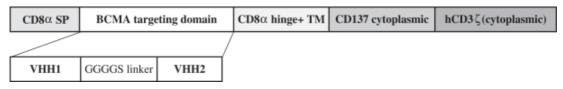
Tissue distribution of BCMA, as determined using quantitative analysis of transcription levels, show that BCMA is generally expressed only in lymphoid cells and not in other tissues in the body. The expression level of BCMA in plasmacytomas, or MM tumors, is hundreds to thousands of times higher than normal tissues, making BCMA a prime candidate for therapeutic agents directed against MM.

Published details of a third-party trial conducted by leading researchers at the U.S. National Institutes of Health report that treatment with anti-BCMA CAR-T cells yielded an ORR of 58 percent in a series of 24 RRMM patients and an ORR of 81 percent in a subset of 16 patients receiving the highest dose of 9 x 106 CAR-T cells/kg. These results provide preliminary evidence for the role that anti-BCMA CAR-T cells may play in the treatment of RRMM. We believe that there are opportunities to build upon these initial results in the development of next-generation CAR-T cell therapies.

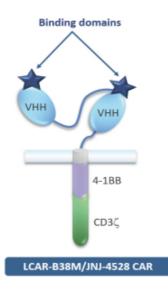
# Our Solution, LCAR-B38M/JNJ-4528

LCAR-B38M/JNJ-4528 is a structurally differentiated autologous CAR-T cell therapy that targets BCMA. We used single-domain antibodies against BCMA that we isolated from llamas to design the LCARB38M/JNJ-4528 CAR construct. Two BCMA binding domains, VHH1 and VHH2, were then linked to a T cell costimulatory domain from the 4-1BB protein, also known as CD137, and the CD3 zeta-chain to form the CAR construct.

# LCAR-B38M/JNJ-4528 CAR construct



### CAR construct of LCAR-B38M/JNJ-4528 has two antigen-binding domains

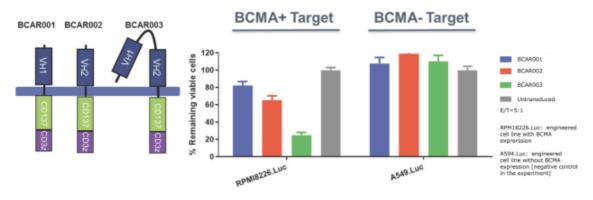


Same antigen dual binding domain CAR

We believe LCAR-B38M/JNJ-4528 has the potential to provide benefits to MM patients through the following mechanisms of action:

- having two antigen-binding domains takes advantage of the concept of higher binding avidity—two points of contact between the CAR and the tumor antigen results in binding much less likely to be reversible than single point of contact with either antigen;
- dual antigen-binding domains could also allow CARs to cross-link epitopes on different molecules, which facilitates the gathering of more CARs in the immune synapse for T cell activation, increases downstream signal strength of T cells, and therefore, enhances overall CAR-T functionality; and
- inclusion of antigen-binding domains that recognize antigenic sites independently could lead to an increased ratio of on-off target binding, resulting in higher specificity thereby resulting in less off-target effects.

We conducted a preclinical study in which the anti-tumor killing effect of a single binder BCMA CAR (BCAR001 and BCAR002) was compared to a dual-binding BCMA CAR (BCAR003). As depicted below, the data from the study demonstrated that, at the same effector-to-target ratio (E/T 5:1), antitumor killing activity of a CAR containing a dual-binder was superior to those containing just one binder in cell lines with BCMA expression.



# Preclinical data demonstrates higher specific cytolytic activity of dual-binder BCMA CAR over single-binder BCMA CAR

#### Completed Clinical Results

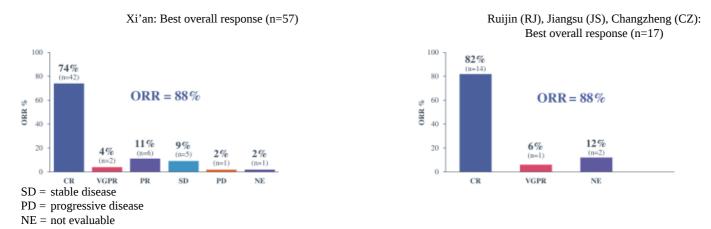
### LEGEND-2 (China)

In October 2015, an investigator-initiated Phase 1 trial of LCAR-B38M was initiated at four independent sites in China, enrolling a total of 74 patients with RRMM. We reported updated data from the trial in December 2019 at the American Society of Hematology conference. The primary endpoint of the trial was the occurrence of treatment-related adverse events and the secondary endpoint was anti-myeloma responses to LCAR-B38M cell treatment. Patients in the trial had failed a median of three prior lines of therapy, in the Xi'an site and a median of four prior lines of therapy, in the remaining three sites. The actual treatment protocol varied between sites, providing us with the opportunity to explore multiple treatment protocols within a single trial. The trial protocol was standardized to the extent possible across sites; however, some variation in methodologies may have occurred due to the flexible nature of this proof-of-concept, first-in-human study. Patients in the trial were preconditioned with either cyclophosphamide, or cy, alone, or cy and fludarabine, or flu, together, which is a standard lymphodepletion, or reduction in the number of the patient's lymphocytes, regimen. The safety and efficacy results presented are based on uniform medical reviews of source hospital medical records by the investigators for all treated patients.

Clinical site	Number of patients	Preconditioning	LCAR-B38M infusion
Xi'an	57	Cy only	Split-dose
Changzheng	3	Cy + flu	Split-dose
Ruijin	5	Cy + flu	Split-dose
Jiangsu	9	Cy only	Single-dose

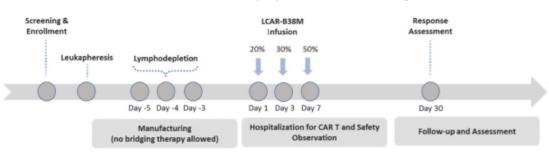
Investigators have publicly presented the results of the LEGEND-2 trial as a set of two independent analyses. The Xi'an site enrolled the largest number of patients, 57, and published additional molecular and cellular profiling data on responses. The Ruijin, Jiangsu and Changzheng sites, which enrolled a total of 17 patients, have reported their data together in a separate analysis. Patients at the Xi'an site and the other three sites achieved an ORR and a CR rate shown below as of July 31, 2019 and October 31, 2019, respectively.

# Efficacy results of the LEGEND-2 trial



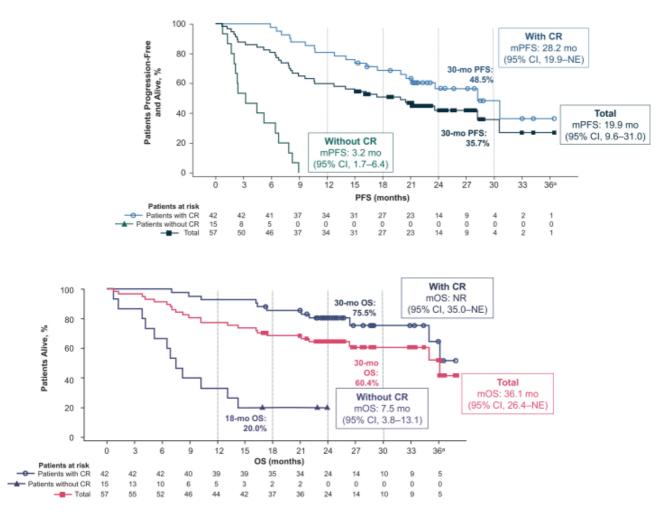
Patients at the Xi'an site had a median duration of response, or mDOR, of 27.0 months and, among the patients achieving a CR, the mDOR for CR was 29.1 months. The median time to achieving an initial response was one month at each of the four independent sites.

At the Xi'an site, all 57 patients treated had lymphodepletion three to five days before receiving LCAR-B38M using cyclophosphamide alone. LCAR-B38M was administered as three split infusions, as shown below, with the total number of CAR-T cells delivered to patients averaging 0.5 x 10<sup>6</sup> cells/kg. Patients were assessed for response to treatment beginning 30 days after the first LCAR-B38M infusion.



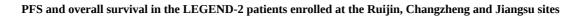
# Dosing regimen in the LEGEND-2 patients at the Xi'an site

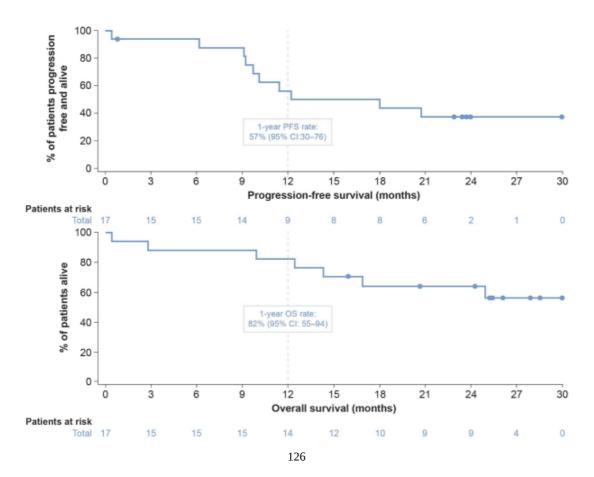
The overall survival of patients enrolled at the Xi'an site is shown in the chart below as of July 31, 2019. Patients from the Xi'an site who achieved a CR had a median progression free survival, or mPFS, of 28.2 months and an OS of 92.9 percent at 12 months and 75.5 percent at 30 months. Patients who did not achieve a CR had poorer survival with a mOS of 7.5 months.



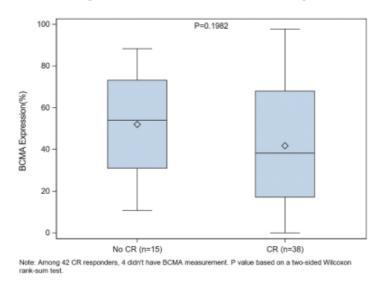
PFS and overall survival of patients enrolled at the Xi'an site in the LEGEND-2 trial

The 17 patients treated at the other three sites had similar outcomes, achieving an ORR of 88 percent and a CR rate of 82 percent as of October 31, 2019. The median progression free survival was 18 months and overall survival was 82 percent at 12 months and 64 percent at 24 months as of October 31, 2019.





There was no significant difference in response rates for patients treated at the Xi'an site based on the level of BCMA expressed by their tumors, as shown below.

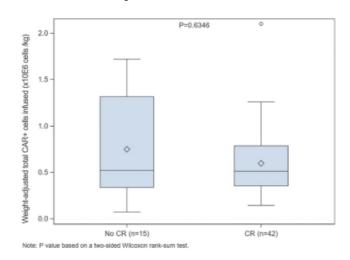


# Levels of BCMA expression did not correlate with clinical response in Xi'an site

A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

There was also a lack of correlation between the number of CAR-T cells infused and response rates. In the LEGEND-2 trial, patients in Xi'an site received a median of 0.5 x 10<sup>6</sup> CAR+ viable T cells/kg (range 0.07 x 10<sup>6</sup> to 2.1 x 10<sup>6</sup>). In the other three sites combined, patients received a mean of 0.70 x 10<sup>6</sup> CAR+ viable T cells/kg. This response was achieved with a relatively low dose compared to other CAR-T product candidates in clinical trials.

#### No significant difference in response rate based on number of CAR-T cells infused



# Safety Results

As of July 31, 2019 for the Xi'an site and October 31, 2019 for the other three sites, adverse events were reported in all patients in LEGEND-2 with over 90 percent reporting fever and CRS. Over 82 percent of patients had Grade 1 or Grade 2 CRS which was managed with standard treatments such as administration of anti-IL-6R, vasopressor or oxygen therapy. In all but two cases CRS was resolved. In one case the patient died on day 13 as a result of CRS and tumor lysis syndrome, or TLS. This is an adverse event caused by rapid tumor lysis causing an accumulation of breakdown products such as uric acid, potassium and phosphorous in the blood, leading to the risk of multi-organ failure. A second patient, who was recovering from Grade 2 CRS, developed difficulty breathing and died at day 22 from a potential pulmonary embolism and acute coronary syndrome. In addition to CRS, thrombocytopenia and leukopenia were reported by 49 percent and 47 percent of patients, respectively.

	Auverse Events Acported, Ar un site (ir 57) und 103,503, und 02 sites (ir 17)				
		All grade		Grade <sup>3</sup> 3	
		n=57	n=17	n=57	n=17
Hematologic AEs, n (%)					
Anemia		17(30)	—	10(18)	
Thrombocytopenia		28(49)	—	13(23)	
Leukopenia		27(47)	—	17(30)	—
Cytopenia		—	14(82)	—	10(59)
Tumor lysis syndrome		—	3(18)	—	0
CAR-T-associated AEs, n (%)					
CRS		51(90)	17(100)	4(7)	7(41)
Neurotoxicity		1(2)	0	0	0
Non-hematologic AEs, n (%)					
Pyrexia		52(91)	—	11(20)	
Hypotension		12(21)	—	3(5)	
Liver toxicity					
Elevated ALT		—	7(41)	—	0
Elevated AST		22(39)	16(94)	12(21)	5(29)
Elevated bilirubin			1(6)	_	1(6)

Adverse Events Reported: Xi'an site (n=57) and RJ, JS, and CZ sites (n=17)

We have submitted data from the LEGEND-2 trial to the FDA and NMPA. While we do not intend to use the data from LEGEND-2 as direct evidence of efficacy or safety in our potential future regulatory approval

submissions with the FDA or NMPA, we may use the data from LEGEND-2 trial as indirect supportive evidence in future regulatory submissions.

#### **Ongoing Clinical Development**

We obtained approval to conduct confirmatory clinical trial, CARTIFAN-1, through multiple centers in China in March 2018. Following the submission of an IND, which was cleared by the FDA in May 2018, we and Janssen are conducting the CARTITUDE-1, CARTITUDE-2 and CARTITUDE-4 trials.

### CARTIFAN-1 (China)

We are enrolling RRMM patients in a pivotal Phase 2 trial involving 8 sites in China. This trial, which we refer to as CARTIFAN-1, began enrolling patients in early 2019 and is expected to enroll up to 60 patients by the second half of 2020. The primary endpoint of this trial is ORR. We intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China in 2021.

#### CARTITUDE-1 (United States and Japan)

Together with Janssen, we are enrolling patients in a Phase 1b/2 clinical trial of JNJ-4528, across 17 sites in the United States and 4 sites in Japan. Enrollment has been completed for the Phase 2 portion of the trial in the United States and 29 patients had been dosed in the Phase 1b portion of the trial. These 29 patients in the Phase 1b portion of the trial had failed a median of five prior therapies (with a range of 3-18 prior therapies). All patients were exposed to immunomodulatory drugs, proteasome inhibitors and anti-CD38 therapies, and 97 percent of patients were refractory to last line of therapy. For the Phase 1b portion of the CARTITUDE-1 trial, the primary endpoint was the incidence and severity of adverse events and secondary endpoints included efficacy results as measured with the IMWG uniform response criteria for MM, duration of and timing to response, progression-free survival, overall survival, pharmacokinetic and pharmacodynamic markers, and presence of anti-JNJ-4528 antibodies. For the CARTITUDE-1 trial, patients received JNJ-4528 infusion following apheresis and lymphodepletion with cyclophosphamide and fludarabine daily for three days. The median administered dose of JNJ-4528 was 0.72 x 10<sup>6</sup> CAR+ viable T cells/kg (range 0.52 – 0.89 x 10<sup>6</sup>). All 29 patients in the Phase 1b portion achieved a response (100% ORR) with 86 percent achieving a sCR, 21 percent having a VGPR, and three percent having a PR with a median follow-up time of 11.5 months. Median time to first response was 1 month (with a range of 1-3 months) and median time to CR was 3 months (with a range of 1-13 months). The 9-month progression free survival rate was 86% and 22 of 29 patients remained alive and progression free at the time of data cut-off on April 20, 2020.

Of the 16 patients evaluable, 81 percent were minimal residual disease, or MRD, negative at the time of first suspected CR. MRD refers to the presence and number of malignant B or T cells that may remain in a patient's body during and following treatment and can contribute to relapse and disease progression. MRD is measured by next-generation technologies and MRD negativity is defined as the absence of tumor plasma cells within bone marrow.

As of April 29, 2020, with a median follow-up of 11.5 months, CRS was reported in 93 percent of patients, most of which were Grade 1 or Grade 2 CRS, with one case of Grade 3 CRS and one case of Grade 5 CRS at day 99 subsequent to dose-limiting toxicity of prolonged Grade 4 CRS. Median time to onset of CRS was 7 days (with a range of 2-12 days). Neurotoxicity, consistent with Immune Effector Cell-associated Neurotoxicity Syndrome, was observed in three patients (10 percent) including one patient (3 percent) with <sup>3</sup> grade 3 toxicity. The most common grade <sup>3</sup>3 hematologic AEs were neutropenia (100 percent), thrombocytopenia (69 percent) and leukopenia (66 percent). There were three deaths during the Phase 1b portion of the trial: one due to CRS, one due to acute myeloid leukemia, which was considered unrelated to treatment by the investigator, and one due to progressive disease.

Collectively, we believe these results, together with the consistent results from the LEGEND-2 trial, demonstrate that JNJ-4528 has a manageable safety profile and can deliver early and deep responses in heavily pretreated RRMM patients.

We have completed enrolling patients with the Phase 2 portion of the CARTITUDE-1 trial in the United States. We anticipate that data from the Phase 2 portion of CARTITUDE-1 will be presented at a major medical conference in the second half of 2020. Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, we anticipate that a BLA will be submitted to the FDA and an MAA will be submitted to the EMA for JNJ-4528 for the treatment of RRMM in the second half of 2020. We also intend to use the data from CARTITUDE-1 in support of a regulatory submission in Japan in 2021.

### CARTITUDE-2 (United States and Europe)

We and Janssen began enrolling patients in November 2019 in an 80-patient, multi-cohort, open-label Phase 2 trial of JNJ-4528 in the United States and Europe, which we refer to as CARTITUDE-2. CARTITUDE-2 initially consists of four 20-patient cohorts:

- Treatment of patients with progressive MM with JNJ-4528 after one to three prior lines of therapy
- Treatment of MM patients with JNJ-4528 with early relapse after a front-line therapy
- Treatment of RRMM patients with JNJ-4528 that have failed therapy with a proteasome inhibitor, immunomodulatory therapy, daratumumab, and anti-BCMA therapy
- Treatment of MM patients with JNJ-4528 and lenalidomide who have not achieved a CR after HSCT

The primary endpoint in each cohort of this trial is the percentage of patients with negative MRD one year after treatment. Based on the results of each cohort, we intend to explore expanding our investigation in those patient populations to potentially support regulatory approval submissions upon the agreement of regulatory agencies. We also have the ability to expand CARTITUDE-2 to include further cohorts to evaluate additional unmet needs of MM patients.

# CARTITUDE-4 (United States, Europe and Japan)

We and Janssen are conducting a 400 patient, randomized, open-label Phase 3 trial of JNJ-4528 in Revlimid-refractory MM patients who received one to three prior lines of therapy in the United States, Europe and Japan, which we refer to as CARTITUDE-4. Patients will be randomized to receive standard of care (investigator choice between pomalidomide/bortezomib/dexamethasone or daratumumab/pomalidomide/dexamethasone) or be treated with a single administration of JNJ-4528. The primary endpoint of this trial will be progression free survival.

# **Future Clinical Plans**

Based on the current results which demonstrated that LCAR-B38M/JNJ-4528 has the potential to deliver deep and durable anti-tumor responses in RRMM patients with a manageable safety profile, we intend to conduct clinical trials in earlier-stage MM patients who may have fewer comorbidities and may respond to therapies better than late-stage RRMM patients. Upon approval by regulatory agencies, we may conduct Phase 3 clinical trials of LCAR-B38M/JNJ-4528 as front-line therapy in newly diagnosed patients who are eligible for HSCT, ineligible for HSCT, and who fail to achieve a complete response from HSCT.

# LB1901 for the Treatment of T Cell Lymphoma

We are developing LB1901, an autologous CAR-T cell product candidate for the treatment of TCL. We have demonstrated the ability of LB1901 to destroy CD4 expressing tumor cell lines and in a humanized mouse model. Based on the clinical validation of anti-CD4 antibodies and the results of our preclinical studies, we intend to submit an IND application for LB1901 in relapsed or refractory TCL in the second half of 2020.

#### T Cell Lymphoma Overview

TCL refers to various cancers that arise from mature T cells, representing approximately five percent of all hematological malignancies. TCL can be subdivided into subtypes such as peripheral T cell lymphoma, or PTCL,

angioimmunoblastic T cell lymphoma, anaplastic large cell lymphoma, and cutaneous T cell lymphoma, or CTCL. These subtypes differ by location, distribution and aggressiveness of the primary tumor as well as by specific associated mutations. TCL make up less than 15% of NHL in the United States. Overall there are about 7,900 new cases of TCL in the United States each year. The incidence is approximately 27 per million in men and 16 per million in women.

While TCL represents a smaller percentage of all lymphomas compared to B cell lymphomas in NHL, TCL is an aggressive disease with a very poor prognosis for patients. The five-year survival for patients diagnosed with TCL is approximately 40 percent.

The most common type of TCL is PTCL, which is one of the initial areas of focus for LB1901. It was estimated that there were 3,950 cases of PTCL in the United States in 2016. PTCL represents a heterogeneous group of generally aggressive tumors. Overall survival depends, at least partially, on the subtype of PTCL but, in general, survival is measured in months. With combination chemotherapy, five-year survival for common high-risk patients is between 6 and 21 percent.

First line treatment for PTCL typically consists of the chemotherapy combination known as CHOP that consists of cyclophosphamide, vincristine, doxorubicin, and prednisolone, as well as variants of CHOP. In all cases these chemotherapy treatments are associated with significant toxicities including low blood cell counts, nausea, vomiting, diarrhea, hair loss, mouth sores and increased risk of infections.

Most patients undergoing treatment for PTCL will either not achieve remission or will relapse and become refractory to treatment. There is no standard therapy available for these patients. Pralatrexate, a folate analogue metabolic inhibitor, was the first drug approved by the FDA for relapsed or refractory PTCL based on an ORR of 27 percent. Other FDA-approved agents for relapsed or refractory PTCL include romidepsin, a selective class 1 histone deacetylase, or HDAC, inhibitor, which had an ORR of 26 percent in single-arm pivotal trial in relapsed or refractory PTCL and belinostat, a HDAC inhibitor with activity against class I, II, and IV HDACs, which had an ORR of 26 percent. Despite these approved drugs, current treatment guidelines recommend participation in a clinical trial as a preferred option for many patients with relapsed PTCL after first line, highlighting the unmet medical need.

Allogeneic HSCT remains a valuable treatment option for patients who have achieved a CR but subsequently relapsed. However, cure rates for HSCT are at 30 to 50 percent and not all CR patients are eligible for transplant. Thus, there is a high unmet medical need for new, targeted regimens to improve outcomes, particularly for relapsed and refractory patients.

The second most common form of TCL is CTCL, with an incidence of approximately 6.4 per million or 2,000 new cases per year. CTCL is a disease with poor prognosis, few therapeutic options and no standard of care. Treatment generally includes skin-directed therapies, such as topical corticosteroids, chemotherapy, radiation and phototherapy. Brentuximab vedotin has been approved by the FDA for treatment of patients with subtypes of CTCL: primary cutaneous anaplastic large cell lymphoma and CD30-expressing mycosis fungoides who have received prior systemic therapy. In clinical trials the response rate to brentuximab vedotin was 67 percent compared to 20 percent in the control and the median progression-free survival was 16.7 months compared to 3.5 months for the control group. Brentuximab vedotin was associated with a 54% risk of peripheral neuropathy, which led to treatment discontinuation in 11% of the patients and inclusion of a boxed warning on the label. Mogamulizumab, a chemokine receptor type 4, or CCR4, monoclonal antibody is approved for two subtypes of CTCL: relapsed or refractory mycosis fungoides and Sezary syndrome. Patients treated with mogamulizumab had 7.6-month average progression free survival duration compared to 3.1 months for vorinostat-treated controls.

Although these new treatments represent progress in the treatment of CTCL, they are still associated with safety and efficacy limitations. Further, even with these options, the majority of systemic treated patients eventually relapse, and overall survival remains poor.

### CD4

CD4 is a glycoprotein expressed on the surface of T helper cells, which are a type of T cell that help other cells in the immune response by recognizing foreign antigens and secreting cytokines. CD4 is expressed at low levels on other immune cells such as monocytes, macrophages and dendritic cells. In normal T cells CD4 functions as a coreceptor for the TCR, promoting the binding of T cells to peptide-presenting major histocompatibility complex on antigen-presenting cells. CD4 is highly and uniformly overexpressed in a majority of patients with PTCL and CTCL.

Anti-CD4 antibodies have been studied in non-human primates as well as in clinical trials for PTCL and CTCL. A Phase 2 trial of zanolimumab, an anti-CD4 antibody, had a response rate of 24 percent in relapsed or refractory PTCL and was well-tolerated with no major toxicities.

Published studies have shown that anti-CD4 therapeutic approaches do not result in depletion of hematopoietic stem cells or progenitor cells, suggesting that although depletion of CD4 T cells may result in temporary immunosuppression, repopulation of a functional immune system should be not be impaired.

While some anti-tumor activity was observed with anti-CD4 antibodies, we believe that an anti-CD4 CAR-T cell therapy has the potential to bring heightened therapeutic benefit to PTCL and CTCL patients.

### **Our Solution: LB1901**

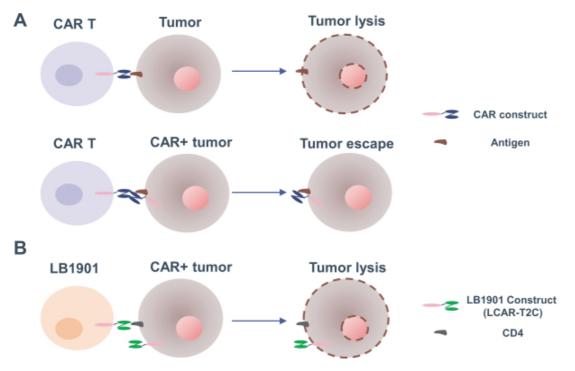
LB1901 is an investigational autologous anti-CD4 CAR-T cell product candidate containing an antibody binding domain derived from a human immunoglobulin transgenic mouse. The LB1901 CAR construct consists of a human CD8a SP, scFv CD4-targeting domain, a CD8a hinge + TM domain, a CD137 (4-1BB) costimulatory domain, and a CD3 intracellular domain.

### LB1901 CAR construct

CD8a SP	CD4 targetin	g domain	$CD8\alpha$ hinge + $TM$	CD137 cytoplasmic	hCD3 ζ (cytoplasmic)
			/		
VH	(GGGGS)3 linker	VL			

In our design of LB1901, we specifically chose a CAR construct that maintained its ability to bind to and kill tumor cells that may inadvertently be transduced and express the CAR construct. In rare cases, during the preparation of CAR-T cell therapies from the patients cells, the CAR construct can be introduced into tumor cells as well as the intended CD8+ T cells. In a 2018 publication in the journal Nature Medicine, a case was described where a patient treated with Kymriah, an anti-CD19 CAR-T cell therapy, relapsed due to the presense of tumor cells that had been transduced with the CAR construct. These CAR-expressing tumor cells were able to mask the expression of CD19 on their surface and avoid killing by Kymriah. The LB1901 CAR was selected for its inability to block CD4, even if it were to be transduced into tumor cells.

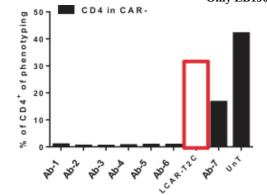
1	2	7
T		4



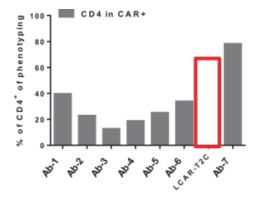
LB1901 was selected to avoid resistance due to inadvertent transduction of the CAR construct into tumor cells

# Preclinical Data

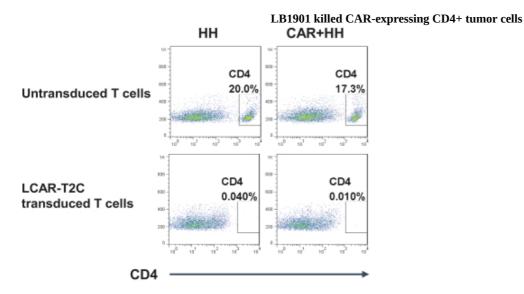
In a preclinical study, we observed that LB1901 as well as a number of other CAR constructs that we tested led to potent killing of T cells expressing CD4. LB1901, however, was the only CAR construct we tested that eliminated CD4 T cells into which the CAR construct was inserted.



# Only LB1901 was able to kill T cells transduced with the CAR construct

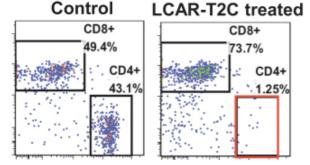


To confirm the ability of LB1901 to effectively target CD4 tumor cells that also express the CAR construct, we deliberately transduced HH, a CD4+ human tumor cell line derived from a patient with CTCL, with the LB1901 CAR construct. The preclinical results showed that LB1901 has the ability to eliminate CD4+ HH cells as well as CD4+ HH cells transduced with the CAR construct. We believe the ability to kill CAR-expressing tumor cells is critically important for a therapy being developed to treat TCL.

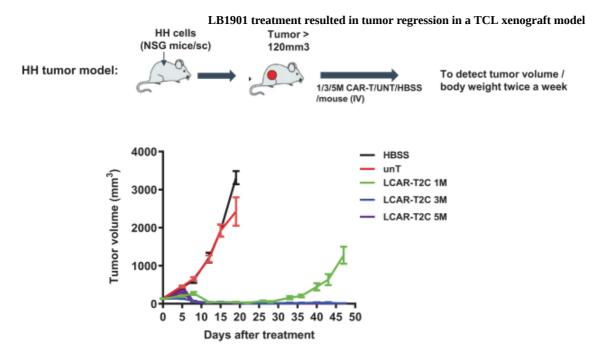


We have observed that LB1901 leads to selective killing of multiple CD4+ T cell lines. We have also observed that CD4+ T cell killing occurs in humanized mice treated with LB1901. In untreated mice, the CD4+ cells represented 43.1 percent of T cells. After treatment with LB1901, the percentage of CD4+ T cells was reduced to 1.25 percent.

# LB1901 killed CD4+ cells in a humanized mouse



We assessed efficacy of LB1901 in a human TCL xenograft mouse model. Immunodeficient mice injected with a human TCL cell line, HH, were subsequently treated with saline (Hanks's Balanced Salt Solution, or HBSS), or 1, 3 or 5 million LB1901 CAR-T cells. All three doses of LB1901 resulted in tumor regression for a minimum of 28 days. Tumors recurred after 28 days in mice receiving the lowest dose but did not recur by day 48 in mice receiving the two higher doses.



Based on the clinical validation of anti-CD4 antibodies and the results of our preclinical studies, we intend to submit an IND application for LB1901 in relapsed or refractory T cell lymphoma in the second half of 2020.

# Other Ongoing Investigator-Initiated and Preclinical Programs in China

In addition to LCAR-B38M/JNJ-4528 and LB1901, we have a broad portfolio of product candidates in investigator-initiated trials and preclinical development targeting various cancers, solid tumors and infectious

diseases. We plan to use data from investigator-initiated clinical trials to prioritize which product candidates to advance into broader clinical testing. In April 2020, we entered the Noile-Immune Agreement (as described below), pursuant to which we obtained a license to develop and commercialize nextgeneration CAR-T and/or TCR-T cell therapies incorporating Noile-Immune's PRIME (proliferation-inducing and migration-enhancing) technology for up to two targets for all indications and uses. The PRIME technology enables CAR-T and/or TCR-T cells to express and secrete cytokine IL-7 and chemokine CCL19. This technology is designed to improve proliferation and trafficking into solid tumors of both engineered CAR-T and/or TCR-T cells.

# Autologous CAR-T Product Candidate Development

LB1909 is an autologous CAR-T therapy targeting CD19 and CD22 being evaluated in a Phase 1 single arm, open-label investigator-initiated trial in patients with relapsed and refractory B-cell lymphoma.

LB1910 is an autologous CAR-T therapy targeting CD33 and CLL-1 being evaluated in a Phase 1 single arm, open-label investigator-initiated trial in patients with AML. CLL-1 is a myeloid lineage protein involved in cell signaling and expressed in over 90% of AML cases.

LB1904 is an autologous CAR-T therapy targeting claudin 18.2 being evaluated in a Phase 1 single arm, open-label investigator-initiated trial in patients with advanced gastric cancer and pancreatic ductal adenocarcinoma.

LB1902 is an autologous CAR-T therapy in preclinical development for treatment in ovarian cancer.

LB1903 is an autologous CAR T therapy in preclinical development for treatment of HIV.

### Allogeneic CAR-T Product Candidate Development

We have developed a proprietary allogeneic CAR-T technology using non-gene-editing approaches, with less concerns in off-target activities. We believe the one-step transduction with large-scale manufacturing capability may differentiate this innovation from other conventional gene-editing allogeneic products.

Based on this approach, we have developed an allogeneic CAR-T product candidate, LB1905, targeting CD20 which is being evaluated in a Phase 1 single arm, open-label investigator-initiated trial in patients with relapsed and refractory diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma or small lymphocytic lymphoma in China.

#### Collaboration and License Agreement with Janssen Biotech, Inc.

In December 2017, we entered into a collaboration and license agreement with Janssen, or the Janssen Agreement, for the worldwide development and commercialization of LCAR-B38M/JNJ-4528.

Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize LCAR-B38M/JNJ-4528. We and Janssen will collaborate to develop and commercialize LCAR-B38M/JNJ-4528 for the treatment of MM worldwide pursuant to a global development plan and global commercialization plan. Janssen will be responsible for conducting all clinical trials worldwide with participation by our team in the United States and Greater China for LCAR-B38M/JNJ-4528. We will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for Greater China, while Janssen will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for the rest of the world. We and Janssen will share development, production and commercialization costs and pre-tax profits or losses equally in all countries of the world except for Greater China, for which the cost-sharing and profit/loss split will be 70% for us and 30% for Janssen.

In consideration for the licenses and other rights granted to Janssen, Janssen has paid us an upfront fee of \$350.0 million, milestone payments of \$25.0 million, \$30.0 million and \$30.0 million in December 2018, July 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial, and a milestone payment of \$25.0 million in July 2019 for the receipt of a response data readout from a specified number of patients in our CARTITUDE-1 clinical trial showing an ORR of at least 50%. Additionally, we are eligible to receive further milestone payments up to \$125.0 million for the achievement of specified manufacturing milestones and an additional \$1,115 million consisting of \$105.0 million for the

achievement of specified future development milestones, \$800.0 million for the achievement of specified regulatory milestones and \$210.0 million for the achievement of specified net trade sales milestones.

During the term of the Janssen Agreement neither we nor Janssen may develop or commercialize LCAR-B38M/JNJ-4528 except as permitted under the Janssen Agreement. Additionally, for a period of up to 20 years after the effective date of the Janssen Agreement, neither we nor Janssen may develop or commercialize any CAR-T cell therapy targeting BCMA for the treatment of MM, either independently or in collaboration with a third party, except pursuant to the Janssen Agreement, subject to certain exceptions for mergers, acquisitions, in-licenses or similar transactions.

The Janssen Agreement will remain in force as long as LCAR-B38M/JNJ-4528 is being sold. We or Janssen may terminate the Janssen Agreement on 90 days' notice for an uncured material breach by the other party. Janssen may also terminate the Janssen Agreement (i) in its entirety or on a geographic region-by-geographic region basis without cause on 180 days' notice to us or (ii) in its entirety upon the occurrence of an unforeseen material safety event on 60 days' notice to us. Upon any termination, we will have rights under Janssen's intellectual property to independently continue to develop and commercialize LCAR-B38M/JNJ-4528 without compensation to Janssen.

#### Collaborative Research and License Agreement with Noile-Immune Biotech Inc.

In April 2020, we entered into a collaborative research and license agreement with Noile-Immune Biotech Inc. (Noile-Immune), or the Noile-Immune Agreement, pursuant to which we obtained a worldwide, exclusive license to develop and commercialize CAR-T and/or TCR-T cell therapies incorporating Noile-Immune's PRIME (proliferation-inducing and migration-enhancing) technology for up to two targets for all indications and uses. We have the right to nominate such targets during a specific period following the effective date of the Noile-Immune Agreement. Noile-Immune may only refuse our nomination if such targets are the subject of internal development by Noile-Immune, are subject to exclusive third party rights, or are the subject of good faith discussions between Noile-Immune and a third party for exclusive rights, in each case, at the time of our selection. We are solely responsible, at our sole cost, for the development of CAR-T and/or TCR-T cell therapies directed to the selected targets, provided that Noile-Immune may participate in specific aspects of such development subject to our and Noile-Immune's mutual agreement. We are obligated to use commercially reasonable efforts to develop and commercialize such therapies and, in particular, use commercially reasonable efforts to submit an investigational new drug application and achieve a first commercial sale of such a therapy, in each case by a specified period of time in the United States or specified markets in Europe or Asia.

In consideration for the grant of the exclusive license under the Noile-Immune Agreement, we are obligated to pay to Noile-Immune an initial payment upon target selection and milestone payments for the achievement of specified development milestones of up to \$70 million in the aggregate on a target-by-target basis. Noile-Immune will also be entitled to receive royalties based on net sales of the products developed under the Noile-Immune Agreement at single-digit percentages, subject to specified reductions. These royalties are payable, on a product-by-product and country-by-country basis until the latest to occur of: the expiration of the last to expire valid claim covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or a specified number of years after the first commercial sale of such product in such country.

During the term of the Noile-Immune Agreement, Noile-Immune will not work independently or through or with any affiliate or third party to develop or commercialize any CAR-T and/or TCR-T cell therapy directed to the targets that have been selected by us and approved by Noile-Immune. The Noile-Immune Agreement will remain in force until the expiration on a country-by-country, target-by-target and product-by-product basis of all of our obligations to pay milestones and royalties to Noile-Immune. We may terminate the Noile-Immune Agreement in its entirety or on a country-by-country, target-by-target or product-by-product basis, by providing a specified number of days prior notice to Noile-Immune, if in our reasonable judgement, such termination is

justified for any reason, including commercial, scientific or medical reasons. Either party may terminate the Noile-Immune Agreement for cause for the other party's uncured material breach on a specified number of days prior notice or immediately in the event of bankruptcy of the other party.

## Commercialization

We are in the process of establishing a sales, marketing or product distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we will need a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. According to the Janssen Agreement, we have the right to elect to perform up to 50% of the overall commercialization effort in the United States (excluding any activities that Janssen has the exclusive right to perform). Janssen will commercialize the products in all countries excluding the United States and Greater China in accordance with a specified plan, which will be developed with involvement by a senior commercial representative designated by us. In Greater China, we will be leading the commercialization effort and Janssen will have the right to elect to perform up to 30% of the overall commercialization effort, excluding activities that we have the exclusive right to perform. As we move our product candidates through development toward regulatory approval we will evaluate several options for each product candidate's commercialization strategy. These options include further building our own internal sales force, entering into a joint marketing collaboration with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company.

### **Intellectual Property**

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally for our clinical and preclinical products LCAR-B38M/JNJ-4528, LB1901, LB1902, LB1903, LB1904, LB1905, LB1909 and LB1910. However, we do not own any issued patents covering our clinical and preclinical products and our patent portfolio for such products is currently comprised only of applications. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form that will provide us with meaningful protection for our products. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the

earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent or delays on the part of a patentee. In the United States, the patent term of a patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent term extensions are available in Supervol, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further

altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Risk Factors—Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

#### **Company-Owned Intellectual Property**

We own two U.S. patent applications, 59 patent applications outside of the United States, one published PCT application filed in August 2016 and one published PCT application filed in August 2017 relating to the LCAR-B38M BCMA product candidate. National phase applications from both these PCTs were filed broadly to acquire patent coverage in a variety of jurisdictions, including in the United States, Greater China (mainland China and Hong Kong), Yemen, Saudi Arabia, Qatar, Oman, Bahrain, Egypt, United Arab Emirates, Europe, South Korea, Brazil, Canada, Chile, Colombia, Costa Rica, Eurasian, Israel, India, Japan, Mexico, Philippines, Ukraine, Vietnam, Malaysia, South Africa, Singapore, Australia and New Zealand. If issued, composition of matter claims issuing from these applications are projected to expire in 2036 and 2037.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021 and one pending PCT application filed in May 2019 that is due for national phase entry in 2021 relating to our LB1901 CD4 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one patent application outside of the United States, and one pending PCT application filed in August 2019 that is due for national phase entry in 2021 relating to our LB1902 product candidate. If issued, composition of matter claims issuing from this application are projected to expire in 2039.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021, and one pending PCT application filed in May 2019 that is due for national phase entry in 2021 relating to our LB1903 HIV product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one PCT application relating to our LB1904 Claudin 18.2 product candidate filed in 2019 that is due for national phase entry in 2022. If issued, composition of matter claims issuing from this application are projected to expire in 2040.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021 and one pending PCT application filed in August 2019 that is due for national phase entry in 2022 relating to our LB1905 CD20 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one U.S. patent application, 29 patent applications outside of the United States and one published PCT application filed in 2016 relating to our LB1909 CD19/CD22 product candidate. National phase applications from this PCT were filed broadly to acquire patent coverage in a variety of jurisdictions. If issued, composition of matter claims issuing from this application are projected to expire in 2036.

We own two patent applications outside of the United States and two pending PCT applications filed in September 2019 that are due for national phase entry in 2021 relating to our LB1901 CD33/CLL-1 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039.

### Manufacturing

The manufacture and delivery of cell therapies to patients involves complex, integrated processes. Commercial success in cell therapies requires a manufacturing process that is reliable, scalable and economical. We are devoting significant resources to process development and manufacturing in order to optimize process robustness, lower failure rates in developing cell therapy product candidates as well as reduce our per-unit manufacturing costs and enable us to quickly achieve regional and global scale if we obtain regulatory approval for any of our product candidates.

We currently have manufacturing sites in China and the United States supplying clinical materials for our trials. We are also in the process of establishing a manufacturing site in Europe. We also intend to expand the manufacturing capacities in the United States, Europe and China for commercialization at both a regional and global scale, if any of our product candidates are approved.

We are employing a systematic approach to manufacturing which is designed to provide a common platform suitable for manufacturing all of our product candidates. This platform allows for parallel processing and the ability to scale for commercial supply in a controlled environment and at an economical cost. We have improved the viral transduction process to help minimize processing inconsistencies and reduce failure rates. In addition, our manufacturing and logistics process is designed to ensure that product integrity is maintained during shipment along with accurate tracking and tracing of shipments.

Our manufacturing and commercialization strategy requires a fully integrated product delivery cycle. We believe having established a manufacturing platform process and manufacturing hubs within the United States, China and Europe suitable for commercialization early in the development of our cell therapies is a competitive advantage. Over time, we expect to expand regional manufacturing capacity and potentially add external supply nodes to meet projected product requirements for commercialization. We believe that anticipated future clinical and commercial demand for LCAR B38M/JNJ-4528 and new pipeline programs can be met, as our facilities have been designed for ease of expansion.

We believe our scalable robust manufacturing process, along with our proprietary technologies and our industry experienced team, would be challenging and costly for potential competitors to replicate.

## Competition

Our products will compete with novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

Novartis and Kite were the first to achieve FDA approval for autologous T cell therapies. In August 2017, Novartis obtained FDA approval to commercialize Kymriah for the treatment of children and young adults with acute B lymphocytic leukemia, or ALL, that is refractory or has relapsed at least twice. In May 2018, Kymriah received FDA approval for adults with relapsed or refractory DLBCL. In October 2017, Kite obtained FDA approval to commercialize Yescarta, the first CAR-T cell product candidate for the treatment of adult patients with relapsed or refractory large B-cell lymphoma. Kite has published data on Yescarta in ALL as well. Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, has published data on its anti-CD19 CAR therapy, JCAR019. bluebird was the first company to publish data on an anti-BCMA CAR therapy, bb2121, in MM.

Due to the promising therapeutic effect of cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies.

Our potential CAR-T cell therapy competitors include:

- Companies developing cell therapies targeting BCMA for the treatment of MM, including Allogene, Autolus, bluebird, Bristol-Myers Squibb, Carsgen, Innovent, Poseida Therapeutics, Novartis and Precision Biosciences;
- Additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Regeneron, GSK and Pfizer.

We also compete with many companies developing cell therapies, including for trial sites, enrollment in our trials and with respect to diseases that we are targeting and may target in the future. In addition, we may compete with cell therapies companies that are focused on development in Asia.

In addition, our commercial success depends on our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary and modular CAR-T cell technology without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of CAR-T cell therapies and including patents owned or controlled by our competitors. In addition, there are frequent allegations of patent infringement in the area of biotechnology. Third parties, including our competitors, may allege that our product candidates, including LCAR-B38M/JNJ-4528, infringe certain of these patents. While we believe that we would have valid defenses against any assertion of such patents against us, such defenses may be unsuccessful and a successful claim of patent infringement against us could require us to be liable for damages, make substantial licensing, royalty and other payments, or cease development, manufacturing, marketing and commercializing the infringing products. Moreover, if we are unable

to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained or in-licensed is not sufficiently broad or if the validity of such patent protection is threatened, we may not be able to compete effectively, as it could create opportunities for competitors to enter the market or dissuade other companies from collaborating with us to develop products and technology, any of which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, convenience and pricing.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, as well as for technologies complementary to, or necessary for, our programs.

#### **Government Regulation**

# United States Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

In the United States, the FDA regulates biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a BLA and licensure, which constitutes approval, by the FDA before being marketed in the United States. None of our product candidates has been approved by the FDA for marketing in the United States, and we currently have

no BLAs pending. Failure to comply with applicable FDA or other requirements at any time during product development, clinical testing, the approval process or after approval may result in administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, suspension or revocation of approved applications, warning letters, product recalls, product seizures, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practices, or GLP, regulations;

- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness of the proposed biologic product candidate for its intended indications;
- preparation of and submission to the FDA of a BLA when adequate data are obtained from pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP regulations; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

### Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND application to the FDA. An IND application is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND application is on the general investigational plan and the protocol(s) for clinical studies. The IND application also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. If the IND sponsor is not able to address FDA's concerns satisfactorily within the 30-day time frame, the IND may be placed on clinical hold. The IND sponsor and the FDA must resolve any outstanding concerns or questions before the IND is cleared by the FDA and the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Generally, a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, or DSMB, which provides recommendation on whether or not a study should move forward at designated check points based on access to certain data from the study. The

DSMB may recommend halting of the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. For investigational products developed for oncology indications, the Phase 1 trials are normally conducted in patients with serious or life-threatening diseases without other treatment alternatives.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. For certain indications in patients with serious or life-threatening diseases and with no available therapies, it may be possible to obtain BLA approval based on data from Phase 2 trials if a positive benefit risk profile is demonstrated.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically
  significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These
  clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product
  approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

## **BLA Submission and Review**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA unless a waiver or exemption applies.

Once an original BLA has been submitted, FDA has 60 days to determine whether the application can be filed. If FDA determines that an application to be deficient, on its face, in a way that precludes a complete review, FDA may not accept the application for review and may issue a refuse-to-file letter to the sponsor. If FDA determines the application is filable, the FDA's goal is to review standard applications within ten months

after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facilities in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the commercial product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

#### **Expedited Development and Review Programs**

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, in which case the FDA

may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act, which was signed into law in December 2016. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like fast track and breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

# **Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

#### **Post-Approval Requirements**

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or

imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

#### **Biosimilars and Reference Product Exclusivity**

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product be biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered to a patient more than once, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the competing product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of

the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

## Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program; federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters, and which, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also imposes certain requirements on HIPAA covered entities and their business associates relating to the privacy, security and transmission of individually identifiable health information; the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the federal government, information related to payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

### **Coverage and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. As there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States, coverage and reimbursement policies for drug products can differ significantly from payor to payor. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement for our drug products. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

### Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In addition, the Tax Act was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, if any, and other efforts to repeal and rep

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2029 unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration released a "Blueprint," or plan, to

lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

#### **PRC Regulation**

In the People's Republic of China, or PRC, we operate in an increasingly complex legal and regulatory environment. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

#### **PRC Drug Regulation**

#### Introduction

China heavily regulates the development, approval, manufacturing and distribution of drugs, including biologics. The specific regulatory requirements applicable depend on whether the drug is made and finished in China, which is referred to as a domestically manufactured drug, or made abroad and imported into China in finished form, which is referred to as an imported drug, as well as the approval or "registration" category of the drug. For both imported and domestically manufactured drugs, China typically requires regulatory approval for a CTA to conduct clinical trials in China and submit China clinical trial data, prior to submitting an application for marketing approval. For a domestically manufactured drug, there is also a requirement to have a drug manufacturing license for a facility in China.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion in October 2017. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first, manufacture domestically, and develop drugs in high priority disease areas, such as oncology.

To implement the regulatory reform introduced by the Innovation Opinion, the NPC and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law, or DAL. The DAL was promulgated by the Standing Committee of the NPC on September 20, 1984 and last amended on August 26, 2019 and took effect as of December 1, 2019. The DAL is implemented by a high-level regulation issued by the State Council referred to as the DAL Implementing Regulation. The NMPA has its own set of regulations further implementing the DAL; the primary one governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation, or DRR. The DRR was promulgated by the NMPA on February 28, 2005 and the last amended DRR will take effect from July 1, 2020. Although the NMPA has issued several notices and proposed regulations in 2018 and 2019 to implement the reforms, the implementing

regulations for many of the reforms in the Innovation Opinion have not yet been finalized and issued, and therefore, the details regarding the implementation of the regulatory changes remained uncertain in some respects.

### Regulatory Authorities and Recent Government Reorganization

In the PRC, the NMPA is the primary regulatory agency for pharmaceutical products and businesses. The agency was formed from the prior China Food and Drug Administration, or CFDA, in 2018 as part of a government reorganization. Pursuant to the Decision of the First Session of the Thirteenth National People's Congress on the State Council Institutional Reform Proposal made by the NPC on March 17, 2018, NMPA is one of the two half-ministry level agencies under the State Administration for Market Regulation, or SAMR, which are responsible for consumer protection, advertising, anticorruption, pricing and fair competition matters. The National Intellectual Property Administration is the other half-ministry level agency under the SAMR.

Like the CFDA, the NMPA is still the primary drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and it regulates almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

The NHC (formerly known by the names: the Ministry of Health (MOH) and National Health and Family Planning Commission (NHFPC)), is China's primary healthcare regulatory agency. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites, and regulating the licensure of hospitals and other medical personnel. NHC plays a significant role in drug reimbursement. Furthermore, the NHC and its local counterparts at or below the provincial-level of local government also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, through which public hospitals and their pharmacies acquire drugs.

Also, as part of the 2018 reorganization, the PRC government formed the National Healthcare Security Administration which focuses on regulating reimbursement under the state-sponsored insurance plans.

### Non-Clinical Research

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the DRR, nonclinical safety studies must comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. On August 6, 2003, the NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, which was revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory issued by the NMPA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017, respectively, by the State Council, the Administrative Measures on Good Practice of Experimental Animals jointly promulgated by the State Science and Technology

Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

### **Registration Categories**

Prior to engaging with the NMPA on research and development and approval, an applicant will need to determine the registration category for its drug candidate (which will ultimately need to be confirmed with the NMPA), which will determine the application requirements for its clinical trial and marketing application. There are five categories for small molecule drugs: Category 1, or innovative drugs, refers to drugs that have a new chemical entity that has not been marketed anywhere in the world, Category 2, or improved new drugs, refers to drugs with a new indication, dosage form, route of administration, combination, or certain formulation changes not approved in the world, Category 3 is for domestic generics that reference an innovator drug marketed abroad but not in China, Category 4 is for domestic generics that reference an innovator drug marketed abroad but not in China innovative or generic drugs that have already been marketed abroad.

Therapeutic biologics follow a somewhat similar categorization, with three out of the 15 categories depending on marketing approval status: Category 1 is for innovative biologics that have not been approved inside or outside of China, Category 7 for biologics that have been marked abroad but not in China, and Category 15 for biologics that have been marketed in China, and the rest of the 15 categories depending on products characteristics. All biologics follow the new drug application pathway, but a tentative guideline on the development and evaluation of biosimilar drugs was issued by the NMPA in 2015.

### **Expedited Programs**

### Priority Evaluation and Approval Programs to Encourage Innovation

The NMPA has adopted several expedited review and approval mechanisms since 2009 and created additional expedited programs in recent years that are intended to encourage innovation. Applications for these expedited programs can be submitted together with the registration package or after the registration submission is admitted for review by the CDE. The Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation promulgated by the NMPA on December 21, 2017 clarified that fast track CTAs or drug registration pathways will be available to the innovative drugs.

If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the CDE, expedited review and approval, and more agency resources throughout the review approval process.

NMPA also permits conditional approval of certain medicines based on early phase China clinical trial data or only on foreign approval clinical data. Post-approval the applicant may need to conduct one or more post-market studies. The agency has done this for drugs that meet unmet clinical needs for life-threatening illnesses and also for drugs that treat orphan indications. In 2018, NMPA established a conditional approval program for drugs designated by the CDE that have been approved in the US, EU and Japan within the last 10 years and that meet one of three criteria (1) orphan indications, (2) drugs that treat life threatening illnesses for which there are not effective treatment or preventive methods, and (3) drugs that treat life threatening illnesses and that have a clear clinical advantage over other approved therapies.

### **Clinical Trials and Marketing Approval**

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The materials required for this application and the data requirements are determined by

the registration category. The NMPA has taken a number of steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the Administrative Regulations of Quality of Drug Clinical Practice, or the PRC's GCP to ensure data integrity.

# Trial Approval

All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions which shall be under the filing administration. For imported drugs, proof of foreign approval is required prior to the trial, unless the drug has never been approved anywhere in the world. In addition to a standalone China trial to support development, imported drug applicants may establish a site in China that is part of an international multicenter trial, or IMCT, at the outset of the global trial. Domestically manufactured drugs are not subject to foreign approval requirements, and in contrast to prior practice, the NMPA has recently decided to permit those drugs to conduct development via an IMCT as well.

In 2015, the NMPA began to issue an umbrella approval for all phases (typically three) of a new drug clinical trial, instead of issuing approval phase by phase. For certain types of new drug candidates, CTAs may be prioritized over other applications and put in a separate expedited queue for approval.

The NMPA has now adopted a system for clinical trials of new drugs where trials can proceed if after 60 business days, the applicant has not received any objections from the CDE. China is also expanding the number of trial sites by changing from a clinical trial site certification procedure into a notification procedure.

#### Drug Clinical Trial Registration

Pursuant to the DRR, upon obtaining the clinical trial approval and before commencing a clinical trial, the applicant shall file a registration with the NMPA containing various details of the clinical trial, including the clinical study protocol, the name of the principal researcher of the leading institution, names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the Informed Consent Form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. On September 6, 2013, the NMPA released the Announcement on Drug Clinical Trial Information Platform, providing that for all clinical trials approved by the NMPA and conducted in China, instead of the aforementioned registration filed with the NMPA, clinical trial registration shall be completed and trial information shall be published through the Drug Clinical Trial Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete registration of certain follow-up information before the first subject's enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

#### Human Genetic Resources Approval

According to the Interim Measures for the Administration of Human Genetic Resources, promulgated by the Ministry of Science and Technology and the MOH jointly on June 10, 1998, an additional approval is required for any foreign companies or foreign affiliates that conduct trials in China. Prior to beginning a trial, the foreign sponsor and the Chinese clinical trial site are required to obtain approval from the Human Genetic Resources Administration of China, or HGRAC, which is an agency under the Ministry of Science and Technology, to collect any biological samples that contain the genetic material of Chinese human subjects, and to transfer any cross-border transfer of the samples or associated data. Furthermore, one of the key review points for the HGRAC review and approval process is the IP sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights to inventions arising from the samples. Conducting a clinical trial in China without obtaining the relevant HGRAC preapproval will subject the sponsor and trial site to administrative liability, including confiscation of HGRAC samples and associated data, and administrative fines.

On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that foreigninvested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. On May 28, 2019, the State Council of PRC issued the Administration Regulations on Human Genetic Resources, which became effective on July 1, 2019. The Administration Regulations on Human Genetic Resources formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to the new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

### Trial Exemptions and Acceptance of Foreign Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, or the Guidance Principles, as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of foreign clinical trials must meet the authenticity, completeness, accuracy and traceability requirements and such data must be obtained consistent with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without the need for pre-approval clinical trials inside China. Specifically, on October 23, 2018, the NMPA issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, which established a program permitting drugs that have been approved within the last ten years in the United States, EU or Japan and that i) treat orphan diseases, ii) prevent or treat serious life-threatening illnesses for which there is either no effective therapy or prevention in China, or iii) prevent or treat serious life-threatening illnesses and the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug is marketed. By May 29, 2019, the CDE has developed two lists of qualifying drugs that meet this criteria.

### Clinical Trial Process and Good Clinical Practices

Typically drug clinical trials in China have four phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the pivotal study) refers to clinical trials to further verify the drug candidate's therapeutic efficacy and safety in patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. Phase 4 refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval and comply with the PRC's GCP. The NMPA conducts inspections to assess the PRC's GCP compliance and will cancel the CTA if it finds substantial issues.

On August 6, 2003, the NMPA promulgated the PRC's GCP to improve the quality of clinical trials. According to the PRC's GCP, the sponsor shall provide insurance to the subjects participating in the clinical trial and bear the cost of the treatment and the corresponding financial compensation for the subjects who suffer harm or death related to the trial. The sponsor shall provide legal and economic guarantee to the investigator, but harm or death caused by the medical accident shall be excluded. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the PRC's GCP, and the protocols must be approved by the ethics committees of each study site. Pursuant to the newly amended DAL, and the Regulations on the Administration of Drug Clinical Trial Institution jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be under filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed.

#### New Drug Application (NDA) and Approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug. For imported drugs, this means issuance of an import license. Again, the applicant must submit evidence of foreign approval, unless it is an innovative drug that has never been approved anywhere in the world.

NDA sponsors must submit data derived from domestically manufactured drugs in support of a drug approval. Under the current regime, upon approval of the registration application, the NMPA will first issue a new drug certificate to the applicant. Only when the applicant is equipped with relevant manufacturing capability will the NMPA issue a Drug Approval Serial Number, which is effectively the marketing approval allowing the holder to market/commercialize the drug in China.

Pursuant to the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015, the State Council published the policy for carrying out a pilot plan for the drug marketing authorization holder mechanism.

Pursuant to the newly amended DAL, under the drug marketing authorization holder mechanism, an enterprise obtained drug registration certificate and a research and development institution are eligible to be a pharmaceutical marketing authorization holder, and this pharmaceutical marketing authorization holder shall be responsible for nonclinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. The pharmaceutical marketing authorization holder may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon the approval of the medical products administrative department under the State Council, a drug marketing authorization holder may transfer the drug marketing license and the transferee shall have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing license holder.

## Manufacturing and Distribution

According to the newly amended DAL and the implementing Measures of the DAL, all facilities that manufacture drugs in China must receive a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years.

Similarly, to conduct sales, importation, shipping and storage, or distribution activities, a company must obtain a Drug Distribution License with an appropriate "scope of distribution" from the local drug regulatory authority, subject to renewal every five years.

China has formed a "Two Invoice System" to control distribution of drugs. The "Two-Invoice System" generally requires that no more than two invoices may be issued throughout the distribution chain, with one from

the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System will become a prerequisite for pharmaceutical companies to participate in procurement processes with public hospitals, which currently provide most of China's healthcare. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Two-Invoice System was first implemented in 11 provinces that are involved in pilot comprehensive medical reforms, but the program has expanded to nearly all provinces, which have their own individual rules for the program.

## Human Cell Therapy

On March 20, 2003, the NMPA published the Technical Guidelines for Research on Human Cell Therapy and Quality Control of Preparations, which set some principles for the research of human cell therapy.

Pursuant to the DRR promulgated by the NMPA on July 10, 2007 and effective from October 1, 2007, human cell therapy and its products belong to biological products and the application for biological products shall be submitted as the process of new drug application.

On March 2, 2009, the MOH published the Management Measures for Clinical Application of Medical Technology, which came into effect on May 1, 2009 and prescribed that cell immunotherapy belongs to the Category 3 medical technology of which the clinical application shall be subject to the additional provisions of the MOH. In May, 2009, the MOH published the First List of Category 3 Medical Technologies Allowed for Clinical Application, or the Category 3 Medical Technologies which prescribed cell immunotherapy technology as Category 3 medical technologies were allowed for clinical application, and was abolished by the Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application on June 29, 2015. The Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application also cancelled the approval of Category 3 medical technology clinical application.

On November 30, 2017, the CFDA promulgated the Notice of Guidelines for Acceptance and Examination of Drug Registration (Trial), the application of clinical trials of therapeutic biological products and the production and listing application of therapeutic biological products shall be subject to the provisions thereof. On December 18, 2017, the CFDA promulgated the Technical Guiding Principles for Research and Evaluation of Cell Therapy Products (Trial) to regulate and guide the research and evaluation of cell therapy products that are researched on, developed and registered as drugs.

### Post-Marketing Surveillance

Pursuant to the newly amended DAL, the drug marketing authorization holder shall be responsible for the monitoring, reporting and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. Marketing authorization holders, pharmaceutical manufacturer, pharmaceutical distributors and medical institutions shall regularly inspect the quality, efficacy and adverse reactions of drugs manufactured, distributed and used by them. Cases of suspected adverse reactions shall be promptly reported to the drug administrative authorities and the competent health administrative authority. The drug marketing authorization holder shall forthwith stop selling, notify the relevant pharmaceutical distributors and medical institutions to stop sales and use, recall sold drugs, promptly announce recall information if the drugs have quality issues or other safety hazards.

### Advertising and Promotion of Pharmaceutical Products

China has a strict regime for the advertising of approved drugs. No unapproved drugs may be advertised. The definition of an advertisement is very broad and it can be any media that directly or indirectly introduces the product to end users. There is no clear line between advertising and any other type of promotion.

Each advertisement for drugs requires an approval from a local drug regulatory authority, and the content of an approved advertisement may not be altered without filing a new application for approval. An enterprise seeking to advertise a prescription drug may do so only in medical journals jointly approved by NMPA and the NHC, and the advertisement for a prescription drug shall tag "this advertisement is for medical and pharmaceutical professionals reading only."

Drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug's approval documentation, off-label content, is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

### **Product Liability**

The Product Quality Law of the PRC, or the Product Quality Law promulgated by the Standing Committee of the NPC on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018, respectively, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the General Principles of the Civil Law of the PRC promulgated by the NPC on April 12, 1986 and amended on August 27, 2009, both manufacturers and sellers shall be held liable where the defective products result in property damages or bodily injuries to others. Pursuant to the Tort Liability Law of the PRC promulgated by the Standing Committee of the NPC on December 26, 2009 and effective from July 1, 2010, manufacturers shall assume tort liabilities where the defects in products cause damages to others. Sellers shall assume tort liabilities where the defects in products that have caused damages to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the defected product that has caused damage.

### **Commercial Bribery**

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by their respective provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which were promulgated by the NHFPC on December 25, 2013 and became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. Where a pharmaceutical company or its agent is listed in the Adverse Records of

Commercial Briberies on one occasion, it will be prohibited from participating in the procurement bidding process or selling its products to public medical institutions located in the local provincial-level region for two years from the publication of the adverse records. Where a pharmaceutical company or its agent is listed in the Adverse Records of Commercial Briberies on two or more occasions within five years, it will be prohibited from participating in the procurement bidding process or selling its products to all public medical institutions in the PRC for two years from the publication of these adverse records.

### **Regulatory Intellectual Property Protections**

Non-Patent Exclusivities

## New drug monitoring period

According to the DRR and the Implementing Regulations of the DAL, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period, the NMPA will not approve another CTA from another applicant for the same type of drug, except if another sponsor has an approved CTA at the time that the monitoring period is initiated it may proceed with its trial and once approved become another drug that is part of the monitoring period.

#### Regulatory data protection

The Innovation Opinion also lays the foundation for the establishment of a system for regulatory data protection to protect innovators. This protection will be available to the undisclosed clinical trial data of drugs falling into the following categories: innovative drugs, innovative therapeutic biologics, drugs that treat orphan diseases, pediatric drugs, and drugs for which there has been a successful patent challenge.

On April 25, 2018, NMPA published a draft on Implementing Regulations for Pharmaceutical Study Data Protection for public comment that would set regulatory data protection for innovative small molecule drugs at six years and for innovative therapeutic biologics at 12 years; pediatric and orphan drugs would receive six years to run concurrently from their approval dates. Full terms of protection would require reliance on local trials or sites of multicenter trials in China and simultaneous submissions of marketing applications in China and other countries. Submissions in China that are up to six years after those made abroad would result in the term being reduced to 1-5 years. Submissions made in China over six years after those made abroad may not receive protection.

#### Patent-Related Protections

#### Patent linkage

The Innovation Opinion also sets forth the basic elements of a patent linkage system to protect innovators, in which a follow-on applicant will be required to specify patents that are relevant to its application and notify relevant patent holders (including, innovators) within a specified period after filing its application, permitting them to sue to protect their rights. The system will require that the NMPA continue to review the potentially infringing follow-on application during any lawsuit by the innovator. However, the NMPA may not approve the follow-on application pending resolution of the patent litigation in favor of the follow-on application or for a specified period of time, whichever is shorter. This reform will require implementing regulations. To date, the NMPA has not issued the relevant implementing regulations.

### Patent term extension

In early 2019, pursuant to the Innovation Opinion, the NPC issued a proposal for patent term extension as part of a proposed amendment to the Patent Law. Under this proposal, the State Council may grant a patent term

extension of up to five years to compensate for delays in the review process for innovative drugs that are applying simultaneously for marketing approval in both China and abroad. The patent term may not be extended to more than 14 years post-marketing. It is not clear when this will be finalized.

#### Trademarks

Pursuant to the Trademark Law of the PRC promulgated by the Standing Committee of the NPC on August 23, 1982 and amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, respectively and became effective from November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

## Domain names

Domain names are protected under the Administrative Measures on China Internet Domain Names promulgated by the Ministry of Information Industry on November 5, 2004 and effective from December 20, 2004, which was replaced by the Administrative Measures on the Internet Domain Names issued by the Ministry of Industry and Information Technology, or the MIIT, on August 24, 2017 and effective from November 1, 2017, and the Implementing Rules on Registration of Domain Names issued by China Internet Network Information Center on 25 September 2002 which came into effect on 1 December 2002 and last amended on May 28, 2012, which became effective on May 29, 2012. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

#### Reimbursement and Pricing

China's national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council in 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program. The insurance premium is jointly contributed by the employers and employees. In 2007, the State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL. A pharmaceutical product listed in the NRDL must be clinically needed, safe, effective, reasonably priced, easy to use, and available in sufficient quantity.

Factors that affect the inclusion of a pharmaceutical product in the NRDL include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public. Since 2016, special consideration has been given to, among others, innovative drugs with high clinical value and drugs for serious diseases. In addition, the PRC Ministry of Human Resources and Social Security has also been negotiating with manufacturers of expensive drugs with high clinical demands and proven effectiveness for price cuts in exchange for inclusion into the NRDL. The version of the NRDL released in 2019 covers 2,643 drugs in total, including 148 new additions, with an emphasis on innovative drugs and drugs that treat cancer and other serious diseases.

#### Government price controls

On May 4, 2015, the NDRC and six other ministries and commissions in the PRC issued the Opinion on Promoting Drug Pricing Reform, which lifted the government-prescribed maximum retail price for most drugs, including drugs reimbursed by government medical insurance funds, patented drugs, and some other drugs. The government regulates prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

## Centralized procurement and tenders

Under current regulations, public medical institutions owned by the government or owned by state-owned or controlled enterprises are required to purchase pharmaceutical products through centralized online procurement processes. There are exceptions for drugs on the National List of Essential Drugs, which must comply with their own procurement rules, and for certain drugs subject to the central government's special control such as toxic, radioactive and narcotic drugs, and traditional Chinese medicines.

The centralized procurement process takes the form of public tenders operated by provincial or municipal-level government agencies. The centralized tender process is typically conducted once every year. The bids are assessed by a committee randomly selected from a database of experts. The committee members assess the bids based on a number of factors, including but not limited to bid price, product quality, clinical effectiveness, product safety, level of technology, qualifications and reputation of the manufacturer, after-sale services and innovation.

According to the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State issued by the General Office of the State Council in January 2019, in the 11 pilot cities drugs will be selected from generic brands for centralized medicine procurement. The selected drugs must pass the consistency evaluation on quality and effectiveness. The policy is aimed at lowering drug costs for patients, reducing transaction costs for enterprises, regulating drug use of institutions, and improving the centralized medicine procurement and pricing system. The centralized procurement is open to all approved enterprises that can produce drugs on the procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs will be considered, and their consistency will be the main criteria for evaluation, while production capacity and stability of the supplier will also be considered.

### Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases or released by us to third parties. The privacy of human subjects in clinical trials is also protected under regulations. For example, the case report forms must avoid disclosing names of the human subjects.

These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future, including restrictions on transfer of healthcare data. The Cybersecurity Law that took effect in 2017 designates healthcare as a priority area that is part of critical information infrastructure, and China's cyberspace administration is working to finalize a draft rule on cross-border transfer of personal information.

#### PRC Regulation of Foreign Investment

Investment activities in China by foreign investors are principally governed by the Guidance Catalogue of Industries for Foreign Investment, or the Catalogue, which was promulgated and is amended from time to time

by the MOFCOM and the NDRC. Pursuant to the latest Catalogue which came into effect in July 2017 with the latest amendment being effective as of July 2018, or the 2017 Catalogue, industries are divided into two categories: encouraged industries and the industries within the catalogue of special management measures, or the Negative List. The Negative List is further divided into two sub-categories: restricted industries and prohibited industries. Establishment of wholly foreign-owned enterprises is generally allowed in industries outside of the Negative List. For the restricted industries within the Negative List, some are limited to equity or contractual joint ventures, while in some cases Chinese partners are required to hold the majority interests in such joint ventures. Foreign investors are not allowed to invest in industries in the prohibited category. Industries not listed in the Catalogue are generally open to foreign investment unless specifically restricted by other PRC regulations.

On March 15, 2019, the NPC approved the Foreign Investment Law of the PRC, or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the three old rules on foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperation Joint Venture Law and the Wholly Foreign-Owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law establishes the basic framework for the access to, and the promotion, protection and administration of foreign investments in view of investment protection and fair competition. According to the Foreign Investment Law, "foreign investment" refers to investment activities directly or indirectly conducted by one or more natural persons, business entities, or other organizations of a foreign country (collectively referred to as "foreign investor") within China, and "investment activities" include the following activities: (i) a foreign investor, individually or together with other investors, establishes a foreign-invested enterprise within China; (ii) a foreign investor acquires stock shares, equity shares, shares in assets, or other similar rights and interests of an enterprise within China; (iii) a foreign investor, individually or together with other investors, invests in a new construction project within China; and (iv) investments in other means as provided by the laws, administrative regulations or the State Council. The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the Negative List.

On December 26, 2019, the State Council promulgated the Implementation Rules to the Foreign Investment Law, which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated Measures for Information Reporting on Foreign Investment, which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

#### M&A Rules

According to the M&A Rules jointly issued by the MOFCOM, the State Assets Supervision and Administration Commission of the State Council, the SAT, the State Administration for Industry and Commerce (now known as the SAMR), the CSRC and the SAFE, on August 8, 2006 and amended by the MOFCOM on June 22, 2009, among other things, (i) the purchase of an equity interest or subscription to the increase in the registered capital of non-foreign-invested enterprises, (ii) the establishment of foreign-invested enterprises to purchase and operate the assets of non-foreign-invested enterprises, or (iii) the purchase of the assets of non-foreign-invested enterprises and the use of such assets to establish foreign-invested enterprises to operate such assets, in each case, by foreign investors shall be subject to the M&A Rules. Particularly, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

# Regulations Relating to Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

### Regulations Relating to Foreign Exchange

The PRC Foreign Exchange Administration Regulations promulgated by the State Council on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, respectively, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business; and/or paying the expenses related to the purchase of real estate that is not for self-use, except for the real estate enterprises.

In 2017, new regulations were adopted which, among other things, relax the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation and tighten genuineness and compliance verification of cross-border transactions and cross-border capital flows.

In 2019, SAFE promulgated SAFE Circular 28, which cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the "capital account— account for settled foreign exchange to be paid" to receive the corresponding funds according to relevant provisions.

### SAFE Circular 37

In July 2014, SAFE promulgated SAFE Circular 37, which replaces the previous SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE

or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China. In February 2015, SAFE promulgated SAFE Notice 13. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound direct investments, including those required under SAFE Circular 37, must be filed with qualified banks instead of SAFE. Qualified banks should examine the applications and accept registrations under the supervision of SAFE.

#### Regulations Relating to Dividend Distributions

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the PRC Company Law, promulgated in 1993 and last amended in 2018 and the Foreign Investment Law and its Implementing Regulations, both came into effect on January 1, 2020. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

#### Labor Laws and Labor Contract Law

Pursuant to the PRC Labor Law promulgated by the Standing Committee of the NPC on July 5, 1994 and last amended on December 29, 2018 and the PRC Labor Contract Law promulgated by the Standing Committee of the NPC on June 29, 2007 and amended on December 28, 2012, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

### Regulations Relating to Social Insurance and Housing Provident Funds

In addition, according to the PRC Social Insurance Law promulgated on October 28, 2010 by the Standing Committee of the NPC and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, respectively, employers like our PRC subsidiary in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing

funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

# Regulations Relating to Enterprise Income Tax

Pursuant to the PRC Enterprise Income Tax Law effective as of January 1, 2008 and as amended on February 24, 2017 and December 29, 2018, respectively, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. To clarify certain provisions in the PRC Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law on December 6, 2007, which was amended and became effective on April 23, 2019. Under the PRC Enterprise Income Tax Law and the Implementation Rules of the PRC Enterprise Income Tax Law, enterprises are classified as either "resident enterprises" or "non-resident enterprises." Aside from enterprises established within the PRC, enterprise established outside of China whose "de facto management bodies" are located in China are considered "resident enterprises" and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the PRC Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC, but has an establishment or place of business in the PRC but has income sourced within the PRC.

The Implementation Rules of the PRC Enterprise Income Tax Law provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

#### **Rest of World Regulation**

For other countries outside of the United States and the PRC, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

#### Facilities

Our principal executive offices are currently located at 10 Knightsbridge Road, Piscataway, New Jersey 08854, where we lease an approximately 22,000 square foot facility. In addition, we intend to move our principal executive offices in the first quarter of 2020 to a facility located at 2101 Cottontail Lane, Somerset, New Jersey 08873, where Legend Biotech USA, Inc. owns an approximately 85,371 square foot facility, including approximately 32,039 square feet of office space and 53,332 square feet of warehouse space. We believe that our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

#### Employees

As of December 31, 2019, we had 645 employees, 105 of whom hold Ph.D. and/or M.D. degrees. Of these 645 employees, 336 are engaged in research and development activities and 41 are engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

At each date shown, we had the following number of employees engaged in either administrative or research and development functions, as indicated below.

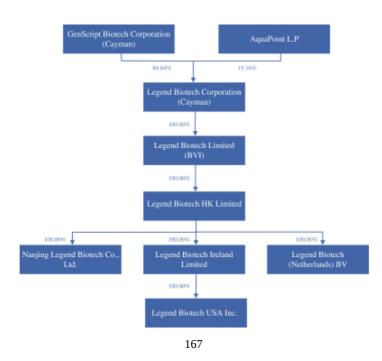
	As of De 2018	As of December 31, 2018 2019	
Function:		2015	
General and administrative	13	41	
Research and development	179	336	
Sales and marketing	7	17	
Others	95	251	
Total	294	645	
Geography:			
United States	37	158	
Asia-Pacific	255	479	
Ireland	2	8	
Total	294	645	

# Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

# **Corporate Structure**

The following diagram illustrates our corporate structure:



### MANAGEMENT

## **Directors and Executive Officers**

The following table sets forth certain information relating to our directors and executive officers as of December 31, 2019.

Name	Age	Position
Executive Officers:		
Yuan Xu, Ph.D.	52	Chief Executive Officer and Director
Ying Huang, Ph.D.	46	Chief Financial Officer
Non-Employee Directors:		
Fangliang (Frank) Zhang, Ph.D.	55	Chairman of the Board of Directors
Ye (Sally) Wang, M.S.	51	Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the nominating and corporate governance committee

# **Executive Officers**

**Yuan Xu, Ph.D.,** has served as our chief executive officer and as a director since March 2018. Before joining us, Dr. Xu was Senior Vice President at Merck from August 2015 to August 2017, where she led teams in biologics and vaccines discovery, development and commercialization. Prior to Merck, Dr. Xu served as a Vice President of Biologics and Site Head at Gilead from March 2014 to August 2015, and previously held positions at Novartis, Amgen, Chiron, GlaxoSmithKline and Genentech. Dr. Xu received a B.S. in biochemistry from Nanjing University and a Ph.D. in biochemistry from the University of Maryland. Dr. Xu also completed her post-degree training in virology and gene therapy at the University of California.

**Ying Huang, Ph.D.**, has served as our chief financial officer since July 2019. Prior to joining us, Dr. Huang was a Managing Director and Head of Biotech Equity Research at BofA Securities, Inc. from August 2014 to July 2019, where he led a team of analysts covering more than 30 biotechnology companies including Amgen, Gilead, Celgene, Biogen and others that encompass a wide range of therapeutic areas. Dr. Huang has been a biotechnology analyst since 2007 and previously worked at Wells Fargo (formerly Wachovia), Credit Suisse, Gleacher and Barclays before joining BofA Securities, Inc. Prior to his Wall Street career, Dr. Huang was a Principal Scientist at Schering-Plough (now Merck & Co.) in the Department of Chemical Research focusing on small molecule drug discovery in the therapeutic areas of cardiovascular and central nervous system. He is also the co-author of multiple patents and peer-reviewed publications. Dr. Huang holds a Ph.D. in Bio-organic Chemistry from Columbia University. Dr. Huang also studied at Columbia Business School and in the Special Class for the Gifted Young at the University of Science and Technology of China.

## **Non-Employee Directors**

**Fangliang (Frank) Zhang, Ph.D.**, has served as the chairman of our board of directors since May 2015. Dr. Zhang has been the chairman, an executive director and chief executive officer of GenScript since 2015. He co-founded the GenScript group in 2002 and has been the director of various group companies prior to GenScript becoming the holding company of the group companies pursuant to the corporate reorganization for GenScript's initial public offering in 2015. In 2015, Dr. Zhang founded our company as a subsidiary of GenScript, expanding GenScript's business goal to research, manufacture and commercialize a broad range of immunotherapy treatments. In 2018, Dr. Zhang was awarded Person of the Year at the China Healthcare Summit in recognition of his contribution to and significant impact on the healthcare field. Dr. Zhang has also authored more than 20 articles published in peer-reviewed journals and is an inventor of 9 scientific patents. Before founding GenScript, Dr. Zhang worked as a Principal Scientist at Schering-Plough from 1995 to 2002 where he received its Presidential Award. Dr. Zhang holds a Ph.D. in biochemistry from Duke University, a Master's degree from Nanjing University and a Bachelor's degree from Chengdu Institute of Geology.

**Ye (Sally) Wang, M.S.,** has served as our director since May 2015. Ms. Wang has been the Chief Operating Officer of GenScript since 2015, has served on GenScript's board of directors since 2009 and has served as GenScript's President since December 2017, responsible for GenScript's strategies and overall operational management. She co-founded the GenScript group in 2002 and has taken various managerial positions in GenScript Corporation before GenScript becoming the holding company of the group companies. Prior to joining GenScript, she worked as an Environmental Monitoring Engineer at Shenzhen Futian Environment Protection Surveillance Station. Ms. Wang holds an M.S. degree from Wuhan University, a Master's degree in Computer Sciences from the University of Bridgeport and an Executive M.B.A degree from the China Europe International Business School.

# **Board of Directors**

directors upon the effectiveness of our registration statement on Form F-1, of which this prospectus is Our board of directors will consist of a part. A director is not required to hold any shares in our company to qualify to serve as a director. A director may vote with respect to any contract or any proposed contract or arrangement in which he or she is interested, and if he or she does so his or her vote shall be counted and he or she may be counted in the quorum at any meeting of our directors at which any such contract or proposed contract or arrangement is considered, provided that (a) such director has declared the nature of his or her interest at the meeting of the board at which the question of entering into the contract or arrangement is first considered if he or she knows his or her interest then exists, or in any other case at the first meeting of the board after he or she knows that he or she is or has become so interested, either specifically or by way of a general notice and (b) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee. The directors may exercise all the powers of the company to borrow money, to mortgage or charge its undertaking, property and uncalled capital, and to issue debentures or other securities whenever money is borrowed or as security for any debt, liability or obligation of the company or of any third party. None of our non-executive directors has a service contract with us that provides for benefits upon termination of service. In accordance with the Nasdaq listing requirements, as a foreign private issuer, we may rely on home country governance requirements and certain exemptions thereunder rather than relying on the stock exchange corporate governance requirements. However, our board of directors has undertaken a review of the independence of the directors. Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, our board of directors determined that . representing

of our directors, are "independent directors" as defined under current rules and regulations of the SEC and Nasdaq. In making such determination, our board of directors considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out their responsibilities. For an overview of our corporate governance principles, see the section of this prospectus entitled "Description of Share Capital."

A company of which more than 50 percent of the voting power is held by a single entity is considered a "controlled company" under the Nasdaq Stock Market Rules. A controlled company is not required to comply with the Nasdaq corporate governance rules requiring a board of directors to have a majority of independent directors, or to have fully independent compensation and nominating and corporate governance committees. Following the completion of this offering, we will be a "controlled company" as defined under the Nasdaq Stock Market Rules.

Following this offering, we intend to rely on the "controlled company" exemption, and we will not have a majority of independent directors, our compensation committee and our nominating and corporate governance committee will not consist entirely of independent directors and such committees will not be subject to annual performance evaluations; accordingly, you will not have the same protections afforded to shareholders of companies that are subject to all of the stock exchange rules. The foreign private issuer and controlled company exemptions do not modify the independence requirements for the audit committee, and we intend to comply with the requirements of the Sarbanes-Oxley Act and Nasdaq Stock Market Rules, which require that our audit committee be composed of at least three members, one of whom will be independent upon the listing of our

ADSs on Nasdaq, a majority of whom will be independent within 90 days of the date of this prospectus, and each of whom will be independent within one year of the date of this prospectus.

# **Duties of Directors**

Under Cayman Islands law, our directors have a fiduciary duty to act honestly and in good faith with a view to our best interests. Our directors also have a duty to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended and restated memorandum and articles of association. A shareholder has the right to seek damages if a duty owed by our directors is breached.

The functions and powers of our board of directors include, among others:

- conducting and managing the business of our company;
- representing our company in contracts and deals;
- appointing attorneys for our company;
- selecting and removing senior management;
- providing employee benefits and pensions;
- managing our company's finance and bank accounts;
- evaluating the performance and determining the compensation level of chief executive officer;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- exercising any other powers conferred by the shareholders meetings or under our amended and restated memorandum and articles of association.

### **Terms of Directors and Executive Officers**

Our directors may be elected by a resolution of our board of directors, or by an ordinary resolution of our shareholders, pursuant to our amended and restated memorandum and articles of association. Each of our directors will hold office until his or her successor takes office or until his or her earlier death, resignation or removal or the expiration of his or her term. A director will cease to be a director if, among other things, the director (i) becomes bankrupt or makes any arrangement or composition with his or her creditors, (ii) is found to be or becomes of unsound mind, (iii) resigns his or her office by notice in writing to the company, or (iv) by reason of an order made under any provisions of any law or enactment. Our officers are elected by and serve at the discretion of the board of directors.

# **Board Committees**

Our board of directors intends to establish an audit committee, a compensation committee and a nominating and corporate governance committee prior to the completion of this offering. We will adopt a charter for each of the committees. Each committee's members and functions are described below.

### Audit Committee

Our audit committee will initially consist of<br/>committee.andwill be the chairperson of our auditcommittee.satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC. Each of<br/>and,andsatisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaqand will meet the criteria for independence set forth in Rule 10A-3 of the Exchange Act.

The audit committee will oversee our accounting and financial reporting processes and the audits of our financial statements. Our audit committee will be responsible for, among other things:

- selecting the independent auditor;
- pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;
- annually reviewing the independent auditor's report describing the auditing firm's internal quality control procedures, any material issues
  raised by the most recent internal quality control review, or peer review, of the independent auditors and all relationships between the
  independent auditor and our company;
- review responsibilities, budget, compensation and staffing of our internal audit function;
- reviewing with the independent auditor any audit problems or difficulties and management's response;
- reviewing and, if material, approving all related party transactions on an ongoing basis;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;
- reviewing and discussing with management and the independent auditors major issues regarding accounting principles and financial statement presentations;
- reviewing reports prepared by management or the independent auditors relating to significant financial reporting issues and judgments;
- discussing earnings press releases with management, as well as financial information and earnings guidance provided to analysts and rating agencies;
- reviewing with management and the independent auditors the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on our financial statements;
- discussing policies with respect to risk assessment and risk management with management and internal auditors;
- timely reviewing reports from the independent auditor regarding all critical accounting policies and practices to be used by our company, all alternative treatments of financial information within IFRS that have been discussed with management and all other material written communications between the independent auditor and management;
- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- such other matters that are specifically delegated to our audit committee by our board of directors from time to time; and
- meeting separately, periodically, with management, internal auditors and the independent auditor.

# Compensation Committee

Our compensation committee will initially consist of<br/>committee. Each of<br/>Listing Rules of the Nasdaq.and<br/>satisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the<br/>

Our compensation committee will be responsible for, among other things:

reviewing, evaluating and, if necessary, revising our overall compensation policies;

- reviewing and evaluating the performance of our directors and relevant senior officers and determining the compensation of relevant senior officers;
- reviewing and approving our senior officers' employment agreements with us;
- setting performance targets for relevant senior officers with respect to our incentive compensation plan and equity-based compensation plans;
- administering our equity-based compensation plans in accordance with the terms thereof; and
- such other matters that are specifically delegated to the compensation committee by our board of directors from time to time.

# Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will initially consist of<br/>chairperson of our nominating and corporate governance committee., and. will be themeaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq.satisfies the requirements for an "independent director" within the

The nominating and corporate governance committee will be responsible for, among other things:

- selecting and recommending to our board of directors nominees for election by the shareholders or appointment by the board;
- reviewing annually with our board of directors the current composition of our board of directors with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of our board of directors meetings and monitoring the functioning of the committees of our board of directors; and
- advising our board of directors periodically with regards to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any remedial action to be taken.

# **Compensation of Directors and Executive Officers**

For the year ended December 31, 2019, we paid an aggregate of approximately \$1,049,732 in cash and benefits to our executive officers. We do not pay our non-employee directors. For share incentive grants to our officers and directors, see "—Equity incentive plans." We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors.

# **Employment Agreements and Indemnification Agreements**

We have employment agreements with each of our executive officers. These agreements provide for base salaries and incentive compensation, and each component reflects the scope of each executive officer's anticipated responsibilities and the individual experience they bring to the company. In addition, each of our executive officers has executed a form of our standard intellectual property rights assignment, non-competition and confidentiality agreement and have agreed to be bound by non-competition and non-solicitation restrictions for 12 months following the date of termination of employment. Each executive officer has also agreed that Dr. Frank Zhang, the chairman of our board of directors, has voting power over any ordinary shares issued pursuant to the exercise of share options under an irrevocable proxy. The material terms of each agreement are described below.

Yuan Xu, Ph.D. We entered into an employment agreement with Dr. Xu in March 2018 setting forth the terms of her employment. The employment agreement has a six-year term, with an initial termination date of

March 27, 2024, and is renewable for successive one-year terms unless either we or Dr. Xu gives notice of non-renewal at least 90 days prior to the end of the term. Pursuant to the employment agreement, Dr. Xu is entitled to an initial annual base salary of \$470,000. Dr. Xu was also granted share options to purchase 4,400,000 ordinary shares at an exercise price of \$1.00 per share, which vest in five equal annual installments of up to 880,000 shares per year, on each of the first five anniversaries of the grant date. The share options are subject to performance-based vesting criteria, including if: (a) the performance rating for Dr. Xu for the applicable annual performance period is A (Exceed Expectations) or S (Substantially Exceed Expectations), as determined by our board of directors, 880,000 shares will vest for that period or (b) the performance rating for the applicable annual performance period, and the remaining 160,000 shares will be cancelled. As long as Dr. Xu remains employed and her performance rating is B, A or S, the options will continue to vest in accordance with the above-referenced schedule. However, if Dr. Xu's performance fails to meet minimum expectations, she will be provided notice in writing of the deficiencies and will have 90 days to cure these deficiencies. At the end of the 90-day cure period, if Dr. Xu's performance has improved to meet minimum expectations (to be decided at the discretion of our board of directors), her employment will remain and right to earn and vest share options for current and any subsequent annual performance period would not be affected. Dr. Xu is also eligible to receive an annual performance bonus, with a target bonus of 55% of her base salary.

Pursuant to the employment agreement, if Dr. Xu's employment with us ends due to her resignation for "good reason" or her termination by us other than for "cause," she is entitled to (i) severance equal to 12 months of the then-current base salary; and (ii) shares underlying options which are then eligible to vest at performance level "B" during the 18-month period following the termination date will become immediately vested and exercisable, irrespective of whether performance criteria are otherwise met, with any remaining unvested option shares to be forfeited.

In the event that we are acquired by another company, if the new ownership decides to terminate and/or not hire Dr. Xu under terms substantially similar in all material respects to Dr. Xu's employment prior to the acquisition, then Dr. Xu will receive severance equal to 24 months of her then-current base salary and all unvested options will vest immediately.

Ying Huang, Ph.D. We entered into an employment agreement with Dr. Huang in April 2019 setting forth the terms of his employment. The employment is "at will" and may be terminated at any time. Pursuant to the employment agreement, Dr. Huang is entitled to an initial annual base salary of \$450,000. Dr. Huang was also granted share options to purchase 1,000,000 ordinary shares at an exercise price of \$1.50 per share, which vest in five equal annual installments of 200,000 shares per year on each of the first five anniversaries of the grant date. Dr. Huang is also eligible to receive an annual performance bonus, with a target bonus of 40% of his base salary.

In the event that we are acquired by another company, if the new ownership decides to terminate and/or not hire Dr. Huang under terms substantially similar in all material respects to Dr. Huang's employment prior to the acquisition, then Dr. Huang will receive severance pay equal to six months of his then-current base salary and all unvested options will vest immediately upon approval by our board.

We intend to enter into indemnification agreements with each of our directors and executive officers prior to the completion of this offering. Under these agreements, we may agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.

### **Equity Incentive Plans**

#### **Share Option Scheme**

On December 2, 2017, our shareholders approved (and on December 21, 2017, Genscript's shareholders approved) our share option scheme, or the Share Option Scheme, under which, subject to the approval of our

board of directors, we may grant options to eligible participants. The material terms of the Share Option Scheme are set forth below.

The Share Option Scheme provides for the grant of share options, which for participants in the United States is represented by the grant of incentive options and nonstatutory options. Incentive options may be granted only to our employees and to employees of our subsidiaries. All other options may be granted to our employees and directors and to employees and directors of Genscript and subsidiaries, subject to applicable law. The Share Option Scheme will continue in effect following the completion of this offering.

The initial Share Option Scheme was sized at 20,000,000 shares, representing 10% of our authorized share capital as of the time the Share Option Scheme was approved. The overall limit on the number of ordinary shares that may be issued upon exercise of all outstanding options granted and yet to be exercised under the Share Option Scheme and any other share option schemes that we may establish may not exceed 30% of our authorized share capital. The total number of ordinary shares issued and to be issued upon exercise of options to any one participant (including exercised, cancelled and outstanding options) in any 12-month period may generally not exceed 1% of our authorized share capital in issue. As of December 31, 2019, options covering 18,013,000 ordinary shares with a weighted-average exercise price of \$0.93 per share were outstanding, and 1,924,000 ordinary shares remained available for the future option grants.

Administration. Our board of directors administers our Share Option Scheme and has the power to, among other things, determine the eligible persons to whom, and the times at which, options will be granted, to determine the terms and conditions of each option (including the number of shares subject to the option, the exercise price of the option, if any, and when the option will vest and become exercisable), to accelerate the time at which an option may vest or be exercised, and to construe and interpret the terms of our Share Option Scheme and options granted thereunder. Certain grants to directors and employees of Genscript are subject to the approval of Genscript's independent directors and/or Genscript's shareholders.

*Options*. The exercise price of options granted under the Share Option Scheme is no less than the fair market value of an ordinary share on the date of grant. Subject to the provisions of the Share Option Scheme, the board of directors determines the other terms of options, including any vesting and exercisability requirements, the method of payment of the option exercise price, the option expiration date, and the period following termination of service during which options may remain exercisable.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a share split or reverse share split, appropriate adjustments will be made to the number of shares covered by, and the exercise price of, each outstanding option granted under the Share Option Scheme.

*Plan Amendment or Termination.* Subject to Hong Kong Stock Exchange listing rules applicable to Genscript and certain amendments requiring approval of Genscript shareholders, the board of directors may amend the Share Option Scheme at any time. An amendment that adversely affects the terms of options previously granted or agreed to be granted must generally be approved by at least three-fourths in nominal value of all shares then subject to options granted under the Share Option Scheme. The Share Option Scheme will terminate on December 21, 2027 and may be terminated prior to that date by the board of directors.

### **Restricted Share Unit Incentive Plan**

#### 2020 Restricted Shares Plan

On , 2020, our shareholders approved our 2020 Restricted Shares Plan, or the RSU Scheme, under which, subject to the approval of our board of directors, we may grant restricted shares and restricted share units to eligible participants. The material terms of the RSU Scheme are set forth below.

The RSU Scheme provides for the grant of restricted shares and restricted share units (referred to as awards). Awards may be granted to our employees, consultants and directors, as well as to employees, consultants and directors of Genscript and our subsidiaries, subject to applicable law. The RSU Scheme will continue in effect following the completion of this offering.

The maximum aggregate number of shares that may be issued pursuant to all awards granted under the RSU Scheme is 11,000,000 shares.

Administration. Our board of directors or the compensation committee thereof (the administrator) administers our RSU Scheme and has the power to, among other things, determine the eligible persons to whom, and the times at which, awards will be granted, to determine the terms and conditions of each award (including the number of shares subject to the award, and when the award will vest), to accelerate the time at which an award may vest, and to construe and interpret the terms of our RSU Scheme and awards granted thereunder.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a share split or reverse share split, appropriate adjustments will be made to the aggregate number and type of shares that may be issued; the terms and conditions of any outstanding awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and the grant or exercise price per share for any outstanding awards.

Amendment or Termination. The administrator may terminate, amend or modify the RSU Scheme; provided, however, that (a) to the extent necessary and desirable to comply with applicable laws or stock exchange rules, the Company must obtain shareholder approval of any amendment in such a manner and to such a degree as required, unless the Company decides to follow home country practice, and (b) unless the Company decides to follow home country practice, shareholder approval is required for any amendment to the RSU Scheme that (i) increases the number of shares available under the RSU Scheme, (ii) permits the compensation committee to extend the term of the RSU Scheme, or (iii) results in a material increase in benefits or a change in eligibility requirements. Generally, no termination, amendment, or modification of the RSU Scheme may adversely affect in any material way any award previously granted pursuant to the RSU Scheme without the prior written consent of the participant.

# PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 31, 2020:

- each of our directors and executive officers;
- all of our directors and executive officers as a group; and
- each person known to us to beneficially own more than 5% of our ordinary shares.

The calculations in the table below are based on 220,591,629 ordinary shares outstanding prior to giving effect to this offering, which consists of 200,000,000 ordinary shares outstanding as of March 31, 2020 and the conversion of all of our Series A Preference Shares into 20,591,629 ordinary shares immediately prior to the closing of this offering, and ordinary shares issued and outstanding immediately after the completion of this offering, assuming the underwriters do not exercise their over-allotment option.

Except as otherwise indicated, the business addresses of the persons listed in the table is c/o Legend Biotech Corporation, 2101 Cottontail Lane, Somerset, New Jersey, 08873.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days of March 31, 2020, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

Number of Ordinary Shares Beneficially	Percentage of Shares Beneficially Owned	
Owned	Before Offering	After Offering
169,680,000	76.9%	
30,320,000	13.7	
880,000	*	
	_	
34,234,267	15.2	
	_	
34,234,267	15.2	
	Ordinary Shares Beneficially Owned 169,680,000 30,320,000 880,000 	Ordinary Shares Beneficially Owned         Percentage of Shar Owne           169,680,000         76.9%           30,320,000         13.7           880,000         *           34,234,267         15.2           —         —

\* Represents beneficial ownership of less than 1% of our total outstanding shares.

 Consists of 169,680,000 ordinary shares held by GenScript Biotech Corporation. The address for GenScript is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cavman KY1-1002, Cavman Islands.

Cayman KY1-1002, Cayman Islands.
 Consists of 30,320,000 ordinary shares held by AquaPoint L.P. The address for AquaPoint L.P. is Cayman Corporate Centre, 27 Hospital Road, P.O. Box 1748, George Town KY1-1109, Caymand Islands.

(3) Consists of 880,000 ordinary shares underlying options that are exercisable within 60 days of March 31, 2020, of which Dr. Xu has dispositive power but not voting power over these shares.

(4) Consists of (i) the shares described in footnote (2), and (ii) 3,914,267 ordinary shares underlying options that are exercisable within 60 days of March 31, 2020, of which Dr. Zhang has voting power over pursuant to an irrevocable proxy with the holders of such options, including those shares described in footnote (3). Dr. Zhang is the chairman and chief executive officer of GenScript Biotech Corporation, a publicly traded company on the Hong Kong Stock Exchange, but does not have voting or dispositive power over the shares held by GenScript Biotech Corporation.

Biotech Corporation.
(5) Consists of (i) 30,320,000 ordinary shares and (ii) 3,914,267 ordinary shares that all employees and directors as a group have the right to acquire within 60 days following March 31, 2020 pursuant to the exercise of options.

As of the date of this prospectus, of our ordinary shares are held by record holders in the United States.

## Significant changes in percentage ownership

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.



# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2017 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our then directors, executive officers or holders of more than 5% of any class of our voting securities at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest.

# **Transactions with our Parent GenScript**

#### Animal Facility Lease Agreements

We are party to an animal facility lease agreement with Nanjing Jinsirui Biotechnology Co., Ltd, or Nanjing Jinsirui, a subsidiary of GenScript. Under the agreement, we leased a 3,260 square meters animal facility in Nanjing, China, at a cost of approximately RMB0.2 million per month (\$24,026 per month, based on the conversion rate of RMB6.9197 to \$1.00, which was the average exchange rate for the year ended December 31, 2019) (valueadded tax, or VAT, included). The term of the lease was from January 2019 to December 2019. In addition, in December 2019, we entered into an additional animal facility lease agreement with Nanjing Jinsirui for the same facility and cost per month. The term of the lease is from January 1, 2020 to December 31, 2025.

### Master Services and Technology Transfer Agreements

In June 2017, we entered into the master services agreement with Nanjing Jinsirui. Pursuant to the agreement, we provided certain research services to Nanjing Jinsirui in accordance with the agreed upon work order, which we also entered into in June 2017 for consideration of RMB3.6 million per year (\$0.5 million per year) (VAT included).

In June 2018, we entered into a technology transfer agreement with Nanjing Jinsirui. The term of the technology transfer agreement was from January 2018 to December 2018. Pursuant to the agreement, we transferred to the Biologics Development Department of Nanjing Jinsirui the sequences of certain antibodies for consideration of RMB3.6 million per year (\$0.5 million per year) (VAT included).

### **Plasmid Preparation Service Agreement**

In January 2018, we entered into a plasmid service preparation service agreement with Nanjing Jinsirui. Pursuant to the agreement, Nanjing Jinsirui was engaged by us to provide plasmid research and development services. The term of the agreement was from January 2018 to December 2018. For the term of the agreement, the service fee amounted to RMB6.6 million (\$1.0 million) (VAT not included).

#### **Drug Testing Service Agreement**

In January 2018, we entered into a drug testing service agreement with Nanjing Jinsirui, with a term of five years from January 2018. Under the agreement, we provide drug testing services to GenScript. The payment of the service fee will be settled within 3 months after the end of each year. For the year ended December 31, 2018, the service fee was RMB3.5 million (\$0.5 million) (VAT not included).

## IT Department and Human Resources Service Level Agreements

In December 2019, we entered into the IT department service level agreement, or the IT Service Agreement, with the IT department of GenScript. Pursuant to the agreement, the GenScript IT team provides us with IT foundational services. The GenScript IT team charges us the cost by hour based on the type of services provided.

In February 2020, we entered into the human resources service level agreement, or the Human Resources Agreement, with GenScript. Pursuant to the agreement, GenScript will provide human resources services to us. The term of the agreement is from January 2020 until being terminated by GenScript with one-month's written notice.

For the year ended December 31, 2019, the aggregate service fees paid under the IT Service Agreement and the Human Resources Agreement amounted to \$0.6 million (VAT not included).

## Lease Agreement

In February 2018, we entered into a lease agreement with GenScript USA Holdings, Inc., a subsidiary of GenScript. Under the lease agreement, we lease an approximately 22,000 square foot facility in Piscataway, New Jersey at a cost of \$60,000 per month.

# October 2019 Entrustment Loan from Nanjing Jinsikang

In October 2019, Jinsikang Technology (Nanjing) Co., Ltd., or Nanjing Jinsikang, a wholly-owned subsidiary of GenScript, advanced RMB20.0 million (\$2.8 million) to us. As of December 2019, the entrustment loan was paid off in full.

## December 2018 Cash Advancement from GenScript USA

In December 2018, GenScript USA Inc., or GenScript USA, a wholly-owned subsidiary of GenScript, advanced \$14.2 million to us. As of December 2018, the cash advancement was paid off in full.

#### February 2018 Cash Advancement from GenScript (Hong Kong) Ltd.

In February 2018, GenScript (Hong Kong) Ltd. advanced \$4,000 to us. This cash advancement was paid off in full in January 2020.

## 2018 Cash Advancement from Nanjing Jinsirui

In 2018, Nanjing Jinsirui advanced \$21.7 million to us. As of December 2018, the cash advancement has been partially paid off with a payment totaling \$19.0 million. As of December 2019, the cash advancement was paid off in full.

## June 2018 Cash Advancement to Nanjing Jinsikang

In June 2018, we advanced \$1.5 million to Nanjing Jinsikang. As of June 2018, the cash advancement was paid off in full.

## April 2018 Cash Advancement to GenScript Biotech Corp.

In April 2018, we advanced \$55.0 million to GenScript Biotech Corp. As of December 2019, the cash advancement was paid off in full.

# March 2018 Cash Advancement to Nanjing Bestzyme

In March 2018, we advanced \$10.5 million to Nanjing Bestzyme. As of March 2018, the cash advancement was paid off in full.

# March 2018 Cash Advancement to GenScript USA

In March 2018, we advanced \$20.0 million to GenScript USA. As of December 2019, the cash advancement was paid in full.

#### December 2017 Cash Advancement from GenScript USA

In December 2017, GenScript USA advanced \$0.5 million to us. As of December 2019, the cash advancement was paid off in full.

#### August 2017 Cash Advancement from Nanjing Bestzyme

In August 2017, Nanjing Bestzyme advanced approximately \$0.9 million to us. As of August 2017, the cash advancement was paid off in full.

## August 2017 Cash Advancement from Nanjing Jinsikang

In August 2017, Nanjing Jinsikang advanced approximately \$0.5 million to us. As of August 2017, the cash advancement was paid off in full.

#### 2017 Cash Advancement from Nanjing Jinsirui

In 2017, Nanjing Jinsirui advanced approximately \$2.3 million to us. As of September 2017, the cash advancement has been partially paid off with a payment totaling approximately \$0.8 million. As of December 2019, the cash advancement was paid off in full.

## **ROFR and Co-Sale Agreement**

In March 2020 and April 2020, we issued and sold an aggregate of 20,591,629 Series A Preference Shares to new investors at a price of \$7.792 per share, resulting in aggregate gross proceeds of approximately \$160.5 million. In connection with the sale of the Series A Preference Shares, we entered into a Right of First Refusal and Co-Sale Agreement on March 31, 2020, or the ROFR and Co-Sale Agreement, with GenScript, AquaPoint L.P. and the new investors. Under the ROFR and Co-Sale Agreement, GenScript and AquaPoint L.P. granted (i) us a right of first refusal to purchase all or any portion of our ordinary shares that they may propose to transfer, at the same price and on the same terms and conditions as those offered to the prospective transferee and (ii) the new investors a secondary right of first refusal to purchase all or any portion of the shares not purchased by us pursuant to our right of first refusal. In the event that a new investor does not exercise its secondary refusal right, such investor has a right of co-sale to participate in such sale on the same terms and conditions.

## Share Option Grants to Directors and Executive Officers

We have granted share options to certain of our directors and executive officers. For more information regarding the share options granted to our directors and named executive officers see "Management—Compensation of Directors and Executive Officers."

#### **Employment Agreements and Indemnification Agreements**

We have entered employment agreements with each of our executive officers, and intend to enter into indemnification agreements with each of our executive officers and directors prior to the completion of this offering. For more information see "Management—Employment Agreements and Indemnification Agreements."

# **Policies and Procedures for Related Person Transactions**

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or

relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds \$120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction, management's recommendation with respect to the proposed related person transaction, and the extent of the related person's interest in the transaction.

# **DESCRIPTION OF SHARE CAPITAL**

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our memorandum and articles of association, the Companies Law (as amended) of the Cayman Islands, which we refer to as the Companies Law below and the common law by the Cayman Islands.

Upon the closing of this offering, our authorized share capital will be \$ divided into shares, of which (i) are designated as ordinary shares of a par value of \$0.0001 each (the "Ordinary Shares") and (ii) of such class or classes (however designated) of shares, par value \$0.0001 each, as our board of directors may determine in accordance with our amended and restated memorandum and articles of association. All of our issued and outstanding ordinary shares are fully paid.

As of December 31, 2019, we had 200,000,000 ordinary shares issued and outstanding. All of our shares issued and outstanding prior to the completion of the offering will be fully paid, and all of our shares to be issued in the offering will be issued as fully paid.

Subsequent to December 31, 2019, we issued an aggregate of 20,591,629 Series A Preference Shares in March 2020 and April 2020. Based on the assumed initial offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, we expect these shares will convert into 20,591,629 ordinary shares immediately prior to the closing of this offering. However, if our initial offering price is below \$ per ADS, the number of our ordinary shares to be issued upon the conversion of our Series A Preference Shares will increase and will depend on the initial public offering price per ADS.

The ratio at which each Series A Preference Share automatically converts into our ordinary shares in connection with this offering is its original issue price of \$7.792 per share divided by a conversion price shall equal the lower of (i) the conversion price at the time in effect for such Series A Preference Share and (ii) the price per share that equals 90% of our initial offering price per ADS.

Upon the completion of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges, and restrictions of up to an aggregate of 1,000,000 other shares, including preference shares, in one or more classes or series and authorize their issuance. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our ordinary shares. The issuance of our other shares, including potentially preference shares, could adversely affect the voting power of holders of ADSs and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of other shares, including preference shares, could have the effect of delaying, deferring, or preventing a change of control or other corporate action. Upon the completion of this offering, no preference shares will be outstanding, and we have no present plan to issue any preference shares.

# Our Amended and Restated Memorandum and Articles of Association

Our shareholders intend to adopt an amended and restated memorandum and articles of association, which will become effective and replace our current amended and restated memorandum and articles of association in its entirety immediately prior to the completion of this offering. The following are summaries of material provisions of the amended and restated memorandum and articles of association that we expect become effective immediately prior to completion of this offering, and of the Companies Law, insofar as they relate to the material terms of our ordinary shares.

*Objects of Our Company.* Under our amended and restated memorandum and articles of association, the objects of our company are unrestricted and we have the full power and authority to carry out any object not prohibited by the law of the Cayman Islands.

Ordinary Shares. Our ordinary shares are issued in registered form and are issued when registered in our register of shareholders. We may not issue shares to bearer. Our shareholders who are nonresidents of the Cayman Islands may freely hold and vote their shares.

*Dividends.* The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our amended memorandum and restated articles of association provide that the directors may, before recommending or declaring any dividend, set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall, in the absolute discretion of the directors, be applicable for meeting contingencies or for equalizing dividends or for any other purpose to which those funds may be properly applied. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or the credit standing in our company's share premium account, provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid.

*Voting Rights.* Holders of our ordinary shares shall be entitled to one vote per ordinary share. Voting at any shareholders' meeting is by show of hands unless a poll is demanded (before or on the declaration of the result of the show of hands). A poll may be demanded by the chairman of such meeting or any one or more shareholders who together hold not less than 10% of the votes attaching to the total ordinary shares which are present in person or by proxy at the meeting.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the outstanding ordinary shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our amended and restated memorandum and articles of association. Holders of the ordinary shares may, among other things, divide or combine their shares by ordinary resolution.

*General Meetings of Shareholders.* As a Cayman Islands exempted company, we are not obliged by the Companies Law to call shareholders' annual general meetings. Our amended and restated memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by a majority of our board of directors. Advance notice of at least ten calendar days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. A quorum required for any general meeting of shareholders consists of at least one shareholder present or by proxy, representing not less than one-third of all votes attaching to all of our shares in issue and entitled to vote.

The Companies Law provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated memorandum and articles of association provide that upon the requisition of shareholders representing in aggregate not less than one-third of the votes attaching to the issued and outstanding shares of our company entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. Shareholders seeking to bring business before the annual general meeting or to nominate candidates for election to our board of directors at the annual general meeting are required to deliver notice not later than the 90th day nor earlier than the 120th day prior to the scheduled date of the annual general meeting.

*Transfer of Ordinary Shares.* Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as The Nasdaq Global Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within three months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of The Nasdaq Global Market, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

*Liquidation.* On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay the whole of the share capital, the assets will be distributed so that the losses are borne by our shareholders in proportion to the par value of the shares held by them.

*Calls on Shares and Forfeiture of Shares.* Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders at least 14 days prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

*Redemption, Repurchase and Surrender of Shares.* We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined by our board of directors. We may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Law, the redemption or repurchase of any share may be paid out of our profits or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Law no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares. If at any time our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound-up, may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking pari passu with such existing class of shares.

*Issuance of Additional Shares.* Our amended and restated memorandum of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our amended and restated memorandum of association also authorizes our board of directors to establish from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights;
- the rights and terms of redemption and liquidation preferences; and
- any other powers, preferences and relative, participating, optional and other special rights.

Our board of directors may issue preference shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

*Inspection of Books and Records.* Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our corporate records (except for the memorandum and articles of association of our company, any special resolutions passed by our company and the register of mortgages and charges of our company). However, we will provide our shareholders with annual audited financial statements. See "Where You Can Find Additional Information."

Anti-Takeover Provisions. Some provisions of our amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and
  restrictions of such preference shares without any further vote or action by our shareholders; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our amended and restated memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

*Exempted Company.* We are an exempted company with limited liability under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

does not have to file an annual return of its shareholders with the Registrar of Companies;

- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

# **Differences in Corporate Law**

The Companies Law is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and accordingly there are significant differences between the Companies Law and the current Companies Act of England. In addition, the Companies Law differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Law applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

*Mergers and Similar Arrangements.* The Companies Law permits mergers and consolidations between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (i) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (ii) a "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company, and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose a company is a "parent" of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his shares (which, if not agreed between the



parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provide the dissenting shareholder complies strictly with the procedures set out in the Companies Law. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Law also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of schemes of arrangement, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Law.

The Companies Law also contains a statutory power of compulsory acquisition which may facilitate the "squeeze out" of dissentient minority shareholder upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares affected within four months, the offeror may, within a two-month period commencing on the expiration of such four month period, require the holders of the remaining shares to transfer such shares to the offeror on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

*Shareholders' Suits.* In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company, and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands court can be expected to follow and apply the common law principles (namely the rule in Foss v. Harbottle and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Indemnification of Directors and Executive Officers and Limitation of Liability. Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for

indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

In addition, we intend to enter into indemnification agreements with our directors and executive officers prior to the completion of this offering, that provide such persons with additional indemnification beyond that provided in our amended and restated memorandum and articles of association.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

*Directors' Fiduciary Duties.* Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party, and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder Action by Written Resolution. Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Our amended and restated articles of association provide that no action shall be taken by the shareholders except at an annual or extraordinary general meeting called in accordance with our amended and restated articles of association and no action shall be taken by the shareholders by written consent or electronic transmission.

*Shareholder Proposals.* Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Companies Law provides shareholders with only limited rights to requisition a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated articles of association allow our shareholders holding in aggregate not less than one-third of all votes attaching to the issued and outstanding shares of our company entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. As an exempted Cayman Islands company, we may but are not obliged by law to call shareholders' annual general meetings. See "-Our Amended and Restated Memorandum and Articles of Association-General Meetings of Shareholders" for more information on the rights of our shareholders' rights to put proposals before the annual general meeting.

*Cumulative Voting.* Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled for a single director, which increases the shareholder's voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands but our amended and restated articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

*Removal of Directors.* Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our amended and restated articles of association, directors may be removed only for cause by an ordinary resolution of our shareholders. In addition, a director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his office by notice in writing to the company; (iv) without special leave of absence from our board of directors, is absent from three consecutive meetings of the board and the board resolves that his office be vacated; or (v) is removed from office pursuant to any other provisions of our amended and restated memorandum and articles of association.

*Transactions with Interested Shareholders.* The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

*Dissolution; Winding up.* Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Law and our amended and restated articles of association, our company may be dissolved, liquidated or wound up by a special resolution of our shareholders.

Variation of Rights of Shares. Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our amended and restated articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the written consent of the holders of two-thirds of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

Amendment of Governing Documents. Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under the Companies Law and our amended and restated memorandum and articles of association, our memorandum and articles of association may only be amended by a special resolution of our shareholders.

*Rights of Non-resident or Foreign Shareholders.* There are no limitations imposed by our amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

#### **History of Securities Issuances**

The following is a summary of the events that have changed the number of our share capital since January 1, 2017.

- On October 19, 2017, we issued an aggregate of 169,680,000 ordinary shares to GenScript Biotech Corporation.
- On October 19, 2017, we issued an aggregate of 30,320,000 ordinary shares to AquaPoint L.P.
- From January 1, 2017 to December 31, 2017, we issued options to purchase an aggregate of 8,100,000 ordinary shares to employees with an exercise price of \$0.50.
- From January 1, 2018 to December 31, 2018, we issued options to purchase an aggregate of 7,990,000 ordinary shares to employees with an exercise price of \$1.00.
- From January 1, 2019 to December 31, 2019, we issued options to purchase an aggregate of 20,000 ordinary shares to employees with an exercise price of \$1.00 and options to purchase an aggregate of 3,737,000 ordinary shares to employees with an exercise price of \$1.50.
- On March 31, 2020, we issued 19,308,262 Series A Preference Shares to new investors for aggregate gross proceeds of approximately \$150.5 million.

On April 16, 2020, we issued 1,283,367 Series A Preference Shares to a new investor for aggregate gross proceeds of approximately \$10.0 million.

## Options

As of December 31, 2019, there were options to purchase 18,013,000 ordinary shares outstanding with a weighted average exercise price of \$0.93 per ordinary share. The options generally lapse after 10 years from date of grant.

# **Registration Rights**

Upon the closing of this offering and the automatic conversion of all of our Series A Preference Shares into ordinary shares, holders of 20,591,629 ordinary shares, which we refer to as registrable securities, or their transferees will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act pursuant to an investors' rights agreement by and among us and certain of our shareholders, until such shares can otherwise be sold without restriction under Rule 144, or until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of our ordinary shares as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

If at any time beginning 180 days after the closing date of this offering the holders of a majority of the registrable securities request in writing that we effect a registration with respect to at least 40% of such registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$30.0 million), we may be required to register their ordinary shares. We are obligated to effect at most two registrations in response to these demand registration rights.

If at any time after we become entitled under the Securities Act to register securities on a registration statement on Form F-3, 20% of the holders of the registrable securities then outstanding request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$10.0 million, we will be required to file such registration statement within 45 days after the date of such request; provided, however, that we will not be required to effect such a registration if, within any twelve-month period, we have already effected two registrations on Form F-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Ordinarily, other than selling expenses, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of our counsel; and reasonable fees and disbursements of a counsel for the selling securityholders up to \$80,000.

The registration rights terminate upon the earliest of (i) the closing of a liquidation event, as defined in our second amended and restated articles of association, or, with respect to the registration rights of an individual holder, (ii) when the holder can sell all of such holder's registrable securities in a three-month period without restriction under Rule 144 under the Securities Act or (iii) upon the fifth anniversary of the closing of this offering.

# Listing

We have applied to list our ADSs on The Nasdaq Global Market under the trading symbol "LEGN."

# DESCRIPTION OF AMERICAN DEPOSITARY SHARES

# **American Depositary Receipts**

JPMorgan Chase Bank, N.A., or JPMorgan, as depositary, will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in a designated number of shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary, yourself as an ADR holder and all other ADR holders, and all beneficial owners of an interest in the ADSs evidenced by ADRs from time to time.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

The ADS to share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you.

A beneficial owner is any person or entity having a beneficial ownership interest ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner of ADSs is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner of ADSs and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive which reflect your ownership of ADSs.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder or beneficial owner, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Cayman Island law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder or of a beneficial owner. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the shares, you must rely on it to exercise the rights of a shareholder on your behalf.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement of which this prospectus forms a part. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement on the SEC's website at http://www.sec.gov.

## Share Dividends and Other Distributions

# How will I receive dividends and other distributions on the shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Shares.* In the case of a distribution in shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such shares. Only whole ADSs will be issued. Any shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.
- *Rights to receive additional shares.* In the case of a distribution of rights to subscribe for additional shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:

(i) sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or

(ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

*Other Distributions*. In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth in the "Depositary Receipt Sale and Purchase of Security" section of https://www.adr.com/Investors/FindOutAboutDRs, the location and contents of which the depositary shall be solely responsible for.

## **Deposit, Withdrawal and Cancellation**

## How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit shares or evidence of rights to receive shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the underwriters named herein to deposit such shares.

Shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of JPMorgan Chase Bank, N.A., as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited shares (including those being deposited by or on our behalf in connection with the offering to which this prospectus relates) for the account and to the order of the depositary, in each case for the benefit of ADR holders. ADR holders and beneficial owners thus have no direct ownership interest in the shares and only have such rights as are contained in the deposited spreament. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares. The deposited shares and any such additional items are referred to as "deposited securities."

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing

such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

Upon each deposit of shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

# How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

# **Record Dates**

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights at a meeting of holders of shares, or
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR,
- to receive any notice or to act in respect of other matters,

all subject to the provisions of the deposit agreement.

# **Voting Rights**

# How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the shares which underlie your ADSs. As soon as practicable after receipt from us of notice of any meeting at which the holders of shares are entitled to vote, or of our solicitation of consents or proxies from holders of shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least 30 days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a "voting notice" stating (i) final information particular to such vote and meeting and any solicitation materials, (ii) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of Cayman Islands law, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder's ADRs and (iii) the manner in which such instructions may be given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder's name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders' instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders' ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

To the extent that (A) we have provided the depositary with at least 35 days' notice of the proposed meeting, (B) the voting notice will be received by all ADR holders and beneficial owners no less than 10 days prior to the date of the meeting and/or the cut-off date for the solicitation of consents, and (C) the depositary does not receive instructions on a particular agenda item from an ADR holder (including, without limitation, any entity or entities acting on behalf of the nominee for DTC) in a timely manner, such ADR holder shall be deemed, and in the deposit agreement the depositary is instructed to deem such ADR holder, to have instructed the depositary to give a discretionary proxy for such agenda item(s) to a person designated by us to vote the deposited securities represented by the ADSs for which actual instructions were not so given by all such ADR holders on such agenda item(s), provided that no such instruction shall be deemed given and no discretionary proxy shall be given unless (1) we inform the depositary in writing (and we agree to provide the depositary with such instruction promptly in writing) that (a) we wish such proxy to be given with respect to such agenda item(s), (b) there is no substantial opposition existing with respect to such agenda item(s) and (c) such agenda item(s), if approved, would not materially or adversely affect the rights of holders of shares, and (2) the depositary has obtained an opinion of counsel, in form and substance satisfactory to the depositary, confirming that (i) the granting of such discretionary proxy does not subject the depositary to any reporting obligations in the Cayman Islands, (ii) the granting of such discretionary proxy will not result in a violation of the laws, rules and regulations or permits of the Cayman Islands, and (iv) the granting of such discretionary proxy will not under any circumstances result in the shares represented by the ADSs being treated as assets of the depositary under the laws, rules or regulations of the Cayman Islands.

The depositary may from time to time access information available to it to consider whether any of the circumstances described above exist, or request additional information from us in respect thereto. By taking any such action, the depositary shall not in any way be deemed or inferred to have been required, or have had any

duty or responsibility (contractual or otherwise), to monitor or inquire whether any of the circumstances described above existed. In addition to the limitations provided for in the deposit agreement, ADR holders and beneficial owners are advised and agree that (a) the depositary will rely fully and exclusively on us to inform it of any of the circumstances set forth above, and (b) neither the depositary, the custodian nor any of their respective agents shall be obliged to inquire or investigate whether any of the circumstances described above exist and/or whether we complied with our obligation to timely inform the depositary of such circumstances. Neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners (i) as a result of our failure to determine that any of the circumstances described above exist or our failure to timely notify the depositary of any such circumstances or (ii) if any agenda item which is approved at a meeting has, or is claimed to have, a material or adverse effect on the rights of holders or shares. Because there is no guarantee that ADR holders and beneficial owners will receive the notices described above with sufficient time to enable such ADR holders or beneficial owners to return any voting instructions to the depositary in a timely manner, ADR holders and beneficial owners may be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us in such circumstances, and neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners in such circumstances, and neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners in such circumstances.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, regulation, or requirement of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of or solicitation of consents or proxies from holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such ADR holders with or otherwise publicizes to such ADR holders instructions on how to retrieve such materials or receive such materials upon request (*i.e.*, by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

We have advised the depositary that under Cayman Islands law and our constituent documents, each as in effect as of the date of the deposit agreement, voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands) demanded. In the event that voting on any resolution or matter is conducted on a show of hands basis in accordance with our constituent documents, the depositary will refrain from voting and the voting instructions received by the depositary from ADR holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by ADR holders or beneficial owners.

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

# **Reports and Other Communications**

# Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written

communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

# Fees and Expenses

# What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, \$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, canceled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of U.S.\$1.50 per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of U.S.\$0.05 or less per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of U.S.\$0.05 or less per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the \$0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- stock transfer or other taxes and other governmental charges;

- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares, ADRs or deposited securities;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within JPMorgan Chase Bank, N.A., or the Bank, and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to an foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosure" page (or successor page) of www.adr.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.* 

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

## **Payment of Taxes**

ADR holders or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, including, without limitation, any Chinese Enterprise Income Tax owing if the SAT Circular 82 issued by the SAT or any other circular, edict, order or ruling, as issued and as from time to time amended, is applied or otherwise, such tax or other governmental charge shall be paid by the ADR holder thereof to the depositary and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect of such tax or other governmental charge. Notwithstanding the depositary's right to seek payment from current and former beneficial owners, by holding or owning, or having held or owned, an ADR, the ADR holder thereof (and prior ADR holder thereof) acknowledges and agrees that the depositary has no obligation to seek payment of amounts owing from any current or former beneficial owner. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

#### **Reclassifications, Recapitalizations and Mergers**

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation,

liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

## **Amendment and Termination**

# How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, SWIFT, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders and beneficial owners a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

Any amendments or supplements which (i) are reasonably necessary (as agreed by us and the depositary) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act of 1933 or (b) the ADSs or shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADRs shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depositary's or our website or upon request from the depositary).

#### How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in

such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered ADR holders unless a successor depositary shall not be operating under the deposit agreement within 60 days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 60<sup>th</sup> day after our notice of removal was first provided to the depositary.

After the date so fixed for termination, (a) all direct registration ADRs shall cease to be eligible for the direct registration system and shall be considered ADRs issued on the ADR register maintained by the depositary and (b) the depositary shall use its reasonable efforts to ensure that the ADSs cease to be DTC eligible so that neither DTC nor any of its nominees shall thereafter be a registered holder of ADRs. At such time as the ADSs cease to be DTC eligible and/or neither DTC nor any of its nominees is a registered holder of ADRs, the depositary shall (a) instruct its custodian to deliver all shares to us along with a general stock power that refers to the names set forth on the ADR register maintained by the depositary, we have agreed to use our best efforts to issue to each registered ADR holder a Share certificate representing the Shares represented by the ADSs reflected on the ADR register maintained by the depositary in such registered ADR holder's name and to deliver such Share certificate to the registered ADR holder at the address set forth on the ADR register maintained by the depositary. After providing such instruction to the custodian and delivering a copy of the ADR register to us, the depositary and its agents will perform no further acts under the deposit agreement or the ADRs and shall cease to have any obligations under the deposit agreement and/or the ADRs.

Notwithstanding anything to the contrary, in connection with any such termination, the depositary may, in its sole discretion and without notice to us, establish an unsponsored American depositary share program (on such terms as the depositary may determine) for our shares and make available to ADR holders a means to withdraw the shares represented by the ADSs issued under the deposit agreement and to direct the deposit of such shares into such unsponsored American depositary share program, subject, in each case, to receipt by the depositary, at its discretion, of the fees, charges and expenses provided for under the deposit agreement and the fees, charges and expenses applicable to the unsponsored American depositary share program.

#### Limitations on Obligations and Liability to ADR holders

# Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial or other ownership of, or interest in, any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, ourselves and our respective agents, provided, however, that no disclaimer of liability under the Securities Act of 1933 is intended by any of the limitations of liabilities provisions of the deposit agreement. The deposit agreement provides that each of us, the depositary and our respective agents will:

- incur or assume no liability (including, without limitation, to holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of the Cayman Islands, Hong Kong, the People's Republic of China, the United States or any other country or jurisdiction, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism, nationalization, expropriation, currency restrictions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, computer failure or circumstance beyond our, the depositary's or our respective agents' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- incur or assume no liability (including, without limitation, to holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve it in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be against all expense (including fees and disbursements of counsel) and liability be furnished as often as may be requested;
- not be liable (including, without limitation, to holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, any person presenting shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information and/or, in the case of the depositary, us; or
- may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADSs or the ADRs. We and our agents shall only be

obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the custodian having (i) committed fraud or willful misconduct in the provision of custodial services to the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide services such as, but not limited to, attendance at any meetings of security holders of issuers. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services. The depositary shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depositary has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of the Cayman Islands, Hong Kong, the People's Republic of China, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

Additionally, none of us, the depositary or the custodian shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depositary is under no obligation to provide the ADR holders and beneficial owners, or any of them, with any information about our tax status. Neither we nor the depositary shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be

liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary. Neither the depositary nor any of its agents shall be liable for any indirect, special, punitive or consequential damages (including, without limitation, legal fees and expenses) or lost profits, in each case of any form incurred by any person or entity (including, without limitation holders or beneficial owners of ADRs and ADSs), whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each ADR holder and beneficial owner) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory). No provision of the deposit agreement or the ADRs is intended to constitute a waiver or limitation of any rights which an ADR holder or any beneficial owner may have under the Securities Act of 1933 or the Securities Exchange Act of 1934, to the extent applicable.

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADRs.

#### **Disclosure of Interest in ADSs**

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of, or interest in, deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof.

#### **Books of Depositary**

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other ADR holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed at any time or from time to time, when deemed expedient by the depositary or, in the case of the issuance book portion of the ADR Register, when reasonably requested by the Company solely in order to enable the Company to comply with applicable law.

The depositary will maintain facilities for the delivery and receipt of ADRs.

## Appointment

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs,
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR or ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and

acknowledge and agree that (i) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (ii) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (iii) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (iv) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us, ADR holders, beneficial owners and/or their respective affiliates may have interests, (v) nothing contained in the deposit agreement or any ADR(s) shall (A) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (B) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships, or to account for any profit made or payment received in any such transactions or relationships, (vi) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (vii) notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

#### **Governing Law**

The deposit agreement, the ADSs and the ADRs are governed by and construed in accordance with the internal laws of the State of New York. In the deposit agreement, we have submitted to the non-exclusive jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may also be instituted by the depositary against us in any competent court in the Cayman Islands, Hong Kong, the People's Republic of China, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each irrevocably agree that any legal suit, action or proceeding against or involving ADR holders or beneficial owners brought by us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may be instituted in a state or federal court in New York, New York, irrevocably waive any objection which you may have to the laying of venue of any such proceeding, and irrevocably submit to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding. By holding or owning an ADR or ADS or an interest therein, ADR holders or beneficial owners each also irrevocably agree that any legal suit, action or proceeding against or involving the depositary brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York.

Notwithstanding the foregoing, (i) the depositary may, in its sole discretion, elect to institute any dispute, suit, action, controversy, claim or proceeding directly or indirectly based on, arising out of or relating to the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including without limitation any question regarding its or their existence, validity, interpretation, performance or termination, against any other party or parties to the deposit agreement (including, without limitation, against ADR holders and beneficial owners of interests in ADSs), by having the matter referred to and finally resolved by an arbitration conducted under the terms described below, and (ii) the depositary may in its sole discretion require, by written notice to the relevant party or parties, that any dispute, suit, action, controversy, claim or proceeding against the depositary by any party or parties to the deposit agreement (including, without limitation, by ADR holders and beneficial owners of interests in ADSs) shall be referred to and finally settled by an arbitration conducted under the terms described below. Any such arbitration shall be conducted in the English language

either in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association or in Hong Kong following the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL).

# Jury Trial Waiver

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory), including any claim under the U.S. federal securities laws.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. The waiver to right to a jury trial in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depositary's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder.

# SHARES AND ADSS ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have ADSs outstanding, representing approximately % of our outstanding ordinary shares, assuming the underwriters do not exercise their over-allotment option to purchase additional ADSs. All of the ADSs sold in this offering will be freely transferable by persons other than by our "affiliates" without restriction or further registration under the Securities Act. Sales of substantial amounts of the ADSs in the public market could adversely affect prevailing market prices of the ADSs. Prior to this offering, there has been no public market for our ordinary shares or the ADSs. We have applied to apply to list the ADSs on The Nasdaq Global Market, but we cannot assure you that a regular trading market will develop in the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

The remaining ordinary shares held by existing shareholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or 701 under the Securities Act.

Additionally, of the options and instruments to purchase ordinary shares outstanding as of ordinary shares will be vested and eligible for sale 180 days after the date of this prospectus.

Under the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, and assuming no exercise of the underwriters' option to purchase additional ADSs, these restricted securities will be available for sale in the public market as follows:

- approximately ordinary shares will be eligible for immediate sale on the date of this prospectus; and
- ordinary shares (including ordinary shares represented by ADSs) will be eligible for sale upon the expiration of the lock-up agreements 180 days after the date of this prospectus, provided that shares held by our affiliates will remain subject to volume, manner of sale and other resale limitations set forth in Rule 144 of the Securities Act, as described below.

## Lock-up Agreements

For a period of 180 days after the date of this prospectus, we have agreed, subject to certain exceptions, not to directly or indirectly pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, except in this offering, any of our ordinary shares or ADSs or securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs subject to certain exceptions, without the prior written consent of Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC. See the section titled "Underwriters" for additional information.

Furthermore, each of our directors, executive officers and substantially all of our existing securityholders has also entered into a similar lock-up agreement for a period of 180 days from the date of this prospectus, subject to certain exceptions, with respect to our ordinary shares, ADSs and securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs. These restrictions also apply to any ADSs acquired by our directors and executive officers in the offering, if any.

Other than this offering, we are not aware of any plans by any significant shareholders to dispose of significant numbers of the ADSs or ordinary shares. However, one or more existing shareholders or owners of securities convertible or exchangeable into or exercisable for the ADSs or ordinary shares may dispose of significant numbers of the ADSs or ordinary shares in the future. We cannot predict what effect, if any, future

sales of the ADSs or ordinary shares, or the availability of ADSs or ordinary shares for future sale, will have on the trading price of the ADSs from time to time. Sales of substantial amounts of the ADSs or ordinary shares in the public market, or the perception that these sales could occur, could adversely affect the trading price of the ADSs.

# Rule 144

All of our ordinary shares that will be outstanding upon the completion of this offering, other than those ordinary shares represented by ADSs sold in this offering, are "restricted securities" as that term is defined in Rule 144 under the Securities Act and may be sold publicly in the United States only if they are subject to an effective registration statement under the Securities Act or pursuant to an exemption from the registration requirement such as those provided by Rule 144 and Rule 701 promulgated under the Securities Act. In general, beginning 180 days after the date of this prospectus, a person (or persons whose shares are aggregated) who at the time of a sale is not, and has not been during the three months preceding the sale, an affiliate of ours and has beneficially owned our restricted securities for at least six months will be entitled to sell the restricted securities without registration under the Securities and have beneficially owned our restricted securities beneficially owned for at least one year without restriction. Persons who are our affiliates and have beneficially owned our restricted securities for at least six months may sell a number of restricted securities within any three-month period that does not exceed the greater of the following:

- 1% of the then outstanding ordinary shares of the same class, in the form of ADSs or otherwise, which immediately after this offering will equal ordinary shares, assuming the underwriters do not exercise their over-allotment option; or
- the average weekly trading volume of our ordinary shares of the same class, in the form of ADSs or otherwise, during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by our affiliates under Rule 144 are also subject to certain requirements relating to manner of sale, notice and the availability of current public information about us.

#### Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, consultants or advisors who purchases our ordinary shares from us in connection with a compensatory share plan or other written agreement executed prior to the completion of this offering is eligible to resell those ordinary shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144. However, the Rule 701 shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

## **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act. Accordingly, restricted securities may be sold in offshore transactions in compliance with Regulation S.

## TAXATION

The following is a general summary of certain Cayman Islands, People's Republic of China and United States federal income tax consequences relevant to an investment in our ADSs and ordinary shares. To the extent that the discussion below relates to matters of Cayman Islands tax law, it is the opinion of Harney Westwood & Riegels, our Cayman Islands counsel. To the extent that the discussion below relates to matters of United States federal income tax law, it is the opinion of Cooley LLP, our United States counsel. The discussion is not intended to be, nor should it be construed as, legal or tax advice to any particular prospective purchaser. The discussion is based on laws and relevant interpretations thereof in effect as of the date of this prospectus, all of which are subject to change or different interpretations, possibly with retroactive effect. The discussion does not address U.S. state or local tax laws, or tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China and the United States. You should consult your tax advisors with respect to the consequences of acquisition, ownership and disposition of our ADSs and ordinary shares.

#### **Cayman Islands Taxation**

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty.

No other taxes are likely to be material to us levied by the Government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within, the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties which are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our ordinary shares and ADSs will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of dividends or capital to any holder of our ordinary shares or ADSs, nor will gains derived from the disposal of our ordinary shares or ADSs be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in respect of the issue of our ordinary shares or on an instrument of transfer in respect of our ordinary shares.

The Cayman Islands enacted the International Tax Co-operation (Economic Substance) Law, 2018, which became effective on January 1, 2019, together with the Guidance Notes published by the Cayman Islands Tax Information Authority from time to time. A Cayman Islands company is required to comply with the economic substance requirements from July 1, 2019 and make an annual report in the Cayman Islands as to whether or not it is carrying on any relevant activities and if it is, it would be required to satisfy an economic substance test.

#### Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our ADSs by U.S. Holders (as defined below). This discussion applies to U.S. Holders that purchase ADSs pursuant to this offering and hold such ADSs as capital assets within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain

former citizens or residents of the United States, persons who hold ADSs as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment, persons who received their ADSs as compensatory payments, persons that have a "functional currency" other than the U.S. dollar, persons that own directly, indirectly or through attribution 10% or more of our shares by vote or value, persons who are subject to special tax accounting under Section 451(b) of the Code, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities and arrangements that are classified as partnerships for U.S. federal income tax purposes, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of ADSs that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs, the U.S. federal income tax consequences relating to an investment in the ADSs will depend in part upon the status and activities of such entity or arrangement and the particular partner. Any such entity or arrangement should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of ADSs.

Persons considering an investment in ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

## **Passive Foreign Investment Company Consequences**

In general, a corporation organized outside the United States will be treated as a passive foreign investment company, or PFIC, for any taxable year in which either (1) at least 75% of its gross income is "passive income", (the "PFIC income test"), or (2) on average at least 50% of its assets, determined on a quarterly basis, are assets that produce passive income or are held for the production of passive income, (the "PFIC asset test"). Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities, and other assets that may produce passive income. Generally, in determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value being determined in large part by reference to the market value of our common shares, which may be volatile). We have not yet determined our expected PFIC status for the current taxable year or any future taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Our status as a PFIC is a fact-intensive determination made on an annual basis after the end of each taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2020, and expresses no opinion with regard to our expectations regarding our PFIC status in the future.

If we are a PFIC in any taxable year during which a U.S. Holder owns ADSs, the U.S. Holder could be liable for additional taxes and interest charges under the "PFIC excess distribution regime" upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the ADSs, and (2) any gain recognized on a sale, exchange or other disposition, including a pledge, of the ADSs, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder's holding period for ADSs. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax.

If we are a PFIC for any year during which a U.S. Holder holds ADSs, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the ADSs, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to the ADSs. If the election is made, the U.S. Holder will be deemed to sell the ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's ADSs would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds ADSs and one of our non-U.S. corporate subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to our non-U.S. subsidiaries.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on ADSs if such U.S. Holder makes a valid "mark-to-market" election for our ADSs. A mark-to-market election is available to a U.S. Holder only for "marketable stock." Our ADSs will be marketable stock as long as they remain listed on The Nasdaq Global Market and are regularly traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. If a mark-to-market election is in effect, a U.S. Holder generally would take into account, as ordinary income for each taxable year of the U.S. holder, the excess of the fair market value of ADSs held at the end of such taxable year over the adjusted tax basis of such ADSs. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such ADSs over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in ADSs would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of ADSs in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss.

A mark-to-market election will not apply to ADSs for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any non-U.S. subsidiaries that we may organize or acquire in the future. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs that we may organize or acquire in the future notwithstanding the U.S. Holder's mark-to-market election for the ADSs.

The tax consequences that would apply if we are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

Each U.S. person that is an investor of a PFIC is generally required to file an annual information return on IRS Form 8621 containing such information as the U.S. Treasury Department may require. The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. Holders are strongly urged to consult their own tax advisors with respect to the impact of PFIC status on the purchase, ownership and disposition of ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ADSs of a PFIC.

#### Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our ADSs in the foreseeable future. However, if we make a distribution contrary to the expectation, subject to the discussion above under "—Passive Foreign Investment Company Consequences," a U.S. Holder that receives a distribution with respect to ADSs generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's ADSs. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's ADSs, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends.

Distributions on ADSs that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. Subject to certain complex conditions and limitations, Cayman Island taxes withheld on any distributions on ADSs may be eligible for credit against a U.S. Holder's federal income tax liability. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit in their particular circumstances and the possibility of claiming an itemized deduction (in lieu of the foreign tax credit) for any foreign taxes paid or withheld.

Distributions on ADSs that are treated as dividends generally will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation" are eligible for taxation to non-corporate U.S. Holders at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain requirements are met. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on shares that are readily tradable on an established securities market in the United States. Our ADSs will generally be considered to be readily tradable on an established securities market in the Nasdaq Global Market. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

## Sale, Exchange or Other Disposition of ADSs

Subject to the discussion above under "—Passive Foreign Investment Company Consequences," a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of ADSs in an amount equal to the difference, if any, between the amount realized (*i.e.*, the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ADSs. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ADSs were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of ADSs will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

## **Medicare Tax**

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your investment in ADSs.

## **Information Reporting and Backup Withholding**

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "—Passive Foreign Investment Company Consequences", each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than US\$100,000 for ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of ADSs may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate United States taxpayer identification number or otherwise establish a basis for exemption (usually on IRS Form W-9), or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

# EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSS IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

#### **PRC** Taxation

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside China with "de facto management body" within China is considered as a Tax Resident Enterprise for PRC enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its

worldwide income. The implementation rules of the PRC Enterprise Income Tax Law define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In April 2009, the SAT issued SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel located in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in China.

We believe that we should not be considered as a PRC resident enterprise for PRC tax purposes as (i) we are incorporated outside of China and not controlled by a PRC enterprise or PRC enterprise group; and (ii) we do not meet all of the conditions above. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." There can be no assurance that PRC tax authorities will ultimately not take a different view.

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident enterprise holders of our common shares or ADSs may be treated as income derived from sources within China and therefore, subject to a 10% withholding tax (or 20% in the case of non-resident individual holders) unless an applicable income tax treaty provides otherwise. In addition, capital gains realized by non-resident enterprise shareholders (including our ADS holders) upon the disposition of our common shares or ADSs may be treated as income derived from sources within PRC and therefore, subject to 10% income tax (or 20% in the case of non-resident individual shareholders or ADS holders) unless an applicable income tax treaty provides otherwise. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. See "Risk Factors—Risks Related to Doing Business in China—If we are classified as a "resident enterprise" of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected. "

## UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC are acting as representatives, or the representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of ADSs indicated below:

Name	Number of ADSs
Morgan Stanley & Co. LLC	
J.P. Morgan Securities LLC	
Jefferies LLC	
Total:	

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the ADSs offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the ADSs offered by this prospectus if any such ADSs are taken. However, the underwriters are not required to take or pay for the ADSs covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of ADSs directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ per ADS under the public offering price. After the initial offering of the ADSs, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional ADSs at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the ADSs offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional ADSs as the number listed next to the underwriter's name in the preceding table bears to the total number of ADSs listed next to the names of all underwriters in the preceding table.

The following table shows the per ADS and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional ADSs.

		Tot	tal
	Per		Full
	ADS	No Exercise	Exercise
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$ . We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$ .

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of ADSs offered by them.

We have applied to list the ADSs on the Nasdaq Global Market, or Nasdaq, under the symbol "LEGN."

We have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus, or the restricted period, subject to certain exceptions: (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs; (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our ordinary shares or ADSs, whether any such transaction described in (1) or (2) above is to be settled by delivery of our ordinary shares or ADSs or such other securities, in cash or otherwise; or (3) file any registration statement with the SEC relating to the offering of any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs.

The restrictions described in the immediately preceding paragraph to do not apply in certain circumstances, including:

- (1) the sale of the ADSs and the ordinary shares represented by such ADSs in this offering;
- (2) the issuance by us of ordinary shares or ADSs upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus;
- (3) the issuance by us of options, restricted stock units or restricted stock awards (including the ordinary shares or ADSs issued upon the settlement or exercise thereof) pursuant to employee benefit plans described in this prospectus;
- (4) facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, provided that (i) such plan does not provide for the transfer of ordinary shares or ADSs during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of ordinary shares or ADSs may be made under such plan during the restricted period; or
- (5) the issuance of up to 10.0% of our ordinary shares or ADSs outstanding immediately following the closing of this offering in acquisitions or other similar strategic transactions.

Each of our directors, executive officers and substantially all of our securityholders have agreed that, without the prior written consent of the representatives on behalf of the underwriters, it will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs; (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our ordinary shares or ADSs, whether any such transaction described in (1) or (2) above is to be settled by delivery of our ordinary shares or ADSs or such other securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph to do not apply in certain circumstances, including:

(1) transactions relating to our ordinary shares or ADSs or other securities acquired in this offering or in open market transactions after the completion of this offering, provided that no filing under

Section 16(a) of the Exchange Act or any other public filing or disclosure reporting a reduction in beneficial ownership of ordinary shares or ADSs shall be required or voluntarily made during the restricted period;

- (2) transfers of our ordinary shares or ADSs as bona fide gifts, by will, to an immediate family member, not involving a change in beneficial ownership or to certain trusts, provided that no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure reporting a reduction in beneficial ownership of ordinary shares or ADSs shall be required or voluntarily made during the restricted period and provided further that each transferee or donee signs a lock-up agreement;
- (3) distributions of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for our ordinary shares or ADSs to shareholders, direct or indirect affiliates, current partners (general or limited), members or managers of such holders, provided that such distribution shall not involve a disposition for value and no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure reporting a reduction in beneficial ownership of ordinary shares or ADSs shall be required or voluntarily made during the restricted period and provided further that each distributee signs a lock-up agreement;
- (4) the receipt by such holder of our ordinary shares or ADSs upon the exercise of options or warrants outstanding described in this prospectus provided that the ordinary shares or ADSs received upon exercise of such option or warrant shall remain subject to this agreement and provided further no filing under Section 16(a) of the Exchange Act, or any other public filing or disclosure of such receipt or transfer by or on behalf of such holder shall be required or shall be voluntarily made within 60 days after the date of this prospectus, and after such 60th day, any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in this clause (4), (B) no shares were sold by the reporting person and (C) the shares received upon exercise of the option are subject to a lock-up agreement;
- (5) transfers of our ordinary shares or ADSs to us upon a vesting event of our securities or upon the exercise of options or warrants to purchase our securities on a "cashless" or "net exercise" basis to the extent permitted by the instruments representing such options or warrants so long as such "cashless" exercise or "net exercise" is effected solely by the surrender of outstanding options or warrants to us and our cancellation of all or a portion thereof to pay the exercise price and/or withholding tax obligations provided no filing under Section 16(a) of the Exchange Act, or any other public filing or disclosure of such receipt or transfer by or on behalf of such holder shall be required or shall be voluntarily made within 60 days after the date of this prospectus, and after such 60th day, any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in this clause (5) and (B) no shares were sold by the reporting person;
- (6) sales of securities pursuant to the terms of the underwriting agreement;
- (7) the establishment by such holders of trading plans under Rule 10b5-1 under the Exchange Act provided that such plan does not provide for the transfer of ordinary shares or ADSs during the restricted period and provided further that to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of such holder or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of our ordinary shares or ADSs may be made under such plan during the restricted period;
- (8) transfers of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for our ordinary shares or ADSs pursuant to a qualified domestic order in connection with a divorce settlement or other court order provided that each transferee signs a lock-up agreement and provided further that no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure shall be voluntarily made during the restricted period, and any required filing shall clearly indicate in the footnotes thereto that such transfer is by operation of law, court order or in connection with a divorce settlement, as the case may be;

- (9) transfers of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for our ordinary shares or ADSs to us pursuant to any contractual arrangement described in this prospectus under which we have the option to repurchase such shares or a right of first refusal over such shares in the event such holder ceases to provide services to us and provided further that no filing under the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made during the restricted period within 60 days after such holder ceases to provide services to us, and after such 60th day, if such holder is required to file a report under the Exchange Act reporting a change in beneficial ownership during the restricted period, such holder shall clearly indicate in the footnotes thereto that the filing relates to the termination of such holder's employment or other services and no other filing or public announcement shall be made voluntarily during the restricted period in connection with such transfer;
- (10) conversion of our outstanding preferred shares into ordinary shares or ADSs in connection with the closing of this offering provided that any such ordinary shares or ADSs received upon such conversion shall be subject to the terms of the lock-up agreement and provided further that any filing required under Section 16(a) of the Exchange Act during the restricted period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (10);
- (11) transfers of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for our ordinary shares or ADSs pursuant to a bona fide third-party tender offer, merger, consolidation, or other similar transaction that is approved by our board of directors; and
- (12) a transfer pursuant to the "assured entitlement" requirement under Paragraph 3(f) of Practice Note 15 of the Rules Governing the Listing on Securities on the Stock Exchange of Hong Kong Limited by GenScript to its shareholders of our ordinary shares or ADSs or any security convertible into or exerciseable or exchangeable for our ordinary shares or ADSs.

The representatives, in their sole discretion, may release the ordinary shares, ADSs and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the ADSs, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the ADSs. Specifically, the underwriters may sell more ADSs than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of ADSs available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing ADSs in the open market. In determining the source of ADSs to close out a covered short sale, the underwriters will consider, among other things, the open market price of ADSs compared to the price available under the over-allotment option. The underwriters may also sell ADSs in excess of the over-allotment option, creating a naked short position. The underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, ADSs in the open market to stabilize the price of the ADSs. These activities may raise or maintain the market price of the ADSs above independent market levels or prevent or retard a decline in the market price of the ADSs. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of ADSs to underwriters for sale to their online brokerage account holders. Internet

distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Pricing of the Offering**

Prior to this offering, there has been no public market for our ADSs. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

### **Selling Restrictions**

#### European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no ADSs have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that it may make an offer to the public in that Relevant State of any ADSs at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of the ADSs shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation,

provided that no such offer of the ADSs shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the ADSs in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

## United Kingdom

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or FSMA, received by it in connection with the issue or sale of our ADSs in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to our ADSs in, from or otherwise involving the United Kingdom.

#### Canada

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### Hong Kong

Our ADSs may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32, Laws of Hong Kong), and no advertisement, invitation, or document relating to our ADSs may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to our ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

#### Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our ADSs may not be circulated or distributed, nor may our ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA) (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where our ADSs are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired our ADSs under Section 275 except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (ii) where no consideration is given for the transfer; or (iii) by operation of law.

Solely for purposes of the notification requirements under Section 309B(1)(c) of the Securities and Futures Act, Chapter 289 of Singapore. The ADSs are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

#### **Dubai International Financial Center**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the ADSs offered should conduct their own due diligence on the ADSs. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **United Arab Emirates**

The ADSs have not been offered or sold, and will not be offered or sold, directly or indirectly, in the United Arab Emirates, except: (1) in compliance with all applicable laws and regulations of the United Arab Emirates; and (2) through persons or corporate entities authorized and licensed to provide investment advice and/or engage in brokerage activity and/or trade in respect of foreign securities in the United Arab Emirates. The information contained in this prospectus does not constitute a public offer of securities in the United Arab Emirates in accordance with the Commercial Companies Law (Federal Law No. 8 of 1984 (as amended)) or otherwise and is not intended to be a public offer and is addressed only to persons who are sophisticated investors.

#### Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This

prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the ADSs may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the ADSs without disclosure to investors under Chapter 6D of the Corporations Act.

The ADSs applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring ADSs must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

#### Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, Legend Biotech Corporation, or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA ("FINMA"), and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

#### Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the "FIEL") has been made or will be made with respect to the solicitation of the application for the acquisition of the ADSs.

Accordingly, the ADSs have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

### For Qualified Institutional Investors ("QII")

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the ADSs constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the ADSs. The ADSs may only be transferred to QIIs.

### For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the ADSs constitutes either a "small number private placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the ADSs. The ADSs may only be transferred en bloc without subdivision to a single investor.

## **Cayman Islands**

This prospectus does not constitute a public offer of the ADSs or ordinary shares, whether by way of sale or subscription, in the Cayman Islands. Each underwriter has represented and agreed that it has not offered or sold, and will not offer or sell, directly or indirectly, any ADSs or ordinary shares in the Cayman Islands.

#### Indonesia

This prospectus does not, and is not intended to, constitute a public offering in Indonesia under Law Number 8 of 1995 regarding Capital Market. This prospectus may not be distributed in the Republic of Indonesia and the ADSs may not be offered or sold in the Republic of Indonesia or to Indonesian citizens wherever they are domiciled, or to Indonesia residents, in a manner which constitutes a public offering under the laws of the Republic of Indonesia.

#### Israel

In the State of Israel, the ADSs offered hereby may not be offered to any person or entity other than the following:

- a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;
- a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;
- an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;

- a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;
- a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and
- an entity, other than an entity formed for the purpose of purchasing the ADSs in this offering, in which shareholders' equity (including pursuant to foreign accounting rules, international accounting regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the ADSs offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

### Korea

The ADSs may not be offered, sold and delivered directly or indirectly, or offered or sold to any person for reoffering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the Korea Securities and Exchange Act and the Foreign Exchange Transaction Law and the decrees and regulations thereunder. The ADSs have not been registered with the Financial Services Commission of Korea for public offering in Korea. Furthermore, the ADSs may not be resold to Korean residents unless the purchaser of the ADSs complies with all applicable regulatory requirements (including but not limited to government approval requirements under the Foreign Exchange Transaction Law and its subordinate decrees and regulations) in connection with the purchase of the ADSs.

#### Kuwait

Unless all necessary approvals from the Kuwait Ministry of Commerce and Industry required by Law No. 31/1990 "Regulating the Negotiation of Securities and Establishment of Investment Funds," its Executive Regulations and the various Ministerial Orders issued pursuant thereto or in connection therewith, have been given in relation to the marketing and sale of the ADSs, these may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

### Malaysia

The offering of the ADSs has not been and will not be approved by the Securities Commission Malaysia, or SC, and this document has not been and will not be registered as a prospectus with the SC under the Malaysian Capital Markets and Services Act 2007, or CMSA. Accordingly, no ADSs or invitation to purchase is being made to any person in Malaysia under this document except to persons falling within any of paragraphs 2(g)(i) to (xi) of Schedule 5 of the CMSA and distributed only by a holder of a Capital Markets Services License who carries on the business of dealing in securities.

### People's Republic of China

This prospectus may not be circulated or distributed in the PRC and the ADSs may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws and regulations of the PRC.

#### **Philippines**

### THE ADSS BEING OFFERED OR SOLD HAVE NOT BEEN AND WILL NOT BE REGISTERED WITH THE PHILIPPINE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES REGULATION CODE OF THE PHILIPPINES, OR THE SRC. ANY FUTURE OFFER OR SALE OF THE ADSS WITHIN THE PHILIPPINES IS SUBJECT TO THE REGISTRATION REQUIREMENTS UNDER THE SRC UNLESS SUCH OFFER OR SALE QUALIFIES AS A TRANSACTION EXEMPT FROM THE REGISTRATION UNDER THE SRC.

Accordingly, this prospectus, and any other document or material in connection with the offer or sale, or invitation for subscription or purchase of the ADSs, may not be circulated or distributed in the Philippines, and the ADSs may not be offered or sold, or be made the subject of an invitation for subscription or purchase, to persons in the Philippines, other than (i) to qualified investors in transactions that are exempt from the registration requirements of the SRC; and (ii) by persons licensed to make such offers or sales in the Philippines.

#### Qatar

In the State of Qatar, the offer contained herein is made on an exclusive basis to the specifically intended recipient thereof, upon that person's request and initiative, for personal use only and shall in no way be construed as a general offer for the sale of securities to the public or an attempt to do business as a bank, an investment company or otherwise in the State of Qatar. This prospectus and the underlying securities have not been approved or licensed by the Qatar Central Bank or the Qatar Financial Center Regulatory Authority or any other regulator in the State of Qatar. The information contained in this prospectus shall only be shared with any third parties in Qatar on a need to know basis for the purpose of evaluating the contained offer. Any distribution of this prospectus by the recipient to third parties in Qatar beyond the terms hereof is not permitted and shall be at the liability of such recipient.

#### Saudi Arabia

This prospectus may not be distributed in the Kingdom except to such persons as are permitted under the Offers of Securities Regulations issued by the Capital Market Authority. The Capital Market Authority does not make any representation as to the accuracy or completeness of this prospectus, and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this prospectus you should consult an authorized financial adviser.

#### Taiwan

The ADSs have not been and will not be registered or filed with, or approved by, the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be offered or sold in Taiwan through a public offering or in circumstances which constitute an offer within the meaning of the Securities and Exchange Act of Taiwan or relevant laws and regulations that require a registration, filing or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer or sell the ADSs in Taiwan through a public offering or in such an offering that require registration, filing or approval of the Financial Supervisory Commission of Taiwan and the competent authority's rulings thereunder.

#### Thailand

This prospectus does not, and is not intended to, constitute a public offering in Thailand. The ADSs may not be offered or sold to persons in Thailand, unless such offering is made under the exemptions from approval and

filing requirements under applicable laws, or under circumstances which do not constitute an offer for sale of the shares to the public for the purposes of the Securities and Exchange Act of 1992 of Thailand, nor require approval from the Office of the Securities and Exchange Commission of Thailand.

## Vietnam

This offering of ADSs has not been and will not be registered with the State Securities Commission of Vietnam under the Law on Securities of Vietnam and its guiding decrees and circulars. The ADSs will not be offered or sold in Vietnam through a public offering and will not be offered or sold to Vietnamese persons other than those who are licensed to invest in offshore securities under the Law on Investment of Vietnam.

# EXPENSES RELATED TO THIS OFFERING

Set forth below is an itemization of the total expenses, excluding underwriting discounts and commissions, that we expect to incur in connection with this offering. With the exception of the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee, and The Nasdaq Global Market, or Nasdaq, entry and listing fee, all amounts are estimates.

SEC Registration Fee	\$
FINRA Fee	
Nasdaq Entry and Listing Fee	
Printing and Engraving Expenses	
Legal Fees and Expenses	
Accounting Fees and Expenses	
Miscellaneous	
Total	\$

\* To be completed by amendment.

## LEGAL MATTERS

We are being represented by Cooley LLP with respect to certain legal matters as to United States federal securities and New York State law. The underwriters are being represented by Davis Polk & Wardwell LLP with respect to certain legal matters as to United States federal securities and New York State law. The validity of the ordinary shares represented by the ADSs offered in this offering and legal matters as to Cayman Islands law will be passed upon for us by Harney Westwood & Riegels. Certain legal matters as to the People's Republic of China, or PRC, law will be passed upon for us by JunHe LLP and the underwriters by Jingtian & Gongcheng. Cooley LLP may rely upon Harney Westwood & Riegels with respect to matters governed by PRC law. Our controlling shareholder GenScript is being represented by Jones Day with respect to certain legal matters as to United States federal securities law, New York State law and Hong Kong law.

## EXPERTS

The consolidated financial statements of Legend Biotech Corporation at December 31, 2018 and 2019, and for the years then ended, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young Hua Ming LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The offices of Ernst & Young Hua Ming LLP are located at 50/F, Shanghai World Financial Center, 100 Century Avenue, Pudong New Area, Shanghai 200120, the People's Republic of China.

### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement, including relevant exhibits, with the SEC on Form F-1 under the Securities Act with respect to the underlying ordinary shares represented by the ADSs to be sold in this offering. We have also filed a related registration statement on Form F-6 with the SEC to register the ADSs. This prospectus, which constitutes a part of the registration statement on Form F-1, does not contain all of the information contained in the registration statement. You should read our registration statements and their exhibits and schedules for further information with respect to us and the ADSs. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summarises of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file any of these documents as an exhibit to the registration statement, we refer you to the copy of the document that has been filed for a complete description of its terms. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Immediately upon the effectiveness of the registration statement on Form F-1 of which this prospectus forms a part, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC. All information filed with the SEC can be obtained over the internet at the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to furnish the depositary with our annual reports, which will include a review of operations and annual audited consolidated combined financial statements prepared in conformity with IFRS, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

We maintain a corporate website at www.legendbiotech.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and our website address is included in this prospectus as an inactive textual reference only.

-

# LEGEND BIOTECH CORPORATION

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page(s)
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
AUDITED CONSOLIDATED FINANCIAL STATEMENTS	
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEARS ENDED	
<u>DECEMBER 31, 2018 AND 2019</u>	F-3
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION AS AT DECEMBER 31, 2018 AND 2019	F-4
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019	F-5
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019	F-6 - F-7
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019	F-8 - F-60

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Legend Biotech Corporation

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated statements of financial position of Legend Biotech Corporation (the "Company") as of December 31, 2018 and 2019, the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

## **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young Hua Ming LLP We have served as the Company's auditor since 2020. Shanghai, the People's Republic of China

April 20, 2020

## LEGEND BIOTECH CORPORATION CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

	<u>Notes</u>	2018 US\$'000, except per share data	2019 US\$'000, except per share data
REVENUE	5	49,133	57,264
Other income and gains	5	13,901	7,125
Research and development expenses		(60,637)	(161,943)
Administrative expenses		(2,769)	(6,752)
Selling and distribution expenses		(1,160)	(25,620)
Other expenses		(2)	(221)
Finance costs	7	(82)	(223)
LOSS BEFORE TAX	6	<b>(</b> 1,616)	(130,370)
Income tax expense	8	(1,168)	(2,602)
LOSS FOR THE YEAR		(2,784)	(132,972)
Attributable to:			
Equity holders of the parent		(2,784)	(132,972)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	9		
Basic		(0.01)	(0.66)
Diluted		(0.01)	(0.66)
OTHER COMPREHENSIVE (LOSS)/INCOME			
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:			
Exchange differences:			
Exchange differences on translation of foreign operations		(1,437)	182
Net other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent			
periods		(1,437)	182
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR, NET OF TAX		(1,437)	182
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(4,221)	(132,790)
Attributable to:			
Equity holders of the parent		(4,221)	(132,790)

The accompanying notes are an integral part of the consolidated financial statements.

## LEGEND BIOTECH CORPORATION CONSOLIDATED STATEMENTS OF FINANCIAL POSITION AS AT DECEMBER 31, 2018 AND 2019

	Notes	December 31, 2018 US\$'000	December 31, 2019 US\$'000
NON-CURRENT ASSETS			
Property, plant and equipment	10	28,155	70,079
Advance payments for property, plant and equipment		1,237	665
Right-of-use assets	12	3,733	9,348
Deferred tax assets	21	68,917	—
Intangible assets	11	49	519
Total non-current assets		102,091	80,611
CURRENT ASSETS			
Inventories	14	1,135	1,157
Trade receivables	15	26,221	29,991
Prepayments, other receivables and other assets	16	83,165	16,777
Financial assets at fair value through profit or loss	13	6,014	
Pledged short-term deposits	17	255	256
Time deposits	17	—	75,559
Cash and cash equivalents	17	210,166	83,364
Total current assets		326,956	207,104
Total assets		429,047	287,715
CURRENT LIABILITIES			
Trade and notes payables	18	7,575	9,586
Other payables and accruals	19	36,377	70,854
Lease liabilities	12	373	1,027
Tax payable		74,536	_
Contract liabilities	20	40,324	46,294
Total current liabilities		159,185	127,761
NON-CURRENT LIABILITIES			
Contract liabilities	20	257,269	277,765
Lease liabilities	12	3,944	5,085
Total non-current liabilities		261,213	282,823
Total liabilities		420,398	410,584
EQUITY			
Share capital	22	20	20
Reserves/(deficits)	24	8,629	(122,889)
Total ordinary shareholders' equity/(deficit)		8,649	(122,869)
Total equity/(deficit)		8,649	(122,869)
Total liabilities and equity		429,047	287,715

The accompanying notes are an integral part of the consolidated financial statements.

## LEGEND BIOTECH CORPORATION CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

		Attributable to equity holders of the parent				
	Share <u>capital</u> US\$'000	Share <u>premium*</u> US\$'000	Share option <u>reserves*</u> US\$'000	Foreign currency translation <u>reserve*</u> US\$'000	Retained earnings/ (accumulated losses)* US\$'000	Total (deficit)/ equity US\$'000
As January 1, 2018	20	3,908*	*	(236)*	8,474*	12,166
Loss for the year		—			(2,784)	(2,784)
Other comprehensive loss:						
Exchange differences on translation of foreign operations				(1,437)		(1,437)
Total comprehensive loss for the year	_			(1,437)	(2,784)	(4,221)
Equity-settled share option arrangements		—	704		—	704
As December 31, 2018	20	3,908*	704*	(1,673)*	5,690*	8,649
Loss for the year	_				(132,972)	(132,972)
Other comprehensive income:						
Exchange differences on translation of foreign operations		—		182		182
Total comprehensive income/ (loss) for the year				182	(132,972)	(132,790)
Equity-settled share option arrangements			1,272			1,272
As December 31, 2019	20	3,908*	1,976*	(1,491)*	(127,282)*	(122,869)

\* These reserve accounts comprise the consolidated reserves/(deficits) of US\$8,629,000 and US\$(122,889,000) in the consolidated statements of financial position as at December 31, 2018 and December 31, 2019, respectively.

The accompanying notes are an integral part of the consolidated financial statements.

## LEGEND BIOTECH CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

	Notes	2018 US\$'000	2019 US\$'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax		(1,616)	(130,370)
Adjustments for:			
Finance income	5	(6,214)	(4,581)
Finance costs	7	82	223
(Reversal of) provision for the impairment of trade receivables	15	(60)	1
Depreciation of property, plant and equipment	6	845	4,001
Amortisation of intangible assets	6	15	63
Depreciation of right-of-use assets	6	823	1,198
Fair value gains on financial assets at			
fair value change through profit or loss	5	(89)	(474)
Foreign currency exchange gain, net	5	(7,237)	(250)
Equity-settled share option expenses		704	1,272
		(12,747)	(128,917)
Decrease/(increase) in trade receivables		207,606	(3,771)
Increase in prepayments, other receivables and other assets		(2,507)	(3,928)
Increase in inventories		(1,124)	(22)
Increase in trade and notes payables		3,239	2,011
Increase in other payables and accruals		18,310	31,727
Increase in contract liabilities		93,183	26,466
Cash generated from/(used in) operations		305,960	(76,434)
Income tax paid		—	(15,432)
Finance income received		1,804	9,024
Interest on loan from related party		—	(24)
Interest on lease payments		(82)	(199)
Net cash flows from/(used in) operating activities		307,682	(83,065)

The accompanying notes are an integral part of the consolidated financial statements.

## LEGEND BIOTECH CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued) FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

	Note	2018 US\$'000	2019 US\$'000
Net cash flows from/(used in) operating activities		307,682	(83,065)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment		(20,958)	(38,636)
Purchase of intangible assets		(63)	(534)
Purchase of financial assets at fair value through profit or loss		(6,000)	(314,840)
Cash received from withdrawal of financial assets at fair value through profit or loss		—	320,854
Cash advances to related parties	27	(86,943)	(13,006)
Collection of cash advances to related parties	27	11,943	62,996
Proceeds from disposal of items of property, plant and equipment		20	74
Addition of short-term time deposits		—	(75,559)
Addition of pledged short-term deposits		(255)	(256)
Decrease in pledged short-term deposits			255
Net cash flows used in investing activities		(102,256)	(58,652)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from cash advances from related parties	27	35,939	38,945
Repayment of cash advances from related parties	27	(33,219)	(19,223)
Proceeds from loans from related parties	27	—	2,867
Repayments of loans from related parties	27	—	(2,867)
Principal portion of lease payments		(219)	(5,056)
Net cash flows from financing activities		2,501	14,666
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		207,927	(127,051)
Effect of foreign exchange rate changes, net		124	249
Cash and cash equivalents at beginning of year	17	2,115	210,166
CASH AND CASH EQUIVALENTS AT END OF YEAR	17	210,166	83,364
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances		210,421	159,179
Less: Pledged short-term deposits		255	256
Time deposits		—	75,559
Cash and cash equivalents as stated in the statement of financial position	17	210,166	83,364
Cash and cash equivalents as stated in the statement of cash flows		210,166	83,364

The accompanying notes are an integral part of the consolidated financial statements.

## **1. CORPORATE INFORMATION**

Legend Biotech Corporation (the "Company") was incorporated on May 27, 2015 as an exempted company in the Cayman Islands with limited liability under the Companies Law of the Cayman Islands. The registered office address of the Company is PO Box 10240, Harbour Place, 103 South Church Street, George Town, Grant Cayman KY1-1002, Cayman Islands.

The Company is an investment holding company. The Company's subsidiaries are principally engaged in research and development of biological products.

In the opinion of the Directors, the ultimate holding company of the Company is Genscript Corporation ("GS Corp"), which was incorporated in the United States of America.

#### Information about subsidiaries

Company	Place and date of incorporation	Issued ordinary shares/paid-up capital	Percentage interest attri <u>the Con</u> Direct %	ibutable to	Principal activities
Legend Biotech Limited ("Legend BVI")	The British Virgin Islands		100		T 1 11.
Legend Biotech HK Limited ("Legend HK")	June 2, 2015 Hong Kong June 3, 2015	_	100		Investment holding
Nanjing Legend Biotechnology Co., Ltd. ("Legend Nanjing")	PRC November 17, 2014	US\$ 22,500,000	_	100	Manufacture and sale of life science research products and services
Legend Biotech USA Incorporated ("Legend USA")	United States of America August 31, 2017		_	100	Manufacture and sale of life science research products and services
Legend Biotech Ireland Limited. ("Legend Ireland")	Ireland November 13, 2017	_	_	100	Manufacture and sale of life science research products and services
Legend Biotech (Netherlands) B.V. ("Legend Netherlands")	Netherlands June 12, 2017	_	_	100	Sale of life science research products

## 2.1 BASIS OF PREPARATION

The consolidated financial statements of the Company and its subsidiaries (collectively referred to as the "Group") have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board (the "IASB"), which comprise all standards and interpretations approved by the IASB.

## 2.1 BASIS OF PREPARATION (Continued)

All IFRSs issued by the IASB, effective for the accounting period commencing from January 1, 2019 (including *IFRS 16 Leases* and *IFRIC Interpretation 23 Uncertainty Over Income Tax* Treatments, which are early adopted by the Group), together with the relevant transitional provisions, have been adopted by the Group on a retrospective basis in all periods presented.

The Group prepared the consolidated financial statements that comply with IFRS applicable as at January 1, 2019, together with the comparative period data for the year ended December 31, 2018, as described in the summary of significant accounting policies.

The consolidated financial statements have been prepared on a historical cost basis, except for financial assets and financial liabilities which have been measured at fair value. The consolidated financial statements are presented in US dollars ("US\$") and all values are rounded to the nearest thousand except when otherwise indicated.

## Basis of consolidation

The consolidated financial statements include the financial statements of the Group for the years ended December 31, 2018 and 2019. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income or loss are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above.

Definition of a Business<sup>1</sup>

Insurance Contracts<sup>2</sup>

Definition of Material<sup>1</sup>

Joint Venture<sup>4</sup>

Interest Rate Benchmark Reform1

Sale or Contribution of Assets between an Investor and its Associate or

Classification of Liabilities as Current or Non-current<sup>3</sup>

## 2.2 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in these consolidated financial statements.

Amendments to IFRS 3 Amendments to IFRS 9 IAS 39 and IFRS 7 Amendments to IFRS 10 and IAS 28

IFRS 17 Amendments to IAS 1 and IAS 8 Amendments to IAS 1

- <sup>1</sup> Effective for annual periods beginning on or after January 1, 2020
- <sup>2</sup> Effective for annual periods beginning on or after January 1, 2021
- <sup>3</sup> Effective for annual periods beginning on or after January 1, 2022
- <sup>4</sup> No mandatory effective date yet determined but available for adoption

Further information about those IFRSs that are expected to be applicable to the Group is described below.

Amendments to IFRS 3 clarify and provide additional guidance on the definition of a business. The amendments clarify that for an integrated set of activities and assets to be considered a business, it must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output. A business can exist without including all of the inputs and processes needed to create outputs. The amendments remove the assessment of whether market participants are capable of acquiring the business and continue to produce outputs. Instead, the focus is on whether acquired inputs and acquired substantive processes together significantly contribute to the ability to create outputs. The amendments have also narrowed the definition of outputs to focus on goods or services provided to customers, investment income or other income from ordinary activities. Furthermore, the amendments provide guidance to assess whether an acquired process is substantive and introduce an optional fair value concentration test to permit a simplified assessment of whether an acquired set of activities and assets is not a business. The Group expects to adopt the amendments prospectively from January 1, 2020. Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Group will not be affected by these amendments on the date of transition.

Amendments to IAS 1 and IAS 8 provide a new definition of material. The new definition states that information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. The amendments clarify that materiality will depend on the nature or magnitude of information. A misstatement of information is material if it could reasonably be expected to influence decisions made by the primary users. The Group expects to adopt the amendments prospectively from January 1, 2020. The amendments are not expected to have any significant impact on the Group's consolidated financial statements.

## 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Fair value measurement

The Group measures its financial assets at fair value through profit or loss at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

## Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than contract assets and financial assets,), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists,

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

## **Related parties**

A party is considered to be related to the Group if:

(a) the party is a person or a close member of that person's family and that person

- (i) has control or joint control over the Group;
- (ii) has significant influence over the Group; or
- (iii) is a member of the key management personnel of the Group or of a parent of the Group;

#### or

- (b) the party is an entity where any of the following conditions applies:
  - (i) the entity and the Group are members of the same group;
  - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
  - (iii) the entity and the Group are joint ventures of the same third party;
  - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
  - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
  - (vi) the entity is controlled or jointly controlled by a person identified in (a);
  - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
  - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

#### Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost (or valuation) less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets as follows:

Freehold land	Not depreciated
Buildings	2% to 2.6%
Machinery and equipment	10% to 25%
Computer and office equipment	20% to 331/3%
Transportation equipment	10%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents equipment under installation, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of installation. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

#### Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intangible assets are amortised on the straight-line basis over the following useful economic lives:

Software

### Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditures incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

3 years

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

#### Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

#### (a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Leasehold land	50 years
Buildings	2 to 10 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

### (b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

## 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### (c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option).

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

#### Group as a lessor

When the Group acts as a lessor, it classifies at lease inception (or when there is a lease modification) each of its leases as either an operating lease or a finance lease.

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. Rental income is accounted for on a straight-line basis over the lease terms and is included in revenue in the statement of profit or loss due to its operating nature. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised over the lease term on the same basis as rental income.

#### Investments and other financial assets

#### Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for "Revenue recognition" below.

In order for a financial asset to be classified and measured at amortised cost, it needs to give rise to cash flows that are solely payments of principal and interest ("SPPI") on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Subsequent measurement

#### Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

### Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in the statement of profit or loss.

#### Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a "pass-through" arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

#### Impairment of financial assets

The Group recognises an allowance for expected credit losses ("ECLs") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

#### General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs.

## Simplified approach

For trade receivables and contract assets that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

### Financial liabilities

#### Initial recognition and measurement

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables, and lease liabilities.

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Subsequent measurement

#### Financial liabilities at amortised cost (Loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

#### Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

#### Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

#### Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the first-in, first-out basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

#### Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have an original maturity of three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

#### Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- where the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the end of the reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

#### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss over the expected useful life of the relevant asset by equal annual instalments.

#### **Revenue recognition**

#### **Revenue from contracts with customers**

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

#### (a) License and collaboration revenue

The Group enters into a license and collaboration agreement for research, development, manufacturing and commercialization services with one customer. The terms of the arrangement include: non-refundable upfront fees of US\$350 million, milestone payments for the achievement of specified manufacturing milestones, specified development milestones, specified regulatory milestones and specified net trade sales milestones of US\$125 million, US\$215 million, US\$800 million and US\$210 million. Milestone payment is a form of variable consideration which is included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The contracts generally do not include a significant financing component.

As part of the accounting for this arrangement, the Group must use significant judgement to determine: (a) the performance obligations; and (b) the method to estimate variable consideration.

## 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

At contract inception, the Group assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct.

The Group uses judgement to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. Upon contract inception, the Group has estimated that the total transaction price is constrained to US\$400 million which included upfront fees of US\$350 million and milestone payments of US\$50 million. The transaction price is allocated to each performance obligation on a relative standalone selling price basis, for which the Group recognizes revenue as or when the performance obligations under the contract are satisfied. If a milestone or other variable consideration relates specifically to the Group's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Group generally allocates that milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

The Group recognizes revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria.

- The counterparty simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs.
- The Group's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.
- The Group's performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

The portion of the transaction price that is allocated to performance obligations satisfied at a point in time is recognized as revenue when control of the goods or services is transferred to the counterparty. If the performance obligation is satisfied over time, the portion of the transaction price allocated to that performance obligation is recognized as revenue as the performance obligation is satisfied. The Group adopts an appropriate method of measuring progress for purposes of recognizing revenue. The Group evaluates the measure of progress at the end of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

## Upfront fees

Upfront payment is allocated to the performance obligations based on the Group's best estimate of their relative stand-alone selling prices. The upfront fees of US\$350 million was included in the transaction price upon contract inception in 2017 and fully received by the Group in 2018.

## Milestone payments

At the inception of each arrangement that includes milestone payments, the Group evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Group evaluates factors such as the scientific, clinical, regulatory,

## 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, the Group re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. The milestone payments were allocated to the performance obligations based on the Group's best estimate of their relative stand-alone selling prices unless the criteria under IFRS 15.85 are met, where the milestone payments are allocated entirely to the performance obligation which the milestone payments are specifically related to.

The initial two milestone payments of US\$50 million were included in the transaction price at contract inception in 2017. Subsequently in 2019, an additional two milestones payments of US\$60 million were included in the transaction price when the milestones triggered by dosing of a specified numbers of patients in the CARTITUDE-1 clinical trial were achieved. At December 31, 2019, the Group is eligible to receive further milestone payments up to \$125 million for the achievement of specified manufacturing milestones and an additional \$1,115 million, consisting of \$105 million for the achievement of specified future development milestones, \$800 million for the achievement of specified net trade sales milestones. The Company accessed that achievement of the remaining milestones are highly uncertain and the related milestone payments are not included in the transaction price. The milestone is achieved when the triggering event described in the agreement occurs.

#### Licenses of intellectual property

In assessing whether a license is distinct from the other promises, the Group considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Group considers whether the counterparty can benefit from a license for its intended purpose without the receipt of the remaining promise(s) by considering whether the value of the license is dependent on the unsatisfied promise(s), whether there are other vendors that could provide the remaining promise(s), and whether it is separately identifiable from the remaining promise(s). The Group evaluates the nature of a promise to grant a license in order to determine whether the promise is satisfied over time or at a point in time. The Group evaluated that the licenses are separate performance obligations which represent a right to use the Group's license as it exists at the point in time that the license is granted. Revenue from licenses is recognized when the control of the right to use of the license is transferred to the customer.

#### Steering committee services

In assessing whether the preparation and participation in a Joint Steering Committee which leads to the commercialization of new drug ("JSC service") is a promised service in the arrangement, the Group concluded that the services are capable of being distinct from the intellectual property licenses and distinct within the context of the contract based on a careful evaluation of the specific facts and circumstances. The performance obligation is satisfied over time as services are rendered. Revenue from JSC service is recognized on a straight-line basis over the period when the JSC service is provided.

Pursuant to the license and collaboration agreement, both the Group and the customer jointly perform research and development activities and share the related costs. The research and development activities conducted by the Company are an input to the JSC service to achieve commercialisation of the new drug. Therefore, performing such research and development activities under the arrangement is not considered a distinct performance obligation.

## 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### (b) Rendering of services

The Group render research and development services to customers by delivering research report. Revenue is recognized at the point in time when the research report is delivered and accepted by the customers.

#### (c) Sale of goods

Revenue from the sale of goods is recognised at the point in time when control of the goods is transferred to the customer, generally on delivery of the goods.

#### Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Dividend income is recognised when the shareholders' right to receive payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably

Rental income is recognised on a time proportion basis over the lease terms.

#### Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If the Group performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognised for the earned consideration that is conditional.

#### **Contract liabilities**

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

#### Share-based payments

The Company operates a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments ("equity-settled transactions").

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 23 to the consolidated financial statements.

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefit expense. The

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

cumulative expense recognised for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of earnings per share.

#### Other employee benefits

#### **Pension scheme**

The employees of the Group's subsidiary which operates in Mainland China are required to participate in a central pension scheme operated by the local municipal government. This subsidiary is required to contribute certain percentage of its payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

#### Foreign currencies

These consolidated financial statements are presented in United States dollars, which is the Company's functional currency. Each entity in the Group determines its own functional currency and items included in the consolidated financial statements of each entity are measured using that functional currency. Foreign currency

### 2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss.

Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss with the exception of monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognised in other comprehensive income until the net investment is disposed of, at which time the cumulative amount is reclassified to the statement of profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of certain subsidiaries established in the PRC and Europe are currencies other than the United States dollar. As at the end of the reporting period, the assets and liabilities of these entities are translated into United States dollars at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into United States dollars at the weighted average exchange rates for the year.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the foreign currency translation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

For the purpose of the consolidated statements of cash flows, the cash flows of the subsidiaries established in the PRC and Europe are translated into United States dollars at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of the companies established in the PRC and Europe which arise throughout the year are translated into United States dollars at the weighted average exchange rates for the year.

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

# 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

#### Judgement

In the process of applying the Group's accounting policies, management has made the following judgement, apart from those involving estimations, which has the most significant effect on the amounts recognised in the consolidated financial statements:

#### Revenue from contracts with customers

The Group has applied the following judgements that significantly affect the determination of the performance obligations and the method to estimate variable consideration of revenue from contracts with customers:

#### (i) Determining the performance obligations of the contract

A good or service that is promised to a customer is distinct if both of the following criteria are met: (a) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (b) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Group determined that both license and JSC service are each capable of being distinct. In assessing whether each item has standalone value to the customer, the Group considers factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace, which indicates that the customer can benefit from both license and service on their own. The Group also determined that the promises to transfer the license and to provide JSC service are distinct within the context of the contract. The license is separately identifiable in the contract and will be granted at contract inception. The license is not an input that will be integrated with the service which represents a combined output. The preparation and attendance of the various steering committees is to assist in conducting clinical trials and obtaining regulatory approval of the technology, but does not modify the technology itself. In addition, the license and JSC service are not highly interdependent or highly interrelated, because the delivery of license is not dependent on the service to be provided in the future, and accordingly, it is not interrelated with the service.

In determining whether the license transfers to a customer either at a point in time or over time, the Group considers whether the nature of the Group's promise in granting the license to a customer is to provide a right to access or a right to use the Group's intellectual property. The Group assessed that the Group provides a right to use the license as the license exists (in terms of form and functionality) at a point in time at which it is granted. The license is already developed and has positive results on cancer patient candidates. The next step is to perform clinical trials again in a controlled and monitored environment.

The Group has allocated the transaction price to license and JSC service based on relative standalone selling prices. The standalone selling prices are not directly observable, and therefore, the Group estimates it using income approach for license and expected cost plus margin approach for JSC service with the assistance of an independent third-party valuer. The Group has considered all information that is reasonably available, including but not limited to, third-party or industry pricing, costs incurred to provide the good or service, related profit margins.

## (ii) Determining the method to estimate variable consideration

Certain contract includes milestone payment that give rise to variable consideration. In estimating the variable consideration, the Group is required to use either the expected value method or the most likely amount

### 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (Continued)

method based on which method better predicts the amount of consideration to which it will be entitled. The Group determined that the most likely amount method is the appropriate method to use in estimating the variable consideration for the milestone payments as this method better predicts the amount of variable consideration to which the Group will be entitled.

Before including any amount of variable consideration in the transaction price, the Group considers whether the amount of variable consideration is constrained. The Group evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment.

#### Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

#### Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each reporting period. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

#### Deferred tax assets

Deferred tax assets are recognised for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses and deductible temporary differences can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies. The outcome of their actual utilisation may be different. The amount of unrecognised deferred tax assets for deductible temporary differences and unused tax losses as at December 31, 2018 and 2019 was US\$1,873,000 and US\$46,717,000, respectively. Further details are contained in note 21 to the consolidated financial statements.

#### Share-based compensation

The fair value of share options granted by the Group is estimated using the binomial model. The use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Management estimates expected volatility based on the historical volatility of the stock of comparable companies. Expiration date is the basis for determining the expected life of an option. The risk-free interest rate is based on treasury yield curve rates with a remaining term which approximates to the expected life assumed at the date of grant. Changes in these input variables would affect the amount of expense associated with share-based compensation. The compensation expense recognised for all share-based awards is net of estimated

# 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (Continued)

forfeitures. The Company estimates forfeiture rates based on historical analysis of option forfeitures. If actual forfeitures vary from estimated forfeitures, adjustments to the compensation expense may be required. For the years ended December 31, 2018 and 2019, the equity-settled share option expense was US\$704,000 and US \$1,272,000 respectively. Further details are contained in note 23 to the consolidated financial statements.

### 4. OPERATING SEGMENT INFORMATION

IFRS 8 *Operating Segments* requires operating segments to be identified on the basis of internal reporting about components of the Group that are regularly reviewed by the chief operating decision-maker in order to allocate resources to segments and to assess their performance. The information reported to the directors of the Company, who are the chief operating decision makers, for the purposes of resource allocation and assessment of performance does not contain discrete operation segment financial information and the directors reviewed the financial results of the Group as a whole. Therefore no further information on the operating segment is presented.

#### Geographic information

(a) Revenue from external customers

	2018	2019
	US\$'000	US\$'000
North America	48,104	57,261
China	1,029	3
Total	49,133	57,264

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
China	13,457	27,731
Other countries	19,717	52,880
Total	33,174	80,611

The non-current asset information above is based on the locations of assets and excludes deferred tax assets.

#### Information about major customer

Revenue of US\$48,104,000 and US\$57,261,000 for the years ended December 31, 2018 and 2019, respectively, was derived from sales to a single customer.

# 5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2018 US\$'000	2019 US\$'000
Revenue from contracts with customers*	033 000	030 000
Rendering of services	1,029	_
Sales of goods		3
License and collaboration revenue		
- Licensing of intellectual property	7,570	4,523
- JSC service	40,534	52,738
	49,133	57,264

Revenue from the rendering of services, sales of goods and licensing of intellectual property is recognized at a point in time. Revenue from licensing of intellectual property in 2018 represents revenue recognized for the right to use the license in non-US territories, which was transferred in 2018 when the customer is able to use and benefit from the license. Revenue from licensing of intellectual property in 2019 represents variable consideration relating to the milestone payments which were constrained in prior years but included in the transaction price in 2019 when the milestones were highly probable achieved. At inception, the amount allocated to licensing of intellectual property was US\$30 million, which was updated to US\$34.5 million as at December 2019.

Revenue from JSC service is recognized overtime. Transaction price allocated to JSC service is recognized as revenue on straight-line basis over the service period, which is estimated to be 9 years, starting from the point when the license is transferred and JSC activities are initiated. At inception the amount allocated to JSC service was US\$370 million, which was updated to US\$425.5 million as at December 2019.

The following table shows the amounts of revenue recognized in the current reporting period that were included in the contract liabilities at the beginning of the reporting period and recognized from performance obligations satisfied in previous periods:

2018	2019
US\$ <sup>7</sup> 000	US\$'000
30,212	40,324
2018	2019 US\$'000
055,000	059.000
_	4,523
	6,334
	10,857
	US\$'000 30,212

# 5. REVENUE, OTHER INCOME AND GAINS (Continued)

### (i) Performance obligations

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at December 31, 2018 and 2019 are as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Amounts expected to be recognized as revenue:		
Within 1 year	40,324	46,294
1 - 2 years	40,324	46,294
2 - 3 years	40,324	46,294
3 - 4 years	40,324	46,294
After 4 years	160,935	138,883
	322,231	324,059

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue relate to JSC service, of which the performance obligations are to be satisfied over the collaboration period, which is estimated to be 9 years. The amounts disclosed above do not include variable consideration which is constrained.

	2018 US\$'000	2019 US\$'000
Other income and gains	05\$1000	05\$1000
Other income and gains		250
Foreign currency exchange gain, net	7,237	250
Government grants*	361	1,682
Finance income	6,214	4,581
Fair value gains on financial assets at fair value change through profit or loss	89	474
Rental income		138
	13,901	7,125

\* The amount represents subsidies received from local government authorities to support the Group's business. There were no unfulfilled conditions and other contingencies attached to these government grants.

# 6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

		2018	2019
	Notes	US\$'000	US\$'000
Research and development expense		16,568	32,997
Depreciation of property, plant and equipment	10	845	4,001
Amortization of intangible assets *	11	15	63
Depreciation of right-of-use assets	12	823	1,198
Lease payments not included in the measurement of lease liabilities	12		272
(Reversal of)/provision for the impairment of trade receivables, net	15	(60)	1
Government grants		(361)	(1,682)
Collaborative research and development expenses **		30,943	83,440
Collaborative selling and distribution expenses ***		—	19,580
Employee benefit expense (excluding directors' remuneration):			
Wages and salaries		12,039	37,038
Pension scheme contributions (defined contribution schemes)		416	1,166
Equity-settled share option expense		704	1,272
Foreign currency exchange gain, net		(7,237)	(250)

\* The amortization of intangible assets for the year is included in "Administrative expenses" on the face of the consolidated statement of profit or loss and other comprehensive income.

- \*\* Collaborative research and development expenses represented research and development expenses charged by a customer under a license and collaboration agreement and are included in "Research and development expenses" on the face of the consolidated statement of profit or loss and other comprehensive income.
- \*\*\* Collaborative selling and distribution expenses represented selling and distribution expenses charged by a customer under a license and collaboration agreement and are included in "Selling and distribution expenses" on the face of the consolidated statement of profit or loss and other comprehensive income.

# 7. FINANCE COSTS

	US\$'000	US\$'000
Interest on lease liabilities	82	199
Interest on an entrusted loan from a related party		24
Total	82	223

2010

2010

## 8. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

## **Cayman Islands**

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains.

# 8. INCOME TAX (Continued)

#### **British Virgin Islands**

Under the current laws of the British Virgin Islands ("BVI"), Legend Biotech Limited ("Legend BVI") is not subject to tax on income or capital gains. Additionally, upon payments of dividends by the Group's subsidiaries incorporated in the British Virgin Islands to their shareholders, no withholding tax will be imposed.

### Hong Kong

Under the current laws of Hong Kong, the subsidiary which operates in Hong Kong is subject to a corporate income tax ("CIT") at a rate of 16.5% on the taxable income. Under the Hong Kong tax law, the subsidiaries in Hong Kong are exempted from income tax on their foreign derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

#### United States of America

Under the current laws of the United States of America ("USA"), the subsidiary which operates in the United States of America is subject to federal tax at a rate of 21% and state tax at a rate of 11.5% in New Jersey. Dividends payable by the Group's US entity, to non US resident enterprises shall be subject to 30% withholding tax, unless the respective non US resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with US that provides for a reduced withholding tax rate or an exemption from withholding tax.

#### Ireland

Under the current laws of the Ireland, the subsidiary which operates in Ireland is subject to CIT at a rate of 12.5% on the taxable income. Dividend withholding tax is imposed on distributions made by Irish companies at a rate of 20% with many exemptions provided.

#### Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income. During the years ended December 31, 2018 and 2019, the applicable income tax rate was 25%. Dividends, interests, rent or royalties payable by the Group's PRC entities, to non PRC resident enterprises, and proceeds from any such non-resident enterprise investor's disposition of assets (after deducting the net value of such assets) shall be subject to 10% EIT, namely withholding tax, unless the respective non PRC resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with China that provides for a reduced withholding tax rate or an exemption from withholding tax.

#### Netherlands

Under the current laws of Netherlands, the subsidiary which operates in Ireland is subject to CIT at a rate of 25% on the taxable income. A tax rate of 19% (2018: 20%) applies to the first EUR200,000 of taxable income. The statutory withholding tax rate for dividends is 15% while several exemptions and reductions can apply.

	2018	2019
	US\$'000	US\$'000
Current – United States of America	64,312	(65,948)
Current – Elsewhere	913	(371)
Deferred (note 21)	(64,057)	68,921
Total tax charge for the year	1,168	2,602

# 8. INCOME TAX (Continued)

A reconciliation of the tax expense applicable to loss before tax at the statutory rates for the countries (or jurisdictions) in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates is as follows:

	2018		2019	
	US\$'000	%	US\$'000	%
Loss before tax	(1,616)		(130,370)	
At the statutory blended income tax rate of 30.1% (2018: 30.1%)	(486)	30.1	(39,222)	30.1
Effect of tax rate differences in other countries	(605)	37.4	6,395	(4.9)
Research and development credit	(2,341)	144.9	(3,746)	2.9
Statutory income/expense	46	(2.9)		—
Effect of non-deductible expenses	112	(6.9)	188	(0.1)
Tax losses and deductible temporary differences not recognized	1,462	(90.5)	44,844	(34.5)
Prior year true up	(76)	4.7	(6,598)	5.1
Uncertain tax positions	3,056	(189.1)	272	(0.2)
Withholding tax on interest		—	393	(0.3)
Others			76	(0.1)
Tax charge at the Group's effective rate	1,168	(72.3)	2,602	(2.0)

# 9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 200,000,000 and 200,000,000 in issue during the years 2018 and 2019, respectively.

The calculation of the diluted earnings per share amount is based on the loss for the year attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year, as used in the basic earnings per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise of all dilutive potential ordinary shares into ordinary shares.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2018 and 2019 in respect of a dilution as the impact of the outstanding share options had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	2018 US\$'000	2019 US\$'000
Earnings		
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(2,784)	(132,972)
	Number o	of shares
	Number o 2018	f shares 2019
<u>Shares</u>		

# **10. PROPERTY, PLANT AND EQUIPMENT**

	<u>Buildings</u> US\$'000	Machinery and <u>equipment</u> US\$'000	Computer and office <u>equipment</u> US\$'000	Transportation equipment US\$'000	Construction in progress US\$'000	<u>Total</u> US\$'000
December 31, 2018						
At January 1, 2018:						
Cost	32	2,668	88	—	171	2,959
Accumulated depreciation and impairment	(7)	(295)	(19)			(321)
Net carrying amount	25	2,373	69		171	2,638
At January 1, 2018, net of accumulated depreciation and						
impairment	25	2,373	69		171	2,638
Additions	98	138	45		26,729	27,010
Disposals	—	(20)		—	—	(20)
Depreciation provided during the year	(23)	(762)	(59)	(1)		(845)
Exchange realignment	(3)	(156)	(10)	(2)	(457)	(628)
Transfers from construction in progress		1,814	250	44	(2,108)	
At December 31, 2018, net of accumulated depreciation						
and impairment	97	3,387	295	41	24,335	28,155
At December 31, 2018:						
Cost	127	4,217	367	43	24,335	29,089
Accumulated depreciation and impairment	(30)	(830)	(73)	(1)		(934)
Net carrying amount	97	3,387	294	42	24,335	28,155

# 10. PROPERTY, PLANT AND EQUIPMENT (Continued)

	Freehold land US'000	<u>Buildings</u> US\$'000	Machinery and <u>equipment</u> US\$'000	Computer and office <u>equipment</u> US\$'000	Transportation equipment US\$'000	Construction in progress US\$'000	<u>Total</u> US\$'000
December 31, 2019							
At January 1, 2019:							
Cost	—	127	4,217	367	43	24,335	29,089
Accumulated depreciation and impairment		(30)	(830)	(73)	(1)		(934)
Net carrying amount		97	3,387	294	42	24,335	28,155
At January 1, 2019, net of accumulated depreciation and							
impairment	_	97	3,387	294	42	24,335	28,155
Additions	2,889	9,476	1,586	53		32,310	46,314
Disposals	—	—	(74)	—		—	(74)
Depreciation provided during the year	—	(1,505)	(2,219)	(273)	(4)	—	(4,001)
Exchange realignment	—	(77)	(70)	(4)	(2)	(162)	(315)
Transfers from construction in progress		23,002	22,442	903		(46,347)	
At December 31, 2019, net of accumulated depreciation							
and impairment	2,889	30,993	25,052	973	36	10,136	70,079
At December 31, 2019:							
Cost	2,889	32,527	27,992	1,314	42	10,136	74,900
Accumulated depreciation and impairment		(1,534)	(2,940)	(341)	(6)		(4,821)
Net carrying amount	2,889	30,993	25,052	973	36	10,136	70,079

During the years ended December 31, 2018 and 2019, the additions of property, plant and equipment included the charge from a customer under a license and collaboration agreement amounting to US\$13,684,000 and US\$19,765,000, respectively.

# **11. INTANGIBLE ASSETS**

	Software US\$'000
December 31, 2018	
At January 1, 2018:	
Cost	5
Accumulated amortization	(3)
Net carrying amount	2
At January 1, 2018, net of accumulated amortisation	2
Additions	63
Amortisation provided during the year	(15)
Exchange realignment	(1)
At December 31, 2018, net of accumulated amortisation	49
At December 31, 2018:	
Cost	67
Accumulated amortisation	(18)
Net carrying amount	49
December 31, 2019	
At January 1, 2019:	
Cost	67
Accumulated amortisation	(18)
Net carrying amount	49
At January 1, 2019, net of accumulated amortisation	49
Additions	534
Amortisation provided during the year	(63)
Exchange realignment	(1)
At December 31, 2019, net of accumulated amortisation	519
At December 31, 2019:	
Cost	598
Accumulated amortisation	(79)
Net carrying amount	519

### 12. LEASES

## The Group as a lessee

The Group has lease contracts for land and buildings. Leases of buildings (including car park spaces) generally have lease terms between 2 and 10 years. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these land leases. Other buildings and rooms generally have lease terms of 12 months.

# 12. LEASES (Continued)

(a) Right-of-use assets

The carrying amounts of the Group's right-of-use assets and the movements during the year are as follows:

	Prepaid land lease <u>payments</u> US\$'000	Buildings US\$'000	<u>Total</u> US\$'000
December 31, 2018			
Right-of-use assets at January 1, 2018, net of accumulated depreciation		291	291
Additions		4,280	4,280
Exchange realignment		(15)	(15)
Depreciation of right-of-use assets	—	(823)	(823)
At December 31, 2018		3,733	3,733
December 31, 2019			
Right-of-use assets at January 1, 2019, net of accumulated depreciation	_	3,733	3,733
Additions	4,677	2,163	6,840
Exchange realignment		(27)	(27)
Depreciation of right-of-use assets	(47)	(1,151)	(1,198)
At December 31, 2019	4,630	4,718	9,348

#### (b) Lease liabilities

Lease liabilities are as indicated below:

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term.

	2018 LIGO1000	2019
Carrying amount at January 1	US\$'000 269	US\$'000 4,317
New leases	4,280	6,840
Accretion of interest recognised during the year	82	199
Payments	(301)	(5,255)
Exchange	(13)	(16)
Carrying amount at December 31	4,317	6,085
Analyzed into:		
Current portion	373	1,027
Non-current portion	3,944	5,058
	4,317	6,085

# 12. LEASES (Continued)

(c) The amounts recognised in profit or loss in relation to leases are as follows:

	2018 US\$'000	2019 US\$'000
Interest on lease liabilities	82	199
Depreciation charge of right-of-use assets	823	1,198
Expense relating to short-term leases	—	272
Total amount recognized in profit or loss	905	1,669

The maturity analysis of lease liabilities is disclosed in note 30 to the financial statements. The total cash outflow for leases is disclosed in note 25(c) to the financial statements.

### The Group as a lessor

The Group leases its right-of-use assets above consisting of five car parking spaces in Ireland for a lease term of 12 months and buildings (note 10) consisting of one office in the US under operating lease arrangements for a lease term of 3 months. Rental income recognised by the Group for the year ended December 31, 2019 was US\$138,000 (2018: none), details of which are included in note 5 to the financial statements.

At December 31, 2019, the undiscounted minimum lease payments receivables by the Group in future periods under non-cancellable operating leases with its tenants are as follows:

<u>2018</u> US\$*0	
Within one year	10

# 13. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	December 31, <u>2018</u> US\$'000	December 31, 2019 US\$'000
Financial assets at fair value through profit or loss		
Investments in financial products, at fair value	6,014	
	6,014	

The above investments in financial products at December 31, 2018 were classified as financial assets at fair value through profit or loss as their contractual cash flows do not qualify for solely payments of principal and interest.

# **14. INVENTORIES**

	December 31, 2018	December 31, 2019
	US\$'000	US\$'000
Raw materials and consumables	1,135	1,157

## LEGEND BIOTECH CORPORATION NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued) FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

# **15. TRADE RECEIVABLES**

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Trade receivables	26,229	30,000
Less: Impairment of trade receivables	(8)	(9)
	26,221	29,991

The Group's trading terms with its customers are mainly on credit. The credit period is 30 to 90 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by management. Trade receivables are non-interest-bearing. The Group has concentration of credit risk as 96.2% and 100% of trade receivables were due from one single customer under a license and collaboration agreement as at December 31, 2018 and 2019, respectively.

Included in the Group's trade receivables were amounts due from the Group's related parties of US\$1,005,000 and nil as at December 31, 2018 and 2019, respectively, which are repayable on credit terms similar to those offered to the major customers of the Group (note 27).

An aging analysis of the trade receivables as at the end of the year, based on the invoice date and net of loss allowance, is as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Within 3 months	26,221	29,991

Movements in the loss allowance for impairment of trade receivables were as follows:

	Total
	US\$'000
At January 1, 2018	68
Impairment losses reversed (note 6)	(60)
At December 31, 2018	8
At January 1, 2019	8
Impairment losses recognised (note 6)	1
At December 31, 2019	9

The Group applies the simplified approach to providing for expected credit losses prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. The Group performed an impairment analysis at the end of each year by considering the probability of default of the debtors or comparable companies with published credit ratings.

# **15. TRADE RECEIVABLES (Continued)**

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

		As at December 31, 2018	
	Gross carrying amount USD'000	Expected loss rate	Expected credit loss USD'000
Within 3 months	26,229	0.03%	8
	A	As at December 31, 2019	
	Gross carrying amount USD'000	Expected loss rate	Expected <u>credit loss</u> USD'000
Within 3 months	30,000	0.03%	9

## Within 3 months

# 16. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	December 31, 2018	December 31, 2019
	US\$'000	US\$'000
Interest receivable	4,486	516
Other receivables	75,111	1,044
Prepaid income tax	—	7,210
VAT recoverable	2,750	4,206
Prepayments	759	3,190
Prepaid expense	59	611
	83,165	16,777

As at December 31, 2018 and 2019, included in the Group's other receivables were amounts due from the Group's related parties that are repayable on demand of US\$75,051,000 and US\$291,000, respectively (note 27).

None of the above assets is either past due or impaired. The financial assets included in the above balances relate to receivables for which there was no recent history of default. The majority of the above balances were settled within 12 months and had no history of default. The Group estimated that the expected credit loss for the above receivables is insignificant.

## 17. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

	December 31, <u>2018</u> US\$'000	December 31, <u>2019</u> US\$'000
Cash and bank balances	210,421	159,179
Less: pledged short-term deposits	(255)	(256)
time deposits for periods over three months		(75,559)
Cash and cash equivalents	210,166	83,364
Denominated in USD	208,120	69,846
Denominated in RMB	1,611	13,180
Denominated in EUR	435	338
Cash and cash equivalents	210,166	83,364

The cash and bank balances of the Group denominated in Renminbi ("RMB") amounted to US\$1,611,000 and US\$13,180,000 in the consolidated statements of financial position as at December 31, 2018 and December 31, 2019, respectively. The RMB is not freely convertible into other currencies, however, under Mainland China's Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

The pledged deposit as at December 31, 2019 was pledged for credit card facilities and the pledged deposit as at December 31, 2018 was pledged for issuing bank notes payables to suppliers of the Group.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default. The carrying amounts of the cash and cash equivalents approximate to their fair values.

# **18. TRADE AND NOTES PAYABLES**

An aging analysis of the trade and notes payables as at the end of the year, based on the invoice date, is as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Trade payables	7,320	9,586
Notes payable	255	
	7,575	9,586

# 18. TRADE AND NOTES PAYABLES (Continued)

An aging analysis of the trade and notes payables at the end of each year, based on the transaction date, is as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Within 3 months	7,575	9,392
3 months to 6 months		194
6 months to 12 months	—	_
Over 1 year		—
	7,575	9,586

The trade payables are non-interest-bearing and are normally settled on 60-day terms.

As at December 31, 2018 and 2019, included in the Group's trade payables were amounts due to the Group's related parties of US\$5,667,000 and US\$5,225,000, respectively (note 27).

# **19. OTHER PAYABLES AND ACCRUALS**

	December 31, 2018 US\$'000	December 31, <u>2019</u> US\$'000
Accrued payroll	2,473	6,633
Other payables	33,904	64,221
	36,377	70,854

Other payables are non-interest-bearing and repayable on demand.

As at December 31, 2018 and 2019, included in the Group's other payables were amounts due to the Group's related parties of US\$7,174,000 and US\$1,544,000, respectively (note 27).

# **20. CONTRACT LIABILITIES**

Details of contract liabilities are as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Advances received from customers		
License and collaboration revenue		
- JSC service	297,593	324,059
Current	40,324	46,294
Non-current	257,269	277,765



# 20. CONTRACT LIABILITIES (Continued)

The movements in contract liabilities during the year are as follows:

	US\$'000
At January 1, 2018	204,410
Advance received/due for payment	140,923
Transferred to revenue	(48,104)
Exchange realignment	364
At December 31, 2018	297,593
At January 1, 2019	297,593
Advance received/due for payment	85,217
Transferred to revenue	(57,261)
Exchange realignment	(1,490)
At December 31, 2019	324,059

Contract liabilities include advances received/due for payment under the license and collaboration agreement at the end of each year. Contract liabilities are recognized as revenue upon the Group satisfying its performance obligations under the agreement. The increase in contract liabilities in 2018 and 2019 was mainly due to the increase in upfront and milestone payments from a customer in relation to the agreement.

# **21. DEFERRED TAX**

The movements in deferred tax assets during the year are as follows:

Deferred tax assets

	Amortized <u>and accrued</u> US\$'000	Expense of share <u>Options</u> US\$'000	Unrealised profit from <u>intercompany</u> US\$'000	Contract <u>liabilities</u> US\$'000	Losses available for offsetting against future taxable profits US\$'000	<u> </u>
At January 1, 2018	540	—	4,282	—	38	4,860
Deferred tax credited/(charged) to the statement of profit or	410	00	2 205	CO 207	(20)	64.057
loss during the year	413	90	3,205	60,387	(38)	64,057
Gross deferred tax assets at December 31, 2018	953	90	7,487	60,387		68,917
At January 1, 2019	953	90	7,487	60,387	—	68,917
Deferred tax charged to the statement of profit or loss during						
the year	(953)	(90)	(7,487)	(60,391)	—	(68,921)
Exchange realignment				4		4
Gross deferred tax assets at December 31, 2019						

The Group has tax losses arising in Hong Kong of US\$919,000 in 2019 (2018: US\$130,000) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

## 21. DEFERRED TAX (Continued)

The Group has tax losses arising in Mainland China of US\$30,766,000 in 2019 (2018: US\$4,736,000) that will expire in 5 years for offsetting against future taxable profits of the companies in which the losses arose.

The Group has tax losses arising in the Netherlands of US\$2,000 in 2019 (2018: Nil) that can be carried back for 1 year and carried forward for 9 years for offsetting against taxable profits of the company.

The Group has tax losses arising in Ireland of US\$31,594,000 in 2019 (2018: Nil) that can be carried back for 1 year and carried forward indefinitely for offsetting against taxable profits of the company.

The Group has tax losses arising in the United States of US\$57,792,000 in 2019 (2018: Nil) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognized in respect of these tax losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

Deferred tax assets have not been recognised in respect of the following items:

	2018	2019
	US\$'000	US\$'000
Deductible temporary differences	1,020	59,399
Tax losses	4,889	121,073
	5,909	180,472

Deferred income tax assets are recognised for tax losses carried-forward to the extent that realization of the related tax benefit through future taxable profits is probable. Deferred tax assets have not been recognized in respect of the above items as it is not considered probable that taxable profits will be available against which the above items can be utilized.

Pursuant to the PRC Corporate Income Tax Law, a 10% withholding tax is levied on dividends declared to foreign investors from the foreign investment enterprises established in Mainland China. The requirement is effective from January 1, 2008 and applies to earnings after December 31, 2007. A lower withholding tax rate may be applied if there is a tax treaty between Mainland China and the jurisdiction of the foreign investors. For the Group, the applicable rate is 10%. The Group is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in Mainland China in respect of earnings generated from January 1, 2008.

At December 31, 2018, no deferred tax has been recognized for withholding taxes that would be payable on the unremitted earnings that are subject to withholding taxes of the Group's subsidiaries established in Mainland China. In the opinion of the directors, it is not probable that these subsidiaries will distribute such earnings in the foreseeable future as the Group's fund will be retained in PRC for the expansion of the Group's operation. The aggregate amount of temporary differences associated with investments in subsidiaries in Mainland China for which deferred tax liabilities have not been recognized in total was US\$1,344,000 at December 31, 2018. At December 31, 2019, the subsidiary in Mainland China had no distributable retained earnings.

According to the US tax laws, dividends payable by the Group's US entity, to non-US resident enterprises shall be subject to 30% withholding tax. A lower withholding tax rate may be applied if there is a tax treaty between US and the jurisdiction of the foreign investors. For the Group, the applicable rate is 5%. The Group is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in US.

# 21. DEFERRED TAX (Continued)

At December 31, 2018, no deferred tax has been recognized for withholding taxes that would be payable on the unremitted earnings that are subject to withholding taxes of the Group's subsidiaries established in US. In the opinion of the directors, it is not probable that these subsidiaries will distribute such earnings in the foreseeable future as the Group's fund will be retained in US for the expansion of the Group's operation. The aggregate amount of temporary differences associated with investments in subsidiaries in US for which deferred tax liabilities have not been recognized in total was US\$525,000 at December 31, 2018. At December 31, 2019, the subsidiary in US had no distributable retained earnings.

### 22. SHARE CAPITAL AND SHARE PREMIUM

The Company was incorporated in the Cayman Islands on May 27, 2015. The authorized share capital of the Company was US\$50,000 divided into 50,000,000 ordinary shares with a par value of US\$0.001 each on the date of incorporation. On May 27, 2015, 50,000,000 ordinary shares were allotted and issued to Genscript Biotech Corporation but not paid. On October 19, 2017, 50,000,000 ordinary shares were redeemed from Genscript Biotech Corporation and cancelled by the Company. On the same day, each of the shares with a par value of US\$0.001 was subdivided into 10 shares of the Company with a par value of US\$0.0001 each, after which, the authorized share capital of the Company was US\$50,000 divided into 500,000,000 shares with par value of US\$0.0001 each. On October 19, 2017, 169,680,000 and 30,320,000 ordinary shares were allocated and issued to Genscript Biotech Corporation and AquaPoint L.P., respectively, with the share capital fully paid.

Shares

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Authorised:		
500,000,000 ordinary shares of US\$0.0001 each	50	50
Issued and fully paid:		
200,000,000 ordinary shares of US\$0.0001 each	20	20

A summary of movements in the Company's share capital and share premium is as follows:

		Share	Share	
	Number of	capital	premium	Total
	shares in issue	US\$'000	US\$'000	US\$'000
At December 31, 2018, January 1, 2019 and December 31, 2019	200,000,000	20	3,908	3,928

# 23. SHARE OPTION SCHEME

The Company operates a share option scheme (the "Scheme") for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Eligible participants of the Scheme include the Company's directors, including independent non-executive directors, and employees of any member of the Group. The Scheme became effective on December 21, 2017 and, unless otherwise cancelled or amended, will remain in force for 10 years from that date. The Scheme has a performance vesting condition and is subject to forfeiture if the participants cannot meet certain performance targets set by the board of directors.

# 23. SHARE OPTION SCHEME (Continued)

Share options do not confer any voting rights, or rights to participate in any dividends or distributions.

The following share options were outstanding under the Scheme during the year:

	2018		2019	
	Weighted average <u>exercise price</u> US\$ per share	Number <u>of options</u> '000	Weighted average <u>exercise price</u> US\$ per share	Number <u>of options</u> '000
At January 1,	0.5000	8,100	0.7782	14,311
Granted during the year	1.0000	7,990	1.4973	3,757
Forfeited during the year	0.5073	(1,779)	1.0909	(55)
At December 31,	0.7782	14,311	0.9273	18,013

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

December 31, 2018			
	Number of options '000	Exercise price* US\$ per share	Exercise period
	6,347	0.5	2019/12/25 - 2027/12/25
	7,288	1.0	2019/07/01 - 2028/08/29
	676	1.0	2019/12/31 - 2028/12/30
	14,311		
	December 31, 2019		
	Number of options '000	Exercise price* US\$ per share	Exercise period
		US\$	Exercise period 2019/12/25 - 2027/12/25
	· 000	US\$ per share	•
	6,347	US\$ per share 0.5	2019/12/25 - 2027/12/25
	6,347 6,283	US\$ per share 0.5 1.0	2019/12/25 - 2027/12/25 2019/07/01 - 2028/08/29
	6,347 6,347 7,283 656	US\$ per share 0.5 1.0 1.0	2019/12/25 - 2027/12/25 2019/07/01 - 2028/08/29 2019/12/31 - 2028/12/30

\* The exercise price of the share options is subject to adjustment in the case of rights or bonus issues, or other similar changes in the Company's share capital.

The fair value of the share options granted during the year was US\$1,099,000 (US\$0.294 each) (2018: US\$4,329,189, US\$0.269 each), of which the Group recognised a share option expense of US\$1,272,000 (2018: US\$704,000) during the year ended December 31, 2019.

# 23. SHARE OPTION SCHEME (Continued)

The fair value of equity-settled share options granted during the period was estimated, using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used:

	2018	2019
Dividend yield (%)		
Expected volatility (%)	64.2-66.4	66.4-80.3
Risk-free interest rate (%)	2.48-2.87	1.98-2.69
Expected life of options (year)	10	10
Weighted average share price (US\$ per share)	0.609-0.615	0.590-0.615

The volatility measured at the standard deviation of expected share price returns is based on statistical analysis of comparable listed companies in the same industry.

As at December 31, 2019, the Company had 18,013,000 share options outstanding under the Scheme. The exercise in full of the outstanding share options would, under the present capital structure of the Company, result in the issue of 18,013,000 additional ordinary shares of the Company, an additional share capital of US\$1,801 and a share premium of US\$16,701,654 (before issue expenses).

#### 24. RESERVES

The amounts of the Group's reserves and the movements therein for the current and prior years are presented in the consolidated statement of changes in equity on page F-5 of the consolidated financial statements.

The foreign currency translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of operations with a functional currency other than US\$.

Under PRC laws and regulations, there are restrictions on the Company's PRC subsidiaries with respect to transferring certain of their net assets to the Company either in the form of dividends, loans, or advances. Amounts of net assets restricted include paid in capital and statutory reserve funds of the Company's PRC subsidiaries and the net assets, totalling US\$4.0 million and US\$24.0 million as at December 31, 2018 and 2019, respectively.

## 25. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

(a) Major non-cash transactions

For the years ended December 31, 2018 and 2019, the Group had non-cash additions to right-of-use assets of US\$4,280,000 and US\$2,163,000, and lease liabilities of US\$4,280,000 and US\$2,163,000, in respect of lease arrangements for buildings, respectively.

For the years ended December 31, 2018 and 2019, the Group had non-cash additions to property, plant and equipment of US\$7,280,000 and US\$8,945,000, respectively.

For the year ended December 31, 2019, Genscript Biotech Corporation utilized the balance due from the Group to settle the balance due to Genscript USA Incorporated in the amount of US\$4,364,000.

# 25. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS (Continued)

For the year ended December 31, 2019, Genscript Biotech Corporation and Genscript USA Incorporated utilized the outstanding balance due from the Group to settle part of the outstanding balance due to the Group of US\$19,510,000 and US\$5,539,000, respectively.

(b) Changes in liabilities arising from financing activities

	Other payables to related parties US\$'000	<u>Lease liabilities</u> US\$'000
At January 1, 2018	1,968	269
Additions of lease liabilities		4,280
Changes from financing cash flows	2,720	(219)
Interest expense		82
Interest paid classified as operating cash flows	—	(82)
Foreign exchange movement		(13)
At December 31, 2018	4,688	4,317
At January 1, 2019	4,688	4,317
Additions of lease liabilities	—	6,840
Changes from financing cash flows	19,722	(5,056)
Non-cash transaction (note 25(a))	(24,374)	—
Interest expense		199
Interest paid classified as operating cash flows	—	(199)
Foreign exchange movement	(32)	(16)
At December 31, 2019	4	6,085

(c) Total cash outflow for leases

The total cash outflow for leases included in the statement of cash flows is as follows:

	2018 US\$'000	2019 US\$'000
Right-of-use assets		
Within operating activities	82	199
Within financing activities	219	5,056
Short-term leases	-	272
	301	5,527

# **26. CAPITAL COMMITMENTS**

The Group had the following capital commitments at the end of the year:

	2018	2019
	US\$'000	US\$'000
Construction in progress	2,628	2,844

# 27. RELATED PARTY TRANSACTIONS

Company	Relationship
Nanjing Jinsirui Biotechnology Co., Ltd.	Company controlled by the ultimate holding company
Jinsikang Technology (Nanjing) Co., Ltd.	Company controlled by the ultimate holding company
Nanjing Bestzyme Bioengineering Co., Ltd.	Company controlled by the ultimate holding company
Shanghai Jingrui Biotechnology Co., Ltd.	Company controlled by the ultimate holding company
Jiangsu Genscript Biotech Co., Ltd	Company controlled by the ultimate holding company
Genscript (HongKong) Ltd.	Company controlled by the ultimate holding company
Genscript USA Incorporated	Company controlled by the ultimate holding company
Genscript USA Holdings Inc	Company controlled by the ultimate holding company
Genscript Biotech (Netherlands) B.V.	Company controlled by the ultimate holding company
Yangtze Investment USA Inc.	Company controlled by the ultimate holding company
Genscript Biotech Corporation	Company controlled by the ultimate holding company

- (a) In addition to the transactions detailed elsewhere in these consolidated financial statements, the Group had the following transactions with related parties during the year:
  - (i) Services provided to related parties:

	2018	2019 US\$'000
	US\$'000	US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	1,029	
(ii) Sales of materials to related parties:		
	2018 US\$'000	2019 US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	_	3

The terms of these services and materials were charged based on the prices agreed by both parties.

(iii) Purchases from related parties:

	2018 US\$'000	2019 US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	2,500	4,480
Genscript USA Incorporated	191	296
Shanghai Jingrui Biotechnology Co., Ltd.	18	
Jiangsu Genscript Biotech Co., Ltd	2	198
Genscript USA Holdings Inc		4
	2,711	4,978

# 27. RELATED PARTY TRANSACTIONS (Continued)

The transactions were made according to the published prices and conditions offered by related parties to their major customers.

(iv) Management fee:

	2018	2019 US\$'000
	US\$'000	US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	511	—
Genscript USA Incorporated	222	198
	733	198

The management fee was charged by related parties based on the cost of services provided.

(v) Shared services:

During the years ended December 31, 2018 and 2019, Nanjing Jinsirui Biotechnology Co., Ltd. provided certain accounting, legal, IT and administrative shared services to the Group for a consideration of nil and US\$2,121,000, respectively.

(vi) Short term lease of properties:

	2018 US\$'000	2019 US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.		265

The lease was made according to the contractual price and the lease term is 12 months.

(vii) Cash advances from related parties:

	2018 US\$'000	2019 US\$'000
Genscript Biotech Corporation	—	28,199
Nanjing Jinsirui Biotechnology Co., Ltd.	21,735	2,168
Nanjing Bestzyme Bioengineering Co., Ltd.	14,200	
Genscript USA Incorporated	—	8,000
Jinsikang Technology (Nanjing) Co., Ltd.		578
Genscript (HongKong) Ltd.	4	—
	35,939	38,945

# 27. RELATED PARTY TRANSACTIONS (Continued)

(viii) Repayment of cash advances from related parties:

	2018	2019
	US\$'000	US\$'000
Genscript Biotech Corporation	—	4,335
Nanjing Jinsirui Biotechnology Co., Ltd.	19,019	6,310
Genscript USA Incorporated	14,200	8,000
Jinsikang Technology (Nanjing) Co., Ltd.		578
	33,219	19,223

# (ix) Cash advances to related parties:

	2018	2019
	US\$'000	US\$'000
Genscript Biotech Corporation	55,000	13,006
Genscript USA Incorporated	20,000	—
Jinsikang Technology (Nanjing) Co., Ltd.	1,493	_
Nanjing Bestzyme Bioengineering Co., Ltd.	10,450	_
	86,943	13,006

# (x) Collection of cash advances to related parties:

	2018	2019
	US\$'000	US\$'000
Genscript Biotech Corporation	—	48,496
Genscript USA Incorporated	_	14,500
Jinsikang Technology (Nanjing) Co., Ltd.	1,493	
Nanjing Bestzyme Bioengineering Co., Ltd.	10,450	
	11,943	62,996

The above cash advances from/to related parties were unsecured, interest free and repayable on demand.

(xi) Entrusted loan from a related party:

	2018 US\$'000	2019 US\$'000
Jinsikang Technology (Nanjing) Co., Ltd.	_	2,867
(xii) Repayments of entrusted loan from a related party:		
	2018 US\$'000	2019 US\$'000
Jinsikang Technology (Nanjing) Co., Ltd.	<u> </u>	2,867

The above entrusted loan from a related party was unsecured, bearing an interest rate of 4.35% p.a. and was repaid in December 2019, with an interest expense of US\$24,000 recognized in 2019.

# 27. RELATED PARTY TRANSACTIONS (Continued)

(xiii) Purchase of equipment

	2018 US\$'000	2019 US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	14	7
(xiv) Sale of equipment		
	<u>2018</u> US\$'000	2019 US\$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	12	13

The sale or purchase of equipment was made at their respective carrying values.

(b) Outstanding balances with related parties:

The Group had the following significant balances with its related parties at the end of the year:

(i) Due from related parties

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Trade receivables		
Nanjing Jinsirui Biotechnology Co., Ltd.	1,005	
	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Other receivables		
Genscript Biotech Corporation.	55,000	_
Yangtze Investment USA Inc.	—	20
Genscript USA Incorporated	20,007	93
Nanjing Jinsirui Biotechnology Co., Ltd.	44	178
	75,051	291

# (ii) Due to related parties

	December 31, 2018	December 31, 2019
	US\$'000	US\$'000
Trade payables		
Nanjing Jinsirui Biotechnology Co., Ltd.	4,725	4,109
Genscript USA Incorporated	921	1,097
Shanghai Jingrui Biotechnology Co., Ltd.	19	-
Jiangsu Genscript Biotech Co., Ltd	2	15
Genscript USA Holdings Inc	<u> </u>	4
	5,667	5,225

# 27. RELATED PARTY TRANSACTIONS (Continued)

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Other payables		
Nanjing Jinsirui Biotechnology Co., Ltd.	4,558	—
Genscript USA Incorporated	2,055	1,006
Genscript (HongKong) Ltd.	545	538
Genscript Biotech Corporation	10	
Jiangsu Genscript Biotech Co., Ltd	6	—
	7,174	1,544
	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Lease liabilities		
Genscript USA Holdings Inc	2,073	2,114
Nanjing Jinsirui Biotechnology Co., Ltd.		1,303
	2,073	3,417

Except for lease liabilities with incremental borrowing rates between 2.00% and 7.28% repayable over 5 years, all other related party balances are unsecured and repayable on demand.

(c) Compensation of key management personnel of the Group:

	2018 US\$'000	2019 US\$'000
Short-term employee benefits	692	1,036
Equity-settled share option expense	210	590
Total compensation paid to key management personnel	902	1,626

# 28. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the reporting periods are as follows:

As at December 31, 2018

Financial assets

	Financial assets at fair value through profit or loss US\$'000	Financial assets at amortised cost US\$'000	Total US\$'000
Financial assets at fair value through profit or loss	6,014	—	6,014
Trade receivables	—	26,221	26,221
Financial assets included in prepayments, other receivables and other assets (note 16)	_	79,597	79,597
Pledged deposits	—	255	255
Cash and cash equivalents	—	210,166	210,166
	6,014	316,239	322,253

# 28. FINANCIAL INSTRUMENTS BY CATEGORY (Continued)

Financial liabilities

	Financial liabilities at <u>amortised cost</u> US\$'000
Trade and notes payables	7,575
Financial liabilities included in other payables and accruals (note 19)	36,377
Lease liabilities	4,317
	48,269

As at December 31, 2019

Financial assets

	Financial assets at amortised cost US\$'000
Trade receivables	29,991
Financial assets included in prepayments, other receivables and other assets (note 16)	1,560
Time deposits	75,559
Pledged deposits	256
Cash and cash equivalents	83,364
	190,730

Financial liabilities

	Financial liabilities at amortised cost US\$'000
Trade and notes payables	9,586
Financial liabilities included in other payables and accruals (note 19)	64,221
Lease liabilities	6,085
	79,892

# 29. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

As at December 31, 2018 and 2019, the fair values of the Group's financial assets or liabilities approximated to their respective carrying amounts.

Management has assessed that the fair values of cash and cash equivalents, pledged deposits, time deposits, financial assets included in prepayments, other receivables and other assets, trade receivables, trade and notes payables and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group's finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the finance manager. At each reporting date, the finance department analyzed the movements in the values of

# 29. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (Continued)

financial instruments and determined the major inputs applied in the valuation. The valuation was reviewed and approved by the finance manager. The valuation process and results are discussed with the directors once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The fair values of the financial assets at fair value through profit or loss have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

#### Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group's financial instruments.

#### Assets measured at fair value:

As at December 31, 2018				
	Fair value measurement using			
	Quoted prices in active markets	Significant observable inputs	Significant unobservable inputs	
	(Level 1)	(Level 2)	(Level 3)	<u>Total</u> US\$'000
	US\$'000	US\$'000	US\$'000	US\$'000
Financial assets at fair value through profit or loss:	<u> </u>	6,014		6,014
		6,014		6,014

During the year ended December 31, 2018, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

# 30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise cash and cash equivalents, pledged deposits, time deposits, financial assets at fair value through profit or loss, prepayments, other receivables and other assets, and financial liabilities included in other payables and accruals. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade receivables and trade and notes payables, which arise directly from its operations.

The main risks arising from the Group's financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

#### Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from sales or purchases by operating units in currencies other than the units' functional currencies. Approximately 22% in 2019 (2018: 39%) of the Group's sales were denominated in currencies other than the functional currencies of the operating units making the sale.

#### 30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (Continued)

As at December 31, 2018 and 2019, the Group had no outstanding foreign currency forward exchange contract. At present, the Group does not intend to seek to hedge its exposure to foreign exchange fluctuations. However, management constantly monitors the economic situation and the Group's foreign exchange risk profile and will consider appropriate hedging measures in the future should the need arise.

The following table demonstrates the sensitivity at the end of the reporting period to a reasonably possible change in the EUR and RMB exchange rate against US\$, with all other variables held constant, of the Group's loss before tax (due to changes in the fair values of monetary assets and liabilities).

	Increase/ (decrease) in the rate of foreign currency %	Decrease/ (increase) in loss before tax US\$'000
Year ended December 31, 2018		
If US\$ strengthens against RMB	5	343
If US\$ weakens against RMB	(5)	(343)
If US\$ strengthens against EUR	5	3,829
If US\$ weakens against EUR	(5)	(3,829)
Year ended December 31, 2019		

If US\$ strengthens against RMB	5	329
If US\$ weakens against RMB	(5)	(329)
If US\$ strengthens against EUR	5	3,310
If US\$ weakens against EUR	(5)	(3,310)

#### Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group's policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group's exposure to bad debts is not significant. For transactions that are not denominated in the functional currency of the relevant operating unit, the Group does not offer credit terms without the specific approval of the Head of Credit Control.

The credit risk of the Group's other financial assets, which comprise cash and cash equivalents, pledged deposits, financial assets at fair value through profit or loss and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments. Further quantitative data in respect of the Group's exposure to credit risk arising from trade receivables and other receivables are disclosed in notes 15 and 16 to the consolidated financial statements, respectively.

Since the Group trades only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by debtor. The Group had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 15 to the consolidated financial statements.

## Liquidity risk

The Group monitors its risk to a shortage of funds using a recurring liquidity planning tool. This tool considers the maturity of both its financial investments and financial assets (e.g., trade receivables and other financial assets) and projected cash flows from operations.



## 30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (Continued)

The maturity profile of the Group's financial liabilities as at the end of the reporting period, based on contractual undiscounted payments, is as follows:

As at December 31, 2018			
	Less than 1 years US\$'000	Over 1 years US\$'000	Total US\$'000
Trade and notes payables	7,575		7,575
Other payables and accruals	36,377	_	36,377
Lease liabilities	373	4,301	4,674
	44,325	4,301	48,626
As at December 31, 2019			
	Less than 1 years US\$'000	Over 1 years US\$'000	Total US\$'000
Trade and notes payables	years	years	
Trade and notes payables Other payables and accruals	years US\$'000	years US\$'000	US\$'000
	years US\$'000 9,586	years US\$'000 —	<u>US\$'000</u> 9,586

#### Capital management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain a strong credit rating and healthy capital ratios in order to support its business and maximise shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the reporting periods.

The Group monitors capital using a gearing ratio, which is total liabilities divided by total assets. The gearing ratios as at the end of each year were as follows:

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Total liabilities	420,398	410,584
Total assets	429,047	287,715
Gearing ratio	98%	143%

# **31. SUBSEQUENT EVENT**

#### (a) The COVID-19 coronavirus impact

The COVID-19 situation is very fluid across the world where each country or the sites within a country could be impacted differently. The Group is in the process of assessing the situation case by case as the pandemic evolves. In the US, the Group has implemented a work-from-home policy for all non-essential employees and have implemented segregation policies within essential personnel to minimize contact among personnel along with other precautions to minimize any potential impact.

Following the guidance recently issued by FDA and EMA on conducting clinical trials in this uncertain period, the Group is working closely with investigators, putting patient's safety first, while trying their best to move the studies forward.

In China, IIT studies slowed down due to clinical sites priority shifting to COVID-19 related work and local policy of quarantine after Chinese New Year. The situation has been improving gradually and majority of IIT studies work resumed since March 2020. Product manufacture and patient treatment have continued unabated, however the Group is experiencing lower enrollment rates in Cartifan-1 trial.

Product manufacturing in both the US and China have continued. Currently the Group has not experienced any material impact to their material supply chain. Increased quantities of certain raw materials and consumables have been stocked as an appropriate safety measure. The Group has established robust sourcing strategies for all necessary materials and does not expect any significant impact.

The Group will continue to monitor and assess the impact of the ongoing development of the epidemic on the financial position and operating results of the Group and respond accordingly. Up to the date of the report, the assessment is still in progress.

#### (b) Issuance of Series A Preference Shares

In March 2020 and April 2020, the Company issued and sold an aggregate of 20,591,629 Series A Preference Shares to new investors at a price of \$7.792 per share, resulting in aggregate gross proceeds of \$160,450,000.

# 32. STATEMENT OF FINANCIAL POSITION OF THE COMPANY

CONDENSED STATEMENTS OF FINANCIAL POSITION

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
NON-CURRENT ASSETS		
Investments in subsidiaries	704	1,976
Total non-current assets	704	1,976
CURRENT ASSETS		
Due from subsidiaries	3,927	3,874
Total current assets	3,927	3,874
Total assets	4,631	5,850
CURRENT LIABILITIES		
Due to subsidiaries	—	22
Other payables and accruals	58	58
Total current liabilities	58	80
Total liabilities	58	80
EQUITY		
Share capital	20	20
Reserves	4,553	5,750
Total ordinary shareholders' equity	4,573	5,770
Total equity	4,573	5,770
Total liabilities and equity	4,631	5,850

# CONDENSED STATEMENTS OF PROFIT OR LOSS

	December 31, 2018 US\$'000	December 31, 2019 US\$'000
Administrative expenses	(39)	(74)
Other expenses		(1)
LOSS BEFORE TAX	(39)	(75)
LOSS FOR THE YEAR	(39)	(75)
CONDENSED STATEMENTS OF CASH FLOWS		

	2018 US\$'000	2019 US\$'000
Net cash flows from operating activities		
Net cash flows from investing activities	_	—
Net cash flows from financing activities	—	—
Net increase in cash and cash equivalents		
Cash and cash equivalents at beginning of the year	_	—
Cash and cash equivalents at end of the year		

## 32. STATEMENT OF FINANCIAL POSITION OF THE COMPANY (Continued)

There was no cash flow for the years ended December 31, 2018 and 2019. All expenses were paid by the Company's subsidiaries. The Company issued equity-settled share options to employees of its subsidiaries and recognized investments in subsidiaries of US\$704,000 and US\$1,272,000, for the years ended December 31, 2018 and 2019, respectively.

#### **Basis of presentation**

Information about the statement of financial position of the Company at the end of the reporting period was prepared using the same accounting policies as set out in the Company's consolidated financial statements except that the parent company accounts for its investments in subsidiaries, using the cost method.

The parent company's condensed financial statements should be read in conjunction with the Company's consolidated financial statements.

# 33. APPROVAL OF THE CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements were approved and authorised for issue by the board of directors on April 20, 2020.

American Depositary Shares



Representing

Ordinary Shares

PROSPECTUS

MORGAN STANLEY

J.P. MORGAN

**JEFFERIES** 

, 2020

#### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 6. Indemnification of Directors and Officers.

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The memorandum and articles of association that we expect to adopt and to become effective immediately prior to the completion of this offering provide that we shall indemnify our directors and officers (each an indemnified person) against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such person's own dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

We intend to enter into indemnification agreements with each of our directors and executive officers prior to completion of this offering, the form of which is filed as Exhibit 10.2 to this registration statement. Under these agreements, we may agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.

The underwriting agreement, the form of which will be filed as Exhibit 1.1 to this registration statement, will also provide indemnification for us and our officers and directors for certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Item 7. Recent Sales of Unregistered Securities.

During the past three years, we have issued the following securities. We believe that each of the following issuances was exempt from registration under the Securities Act in reliance on Regulation D under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering or in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions. No underwriters were involved in these issuances of securities.

Securities/Purchaser Ordinary Shares	Date of Issuance	Number of Shares	 Consideration/ Exercise Price
GenScript Biotech Corporation	October 19, 2017	169,680,000	\$ 3,368,046.82
AquaPoint L.P.	October 19, 2017	30,320,000	\$ 559,822.75
Series A Preference Shares			
New Investors	March 31, 2020	19,308,262	\$ 150,449,977.53
New Investors	April 16, 2020	1,283,367	\$ 9,999,995.67

# **Table of Contents**

#### Options

Since January 1, 2017, we granted to employees, pursuant to our Share Option Scheme, in exchange for services rendered or to be rendered, options to purchase an aggregate of ordinary shares at a weighted average exercise price of \$

#### Assured Entitlement

Pursuant to Practice Note 15 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, in connection with this offering, GenScript intends to make available to its shareholders an "assured entitlement" to a certain portion of our ordinary shares. As our ordinary shares are not expected to be listed on any stock exchange, GenScript intends to effect its assured entitlement distribution by providing to its shareholders a "distribution in specie," or distribution of the ADSs in kind, at a ratio of one ADS for a certain number of ordinary shares of GenScript held at the applicable record date for the distribution. The distribution will be made without any consideration being paid by GenScript's shareholders. GenScript's shareholders who are entitled to fractional ADSs, who elect to receive cash in lieu of ADSs or who are located in the United States or are U.S. persons, or are otherwise ineligible holders, will only receive cash alternative in the assured entitlement distribution.

GenScript currently intends to provide an assured entitlement with an aggregate value of approximately US\$ million. The assured entitlement distribution will only be made if this offering is completed. The distribution in specie of ADSs by GenScript is not part of this offering.

#### Item 8. Exhibits and Financial Statement Schedules.

#### (a) Exhibits

#### See the Exhibit Index.

The agreements included as exhibits to this registration statement contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties were made solely for the benefit of the other parties to the applicable agreement and (i) were not intended to be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate; (ii) may have been qualified in such agreement by disclosure that was made to the other party in connection with the negotiation of the applicable agreement; (iii) may apply contract standards of "materiality" that are different from "materiality" under the applicable securities laws; and (iv) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement.

We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosure of material information regarding material contractual provisions is required to make the statements in this registration statement not misleading.

#### (b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the Consolidated Financial Statements or the Notes thereto.

#### Item 9. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

# **Table of Contents**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 6, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# EXHIBIT INDEX

Exhibit <u>Number</u>	Description of Document
1.1*	Form of Underwriting Agreement
3.1	Second Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect
3.2*	Form of Third Amended and Restated Memorandum and Articles of Association of the Registrant (effective immediately prior to the completion of this offering)
4.1	Registrant's Specimen Certificate for Ordinary Shares
4.2*	Form of Deposit Agreement between the Registrant and JP Morgan Chase Bank, N.A., as depositary
4.3*	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.2)
4.4	Investors' Rights Agreement, dated March 30, 2020, by and among the Registrant and the investors named therein
5.1*	Opinion of Harney Westwood & Riegels
10.1^	Collaboration and License Agreement among Legend Biotech USA, Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc., dated December 21, 2017, as amended
10.2*	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors
10.3+	Employment Agreement between the Registrant and Yuan Xu
10.4+	Employment Agreement between the Registrant and Ying Huang
10.5+	Share Option Scheme (including proxy form, notice of grant, notice of exercise and share purchase agreement and investment representation statement)

# **Table of Contents**

Exhibit	
Number	Description of Document
10.6	Lease Agreement between Legend Biotech USA, Inc. and Genscript USA Holding, Inc., dated February 8, 2018
10.7*	2020 Restricted Shares Plan (including form of Restricted Share Unit Award Agreement)
10.8^	Collaborative Research and License Agreement between Legend Biotech USA, Inc. and Noile-Immune Biotech, inc., dated April 27, 2020
21.1	Principal Subsidiaries of the Registrant
23.1	Consent of Ernst & Young LLP, an independent registered public accounting firm
23.2*	Consent of Harney Westwood & Riegels (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)
00.1*	Code of Dusiness Conduct and Ethics of the Desistment

99.1\* Code of Business Conduct and Ethics of the Registrant

+ Indicates management contract or compensatory plan

\* To be filed by amendment

Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the Securities and Exchange Commission, certain portions of this exhibit have been redacted because they are both not material and would be competitively harmful if publicly disclosed. The Registrant hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, an unredacted copy of this exhibit

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Somerset, New Jersey, on May 13, 2020.

#### **Legend Biotech Corporation**

By:	/s/ Yuan Xu
Name:	Yuan Xu, Ph.D.
Title:	Chief Executive Officer & Director

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Yuan Xu, Ph.D. and Ying Huang, Ph.D. and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Yuan Xu Yuan Xu, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	May 13, 2020
/s/ Ying Huang Ying Huang, Ph.D.	Chief Financial Officer (Principal Financial and Accounting Officer)	May 13, 2020
/s/ Fangliang Zhang Fangliang Zhang, Ph.D.	Chairman of the Board of Directors	May 13, 2020
/s/ Ye Wang. Ye Wang, M.S.	Director	May 13, 2020

# THE COMPANIES LAW (AS REVISED)

# SECOND AMENDED AND RESTATED

# MEMORANDUM AND

# ARTICLES OF ASSOCIATION

OF

# LEGEND BIOTECH CORPORATION

(adopted by special resolution dated March 30, 2020)

#### THE COMPANIES LAW (AS REVISED)

#### SECOND AMENDED AND RESTATED

## MEMORANDUM AND

#### ARTICLES OF ASSOCIATION

# OF

## LEGEND BIOTECH CORPORATION

(adopted by special resolution dated March 30, 2020)

- **1.** The name of the Company is Legend Biotech Corporation.
- 2. The registered office will be situated at Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, PO Box 10240, Grand Cayman, Cayman Islands KY1-1002, or at such other place in the Cayman Islands as the Directors may from time to time decide.
- **3.** The objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object that is not prohibited by any law of the Cayman Islands.
- 4. The Company shall have and be capable of exercising all the powers of a natural person of full capacity as provided by law.
- 5. The liability of the Members is limited to the amount, if any, unpaid on their shares.
- **6.** The authorised share capital of the Company is US\$50,000, divided into 479,408,371 Ordinary Shares, par value US\$0.0001 each, and 20,591,629 Series A Preference Shares, par value US\$0.0001 each.
- 7. The Company has power to register by way of continuation as a body corporate limited by shares under the laws of any jurisdiction outside the Cayman Islands and to apply for deregistration in the Cayman Islands.
- 8. Capitalised terms that are not defined herein bear the same meaning given to them in the second amended and restated Articles of Association of the Company.

		Page
1.	Interpretation	1
2.	Commencement of Business	4
3.	Issue of Shares	4
4.	Register of Members	5
5.	Voting Rights Attaching to Shares	5
6.	Closing Register of Members or Fixing Record Date	5
7.	Certificates for Shares	6
8.	Transfer of Shares	6
9.	Redemption, Repurchase and Surrender of Shares	7
10.	Share Rights	9
11.	Treasury Shares	18
12.	Variation of Rights of Shares	18
13.	Commission on Sale of Shares	20
14.	Non Recognition of Trusts	20
15.	Lien on Shares	20
16.	[Reserved]	21
17.	[Reserved]	21
18.	Transmission of Shares	21
19.	Amendments of Memorandum and Articles of Association and Alteration of Capital	21
20.	Offices and Places of Business	22
21.	General Meetings	22
22.	Notice of General Meetings	23
23.	Proceedings at General Meetings	23
24.	Votes of Members	25
25.	Proxies	25
26.	Corporate Members	26
27.	Shares that May Not be Voted	26
28.	Directors	26
29.	Powers of Directors	27
30.	Appointment, Resignation and Removal of Directors	27
31.	Vacation of Office of Director	28
32.	Proceedings of Directors	28

-i-

# Table of Contents (continued)

		Page
33.	Presumption of Assent	29
34.	Directors' Interests	29
35.	Minutes	30
36.	Delegation of Directors' Powers	30
37.	Alternate Directors	31
38.	No Minimum Shareholding	31
39.	Remuneration of Directors	32
40.	Seals and Deeds	32
41.	Dividends, Distributions and Reserve	32
42.	Capitalisation	33
43.	Books of Account	34
44.	Audit	34
45.	Notices	35
46.	Winding Up	35
47.	Indemnity and Insurance	37
48.	Financial Year	38
49.	Transfer by Way of Continuation	38
50.	Excluded Opportunity	38

-ii-

# THE COMPANIES LAW (AS REVISED)

# SECOND AMENDED AND RESTATED

# MEMORANDUM AND

# ARTICLES OF ASSOCIATION

# OF

# LEGEND BIOTECH CORPORATION

(adopted by special resolution dated March 30, 2020)

# 1. Interpretation

1.1 Table A of the First Schedule to the Law shall not apply to the Company.

1.2 In these Articles, the following terms shall have the following meanings unless the context otherwise requires:

"Articles"	means these articles of association of the Company as amended or supplemented from time to time by Special Resolution.
"Auditor"	the auditors for the time being of the Company (if any).
"Board of Directors"	means the Board of Directors of the Company.
"clear days"	means, in relation to the period of a notice, that period excluding the day on which the notice is served or deemed to be served and the day for which it is given or on which it is to take effect.
"Company"	means the above named company.
"Co-Sale Agreement"	means that certain Right of First Refusal and Co-Sale Agreement, as the same may be amended from time to time in accordance with its terms, to be entered into by and among the Company and all of the holders of the Company's Shares in connection with the issuance of the Series A Preference Shares designated in these Articles.
"Directors"	means the directors for the time being of the Company.
"Dividend"	means any dividend (whether interim or final) resolved to be paid on Shares pursuant to the Articles.
"Electronic Record"	has the same meaning as in the Electronic Transactions Law (as revised) of the Cayman Islands.
"Investors' Rights Agreement"	means that certain Investors' Rights Agreement, as the same may be amended from time to time in accordance with its terms, to be entered into by and among the Company and certain holders of the Company's Shares in connection with the issuance of the Series A Preference Shares designated in these Articles.

"Law"	means the Companies Law (as revised) of the Cayman Islands.
"Legend IP"	means the patents, know-how and all other intellectual property owned or controlled by the Company or its affiliates and licensed to Janssen Biotech, Inc. under the License Agreement.
"License Agreement"	means that certain Collaboration and License Agreement by and among Janssen Biotech, Inc., Legend Biotech USA, Inc. and Legend Biotech Ireland Limited, dated as of December 21, 2017 as in effect as of the date hereof.
"Member"	has the same meaning as in the Law.
"Memorandum"	means the memorandum of association of the Company, as amended and/or restated from time to time.
"Ordinary Resolution"	means a resolution:
	(a) passed by a simple majority of the votes attached to Shares held by such Members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of the Company; or
	(b) a written resolution signed by all of the Members entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Members and the effective date of the resolution so adopted shall be the date on which the instrument, or the last of such instruments, if more than one, is executed.
"Ordinary Shares"	means an ordinary share in the capital of the Company of US\$0.0001 nominal or par value designated as an Ordinary Share and having the rights provided for under these Articles.
"Preference Shares"	means a share in the capital of the Company designated as a Preference Share and having the rights provided for under these Articles, and includes the Series A Preference Shares.
"Registered Office"	the registered office of the Company in the Cayman Islands as of the date hereof, which is at Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, PO Box 10240, Grand Cayman, Cayman Islands KY1-1002.

	"Register of Members"	the register of Members to be kept in accordance with the Law and includes every duplicate Register of Members.
	"SEC"	means the Securities and Exchange Commission of the United States of America.
	"Seal"	the common seal of the Company (if any) and includes every duplicate seal.
	"Securities Act"	means the Securities Act of 1933, as amended, of the United States of America.
	"Series A Preference Shares"	means a Preference Share designated as a Series A Preference Share and having the rights provided for under these Articles.
	"Share" and "Shares"	means a share or shares in the Company and includes Ordinary Shares and Preference Shares, and fractions of shares in the Company.
	"Shareholder Agreements"	means, collectively, the Co-Sale Agreement and the Investors' Rights Agreement.
	"Special Resolution"	means a resolution that is described as such in its terms:
		(a) passed by the holders of not less than two thirds of the votes attached to Shares held by such Members as, being entitled to do so, vote in person or by proxy, at a duly convened general meeting of the Company; or
		(b) a written resolution signed by all of the Members entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Members and the effective date of the resolution so adopted shall be the date on which the instrument, or the last of such instruments, if more than one, is executed.
	"Treasury Share"	means a Share held in the name of the Company as a treasury share in accordance with the Law.
2	In the Articles:	

- 1.3 In the Articles:
  - (a) Words importing the singular number include the plural number and vice versa.
  - (b) Words importing the masculine gender include the feminine gender.
  - (c) Words importing persons include corporations and any other legal or natural persons.

- (d) Any reference to writing includes all modes of representing or reproducing words in a visible and legible form, including in the form of an Electronic Record.
- (e) The word **may** shall be construed as permissive and the word **shall** shall be construed as imperative.
- (f) Any phrase introduced by the terms **including**, **include**, **in particular** or any similar expression shall be merely illustrative and shall not limit the sense of the words preceding those terms.
- (g) Where any provision of the Law is referred to, the reference is to that provision as modified by any subsequent law for the time being in force.
- (h) Unless the context otherwise requires, words and expressions defined in the Law bear the same meanings in these Articles.
- (i) References to **days** are to calendar days, unless otherwise specified.
- (j) Headings are used for convenience only and shall not affect the construction of these Articles.
- (k) In the event of any conflict or inconsistency between any of the terms of these Articles and any of the terms of the Shareholder Agreements, the terms of the Shareholder Agreements shall prevail in all respects, the parties shall give full effect to and act in accordance with the provisions of the Shareholder Agreements over the provisions of these Articles, and the parties shall exercise all voting and other rights and powers (including to procure any required alteration to these Articles to resolve such conflict or inconsistency) to make the provisions of the Shareholder Agreements effective.

## 2. Commencement of Business

- 2.1 The business of the Company may be commenced as soon after incorporation of the Company as the Directors shall see fit.
- 2.2 The Directors may pay, out of the capital or any other monies of the Company, all expenses incurred in or about the formation and establishment of the Company, including the expenses of registration.

#### 3. Issue of Shares

- 3.1 Subject to the provisions, if any, in the Memorandum (and to any direction that may be duly given by the Company in general meeting) and the Shareholder Agreements, and without prejudice to any rights attached to any existing Shares, the Directors may allot, issue, grant options over or otherwise dispose of Shares (including fractions of a Share) with or without preferred, deferred or other rights or restrictions, whether in regard to Dividend or other distribution, voting, return of capital or otherwise and to such persons, at such times and on such other terms as they think proper, and may also (subject to the Law and the Articles) vary such rights.
- 3.2 The Company shall not issue Shares to bearer.

3.3 The Preference Shares may be issued from time to time in one or more series. The first series of Preference Shares shall be designated "Series A Preference Shares" and shall consist of 20,591,629 shares.

#### 4. Register of Members

- 4.1 The Company shall maintain or cause to be maintained the Register of Members in accordance with the Law.
- 4.2 The Directors may determine that the Company shall maintain one or more branch registers of Members in accordance with the Law. The Directors may also determine which register of Members shall constitute the principal register and which shall constitute the branch register or registers, and to vary such determination from time to time.

# 5. Voting Rights Attaching to Shares

5.1 The holders of Shares shall (in respect of such shares) have the right to receive notice of, attend at and vote as a Member at any general meeting of the Company. Every holder of Ordinary Shares present in person or by proxy at any meeting shall on a show of hands be entitled to one vote per Ordinary Share and, on a poll, shall be entitled to one vote per Ordinary Share held by such holder. Every holder of Preference Shares present in person or by proxy at any meeting shall on a show of hands be entitled to the number of ordinary Shares into which such Preference Shares could be converted at the time of the vote at the Conversion Price then in effect, and on a poll, shall be entitled to the number of votes equal to the number of the poll at the Conversion Price then in effect.

## 6. Closing Register of Members or Fixing Record Date

- 6.1 For the purpose of determining Members entitled to notice of, or to vote at any meeting of Members or any adjournment thereof, or Members entitled to receive payment of any Dividend or other distribution, or in order to make a determination of Members for any other purpose, the Directors may provide that the Register of Members shall be closed for transfers for a stated period which shall not in any case exceed 40 days.
- 6.2 In lieu of, or apart from, closing the Register of Members, the Directors may fix in advance or arrears a date as the record date for any such determination of Members entitled to notice of, or to vote at any meeting of the Members or any adjournment thereof, or for the purpose of determining the Members entitled to receive payment of any Dividend or other distribution, or in order to make a determination of Members for any other purpose.
- 6.3 If the Register of Members is not so closed and no record date is fixed for the determination of Members entitled to notice of, or to vote at, a meeting of Members or Members entitled to receive payment of a Dividend or other distribution, the date on which notice of the meeting is sent or the date on which the resolution of the Directors resolving to pay such Dividend or other distribution is passed, as the case may be, shall be the record date for such determination of Members. When a determination of Members entitled to vote at any meeting of Members has been made as provided in this Article, such determination shall apply to any adjournment thereof.

## 7. Certificates for Shares

- 7.1 A Member shall only be entitled to a Share certificate if (a) the Directors resolve that Share certificates shall be issued or (b) such Member submits a written request to the Board requesting that a Share certificate be issued for such Member's Shares. Share certificates, if any, representing Shares, shall be in such form as the Directors may determine. Share certificates shall be signed by one or more Directors or other person authorised by the Directors. The Directors may authorise certificates to be issued with the authorised signature(s) affixed by mechanical process. All certificates for Shares shall be consecutively numbered or otherwise identified and shall specify the Shares to which they relate. All certificates surrendered to the Company for transfer shall be cancelled and subject to the Articles no new certificate shall be issued until the former certificate representing a like number of relevant Shares shall have been surrendered and cancelled.
- 7.2 The Company shall not be bound to issue more than one certificate for Shares held jointly by more than one person and delivery of a certificate to one joint holder shall be a sufficient delivery to all of them.
- 7.3 If a share certificate is defaced, worn out, lost or destroyed, it may be renewed on such terms (if any) as to evidence and indemnity and on the payment of such expenses reasonably incurred by the Company in investigating evidence, as the Directors may prescribe, and (in the case of defacement or wearing out) upon delivery of the old certificate.
- 7.4 Every share certificate sent in accordance with the Articles will be sent at the risk of the Member or other person entitled to the certificate. The Company will not be responsible for any share certificate lost or delayed in the course of delivery.

## 8. Transfer of Shares

- 8.1 Shares are transferable subject to the consent of the Directors who may, in their absolute discretion, decline to register any transfer of Shares without giving any reason; <u>provided</u>, <u>however</u>, that the Directors shall promptly register any transfer of Shares made in accordance with the provisions of the Investors' Rights Agreement and the Co-Sale Agreement, in a timely manner as set forth in such Shareholder Agreements. The Directors may, as a precondition to the sale or transfer of any Ordinary Shares, except as otherwise provided in any of the Shareholder Agreements, request either (a) a written opinion of legal counsel (which can, for the avoidance of doubt, be an opinion issued by the in-house counsel of a Member) who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act, (b) a "no action" letter from the SEC to the effect that the proposed sale or transfer of such Ordinary Shares without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto or (c) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale or transfer of such Ordinary Shares may be effected without registration under the Securities Act. If the Directors refuse to register a transfer they shall notify the transferee promptly of such refusal, but in no event more than two business days after such determination.
- 8.2 The instrument of transfer of any Share shall be in writing and shall be executed by or on behalf of the transferor (and if the Directors so require, signed by or on behalf of the transferee). The transferor shall be deemed to remain the holder of a Share until the name of the transferee is entered in the Register of Members.

#### 9. Redemption, Repurchase and Surrender of Shares

- 9.1 General.
  - (a) Subject to the provisions of the Law and subject to the terms set forth herein and in the Shareholder Agreements, the Company may purchase its own Shares in such manner and on such other terms as the Directors may agree with the relevant Member; <u>provided</u>, <u>however</u>, the Company shall redeem any Series A Preference Shares as provided for herein; <u>provided</u>, <u>further</u>, <u>however</u>, if at any time the Company redeems any Series A Preference Shares pursuant to any terms that vary from (including any terms that are in addition to) the terms of these Articles, the Company shall thereafter offer equivalent terms to every holder of Series A Preference Shares then outstanding.
  - (b) The Company may, subject to the terms set forth herein and in the Shareholder Agreements, make a payment in respect of the redemption or purchase of its own Shares in any manner permitted by the Law, including out of capital.
  - (c) Except as provided for herein, the Directors may accept the surrender for no consideration of any fully paid Share.
- 9.2 <u>Ordinary Shares</u>. The Ordinary Shares shall not be redeemable at the option of the holder thereof.
- 9.3 Preference Shares.
  - Redemption Request. At any time on or after the occurrence of a Trigger Event (as defined below), each holder of Series A Preference (a) Shares may, at such holder's sole discretion and on more than one occasion, deliver a written notice to the Company requesting redemption on a specified date (the "Redemption Date") of all or any portion of the Series A Preference Shares then held by such holder (a "Redemption Request"), which Redemption Date shall be no sooner than 30 calendar days following notice of the Redemption Request, except as otherwise provided in Article 9.3(d). Following notice of a Redemption Request from a holder of Series A Preference Shares, subject to the provisions of the Law, the Company shall redeem the Series A Preference Shares of such holder that are subject to such Redemption Request (the "Redemption Shares") on the Redemption Date at a price per share equal to the Redemption Price (as defined below). Upon receipt of a Redemption Request the Company shall apply all of its assets to any such redemption, and to no other corporate purpose, except to the extent prohibited by the Law. If, on any Redemption Date, the Law prevents the Company from redeeming all Series A Preference Shares to be redeemed, such holder of Series A Preference Shares that has submitted a Redemption Request may choose to withdraw such Redemption Request at such holder's sole discretion at any time prior to the Redemption Date. In such instance, if such holder does not choose to withdraw such Redemption Request, the Company shall ratably redeem the maximum number of shares that it may redeem consistent with the Law, and shall redeem the remaining shares as soon as it may lawfully do so under the Law. The "Redemption Price" shall equal the sum of (i) the Series A Original Issue Price (as defined below), plus (ii) an amount equal to 8% per annum accruing on the Series A Original Issue Price, calculated on an annualized basis from the date of issuance thereof through and including the Redemption Date, plus (iii) any Dividends accrued but unpaid on each Series A Preference Share as of the Redemption Date. A "Trigger Event" means the occurrence of one or more of the following events: (A) as of September 30, 2021, the Company has not consummated a Qualified IPO (as defined below), (B) the Company consummates a non-Qualified IPO, (C) the License

Agreement (i) is terminated as a result of a material breach by any party thereto or (ii) is amended in such a way that with (or without) the passage of time would reasonably be expected to adversely affect the value of the Company or the Series A Preference Shares in any material respect and (D) there occurs or it is discovered that there is a material adverse issue with respect to the Legend IP, which is not capable of being cured within a reasonable period (or, if curable, such issue has not been cured in full within 30 days of the issue arising). In furtherance of the foregoing, so long as any Series A Preference Shares remain outstanding, the Company shall give each holder of Series A Preference Shares prompt written notice of (i) the occurrence of any material breach or threatened or expected material breach of the License Agreement, (ii) any other event or circumstance that would reasonably be expected to result in a material adverse issue with respect to the Legend IP. In each case, any such written notice shall include an explanation of the facts and circumstances that have arisen and the Company's plan to address such facts and circumstances. In any such case, and without limiting any other reasonably informed as to the foregoing facts and circumstances.

- (b) Pro Rata Redemption. If at any time the available funds of the Company legally available for redemption are insufficient to fully redeem the Redemption Shares tendered for redemption as of a Redemption Date in accordance with this Article 9 (a "Default"), redemption shall be made on a pro rata basis among the holders of Series A Preference Shares that submitted a Redemption Request in proportion to the aggregate Redemption Price that each such holder would otherwise be entitled to receive on the applicable Redemption Date and any portion of the Redemption Price that is not paid in full as of the Redemption Date on which it is due hereunder shall accrue interest at a rate of 16% per annum, accruing daily and compounding annually, until such Redemption Price and all accrued but unpaid interest thereon are paid in full, and any payments hereunder after the Redemption Date shall be applied first to the costs of collections and any other expenses incurred in connection with collecting such payments, second to the accrued and unpaid interest accruing under this Article 9(b) and thereafter to payment of the Redemption Price. Upon a Default, the Company shall deliver the affected holder a promissory note evidencing the indebtedness owed to such holder, the form of such promissory note to be reasonably agreed upon by the parties at the time of Default.
- (c) <u>Surrender of Certificates; Payment</u>. On or before the applicable Redemption Date, each holder of Redemption Shares that are to be redeemed on such Redemption Date, shall, if a holder of shares in certificated form, surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Company to indemnify the Company against any claim that may be made against the Company on account of the alleged loss, theft or destruction of such certificate) to the Company, in the manner and at the place reasonably requested by the Company, and thereupon the Redemption Price for such Redemption Shares shall be payable to the order of the person whose name appears on such certificate or certificates, instrument, or book entry representing the unredeemed Series A Preference Shares shall promptly be issued to such holder.

- (d) <u>Notice of Redemption Request</u>. If a Redemption Request shall have been duly made by a Series A Preference Share holder, the Company shall deliver to all holders of any Series A Preference Shares a written notice (a "**Redemption Notice**") setting forth the details of such Redemption Request (including the Redemption Date, the number of Redemption Shares, the Redemption Price, and the Trigger Event constituting the basis for such Redemption Request) within two business days of receiving such a Redemption Request, and any holders of Series A Preference Shares who elect by written notice to exercise their right to submit a Redemption Request pursuant to Article 9.3(a) above within ten days of a Redemption Notice shall be entitled to participate in the redemption of Redemption Shares on the Redemption Date set forth in the Redemption Notice.
- (e) <u>Rights Subsequent to Redemption</u>. If a Redemption Request shall have been duly made, and if on the applicable Redemption Date the Redemption Price payable upon redemption of the Series A Preference Shares to be redeemed on such Redemption Date is paid in full or tendered for payment or deposited with an independent payment agent so as to be available therefor in full and in a timely manner, then notwithstanding that any certificates evidencing any of the Series A Preference Shares so called for redemption shall not have been surrendered, Dividends with respect to such Series A Preference Shares shall cease to accrue after such Redemption Date, and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of any such certificate or certificates therefor.
- (f) <u>Redeemed or Otherwise Acquired Shares</u>. Any Series A Preference Shares that are redeemed or otherwise acquired by the Company or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Company nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Series A Preference Shares following redemption.
- (g) <u>Amendment and Waiver</u>. The rights, powers, preferences and other terms of the Series A Preference Shares set forth in this Article 9.3 may not be amended, modified, terminated or waived with respect to any holder of Series A Preference Shares (in such case, an "Affected Holder") without the affirmative written consent or vote of such Affected Holder of Series A Preference Shares.

#### 10. Share Rights

The Preference Shares and Ordinary Shares of the Company shall have the following rights, preferences, privileges and be subject to the following restrictions:

10.1 <u>Cumulative Dividends</u>. From and after the date of the issuance of any Series A Preference Shares, Dividends at the rate of 8% of the Series A Original Issue Price per annum per share shall accrue on such Series A Preference Shares (subject to appropriate adjustment in the event of any share Dividend, share split, combination or other similar recapitalization with respect to the Series A Preference Shares). Such Dividends (i) shall be declared by the Board of Directors and paid to the holders of Series A Preference Shares each fiscal quarter, or (ii) if not declared and, with respect to any fiscal quarter, paid to the holders of Series A Preference Shares within thirty days after such fiscal quarter, such undeclared and unpaid Dividends shall accrue day to day from the last day of such fiscal quarter, shall be cumulative and compound annually, and shall only be paid

upon a Redemption or Liquidation Event in the manner set forth herein or converted into Ordinary Shares upon an IPO. The Company shall not declare, pay or set aside any Dividends on shares of any other class or series of shares of the Company (other than Dividends on Ordinary Shares payable in Ordinary Shares) unless (in addition to the obtaining of any consents required elsewhere in these Articles) the holders of the Series A Preference Shares then outstanding shall first receive, or simultaneously receive, a Dividend on each outstanding Series A Preference Share in an amount at least equal to the sum of (a) the amount of the aggregate Dividends then accrued on such Series A Preference Share and not previously paid and (b) (i) in the case of a Dividend on Ordinary Shares or any class or series that is convertible into Ordinary Shares, that Dividend per Series A Preference Share as would equal the product of (x) the Dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Ordinary Shares and (y) the number of Ordinary Shares issuable upon conversion of a Series A Preference Share, in each case calculated on the record date for determination of holders entitled to receive such Dividend, or (ii) in the case of a Dividend on any class or series that is not convertible into Ordinary Shares, at a rate per Series A Preference Share determined by (1) dividing the amount of the Dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any share Dividend, share split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the Series A Original Issue Price; provided that if the Company declares, pays or sets aside, on the same date, a Dividend on shares of more than one class or series of shares of the Company, the Dividend payable to the holders of Series A Preference Shares pursuant to this Article 10.1 shall be calculated based upon the Dividend on the class or series of shares that would result in the highest Series A Preference Share Dividend. The "Series A Original Issue Price" means US\$7.792 per Series A Preference Share, subject to appropriate adjustment in the event of any share Dividend, share split, combination or other similar recapitalization with respect to the Series A Preference Shares.

#### 10.2 Voting Rights.

- (a) Except as expressly provided by these Articles or as provided by Law, the holders of Preference Shares shall have the same voting rights as the holders of Ordinary Shares and shall be entitled to notice of any shareholders' meeting in accordance with these Articles, and the holders of Ordinary Shares and Preference Shares shall vote together as a single class on all matters. For purposes of all matters that require a vote of Members, each holder of Ordinary Shares shall be entitled to one vote for each such Ordinary Share held, and each holder of Preference Shares shall be entitled to the number of votes equal to the number of Ordinary Shares into which such Preference Shares could be converted. Fractional votes shall not, however, be permitted and any fractional voting rights available on an as-converted basis (after aggregating all shares into which Preference Shares held by each holder could be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).
- (b) Subject to Article 28.1, at each annual general meeting of the Members, or at any general meeting of the Members at which Directors are to be elected, or whenever Directors are to be elected by written consent, (i) from and after September 30, 2021, if a Qualified IPO has not occurred by such date, and provided that the total number of outstanding Series A Preference Shares represents at least 5% of the Company's fully-diluted capitalization at such time (including shares reserved for issuance under any equity incentive plan), without taking into consideration any issuance of equity securities by the Company after the Purchase Date (as defined below), the holders of the Series A

Preference Shares voting as a separate class shall be entitled to elect one Director (the "**Series A Director**"), and (ii) the holders of the Ordinary Shares, voting as a separate class, shall be entitled to elect any remaining Directors. Only a class of holder or holders having the right to elect a Director pursuant to the foregoing may remove its designated Director at any time and from time to time, with or without cause (subject to any requirements of law), in their sole discretion.

- 10.3 Liquidation. The Preference Shares shall carry a preferential entitlement to distributions on a winding up of the Company as provided in Article 46.
- 10.4 <u>Conversion</u>. The holders of the Preference Shares shall have conversion rights as follows (the "Conversion Rights"):
  - (a) <u>Right to Convert</u>. Subject to and in compliance with the provisions of this Article 10.4, each Series A Preference Share shall be convertible, at the option of the holder thereof, at any time after the date of issuance of such Series A Preference Share, at the office of the Company or any transfer agent for such Series A Preference Shares, into such number of fully paid and non-assessable Ordinary Shares as is determined by dividing the Series A Original Issue Price (plus any Dividends accrued but unpaid on each Series A Preference Share), by the Conversion Price (as defined below) applicable to such Series A Preference Share and in effect on the date of the notice of conversion. The initial "Conversion Price" per Series A Preference Share shall be US\$7.792; provided, however, should a holder choose to convert a Series A Preference Share pursuant to this Article 10.4(a) at or following a public offering of the Company that is not a Qualified IPO (as defined below), the Conversion Price shall equal the lower of (i) the Conversion Price then in effect for such share as otherwise determined pursuant to this Article 10.4(a), and (ii) the lowest net price per share (before discounts or commissions payable to underwriters, placement agents, or the like) received by the Company in such public offering. In addition to the foregoing, the Conversion Price shall be subject to adjustment as set forth in Article 10.4(d).
  - (b) <u>Automatic Conversion</u>. Each Series A Preference Share shall automatically be converted immediately prior to, but conditioned upon, the closing of a Qualified IPO (as defined below) into a number of fully paid and non-assessable Ordinary Shares as is determined by dividing the Series A Original Issue Price (plus any Dividends accrued but unpaid on each Series A Preference Share) by the Qualified IPO Conversion Price (as defined below) applicable to such Series A Preference Share and in effect on the date of the Qualified IPO. The term "Qualified IPO" shall mean the Company's first sale of its Ordinary Shares (or other securities of the Company) in a firm commitment underwritten public offering pursuant to a registration statement after which the Ordinary Shares (or other securities of the Company) are listed on the New York Stock Exchange, the NASDAQ global market or The Stock Exchange of Hong Kong Limited, and in which the public offering price results in aggregate gross proceeds to the Company of not less than US\$200,000,000 (before underwriter's commissions, discounts and expenses). The "Qualified IPO Conversion Price" shall equal the lower of (i) the Conversion Price at the time in effect for such Series A Preference Share and (ii) the price per share that equals 90% of the lowest net price per Ordinary Share (or other security of the Company) (before discounts or commissions payable to underwriters, placement agents, or the like) received by the Company in the Qualified IPO.

#### (c) <u>Mechanics of Conversion</u>.

- (i) To convert any Preference Shares into Ordinary Shares, in whole or in part, pursuant to Article 10.4(a) on any date, the holder thereof shall transmit by electronic mail (or otherwise deliver) a written notice of such conversion (a "Voluntary Conversion Notice"). The Company shall give effect to any such conversion pursuant to Article 10.4(a) as of the date on which such Voluntary Conversion Notice is given by the holder thereof, and the holder of such Preference Shares shall not be required to deliver or physically surrender the certificate(s) representing the Preference Shares to the Company unless and until all Preference Shares then held by such holder have been converted in full into Ordinary Shares.
- (ii) The Company shall give effect to any conversion of Preference Shares into Ordinary Shares pursuant Article 10.4(b) immediately upon the consummation of the Qualified IPO, without regard to whether any such holder has delivered or physically surrendered the certificate(s) representing the Preference Share to the Company or its transfer agent.
- (iii) In each case, whether upon delivery of a Voluntary Conversion Notice pursuant to Article 10.4(c)(i), or upon the consummation of a Qualified IPO, the Company shall (x) promptly make entries in the register of members of the Company in order to record and give effect to the redemption of the corresponding Preference Shares and the issue and allotment of the resulting new Ordinary Shares as of the corresponding date set forth in clause (i) or (ii) above, and (y) promptly thereafter, but in any case within two business days of the effective date of such conversion, issue and deliver to such holder of Preference Shares, or to the nominee or nominees of such holder, a certificate or certificates for the number of Ordinary Shares to which such holder shall be entitled as aforesaid.
- (iv) The person or persons entitled to receive the Ordinary Shares issuable upon any such conversion pursuant to this Article 10.4(c) shall be treated for all purposes as the record holder or holders of such Ordinary Shares as of the corresponding date set forth in clause (i) or (ii) above.
- (v) If a conversion is in connection with an underwritten public offering of securities, the conversion may, at the option of any holder tendering Preference Shares for conversion, be conditioned upon the closing with the underwriters of the sale of securities pursuant to such offering, in which event any persons entitled to receive Ordinary Shares upon conversion of such Preference Shares shall not be deemed to have converted such Preference Shares until immediately prior to the closing of such sale of securities.
- (d) <u>Conversion Price Adjustments of Preference Shares for Certain Dilutive Issuances, Splits and Combinations</u>. The Conversion Price of the Preference Shares shall be subject to adjustments from time to time as follows:
  - (i) <u>Issuance of Additional Shares below Purchase Price</u>. If the Company should issue, at any time after the date upon which any Series A Preference Shares were first issued (the "**Purchase Date**"), any Additional Shares (as defined below) for a consideration per share less than the Conversion Price for the Series A Preference Shares in effect immediately prior to the issuance of such Additional Shares, then the Conversion Price for the Series A Preference Shares shall be reduced, concurrently with such issuance or deemed issuance, to the lowest net

consideration per share (before discounts or commissions payable to underwriters, placement agents, or the like) received by the Company for such issuance or deemed issuance of the Additional Shares; <u>provided</u> that if such issuance or deemed issuance was without consideration, then the Company shall be deemed to have received an aggregate of US\$0.001 of consideration for all such Additional Shares issued or deemed to be issued.

- (A) <u>Definition of "Additional Shares</u>". For the purposes of this Article 10.4(d), "Additional Shares" shall mean any Ordinary Shares issued (or deemed to have been issued pursuant to Article 10.4(d)(i)(D)) by the Company after the Purchase Date, other than:
  - (1) Ordinary Shares issued pursuant to share Dividends, share sub-divisions, recapitalisations or similar transactions, as described in Article 10.4(d)(ii) hereof;
  - (2) Ordinary Shares and/or options therefor issued or issuable to employees, consultants or directors of the Company pursuant to a share option plan or restricted share purchase plan approved by the Board of Directors; provided, that any such issuance or grant after the Purchase Date, and any plan approved by the Board of Directors after the Purchase Date, also shall require consent pursuant to Article 12.1(a);
  - (3) Ordinary Shares or Preference Shares issuable upon exercise of warrants, notes, or other rights to acquire Shares of the Company outstanding as of the date of these Articles;
  - (4) Shares, or warrants or options to purchase Shares, issued in connection with bona fide acquisitions, mergers or similar strategic transactions, not to exceed, in the aggregate, 5% of the Company's fully diluted capitalization as of the date of the first such issuance, the terms of which are approved by the Board of Directors and, to the extent applicable, the holders of a majority of the issued and outstanding Series A Preference Shares pursuant to Article 12.1(a);
  - (5) Ordinary Shares issued or issuable upon conversion of the Series A Preference Shares;
  - (6) Ordinary Shares (or other securities of the Company) issued or issuable in a Qualified IPO prior to or in connection with which all issued and outstanding Preference Shares will be converted to Ordinary Shares;
  - (7) Shares, or warrants or options to purchase Shares, issued to an entity as a component of any business relationship with such entity for the purpose of (i) joint venture, technology licensing or development activities, (ii) distribution, supply or manufacture of the Company's products or services or (iii) any other arrangements involving corporate partners that are primarily for purposes other than raising capital, in each case not to exceed, in

the aggregate, 5% of the Company's fully diluted capitalization as of the date of the first such issuance, the terms of which business relationship with such entity are approved by the Board of Directors and, to the extent applicable, the holders of a majority of the issued and outstanding Series A Preference Shares pursuant to Article 12.1(a); and

- (8) Shares that the holders of a majority of the issued and outstanding Series A Preference Shares elect in writing to exclude from the definition of "Additional Shares" for purposes of this Article 10.4(d).
- (B) <u>No Fractional Adjustments</u>. No adjustment of the Conversion Price for a series of Preference Shares shall be made in an amount less than one-tenth of a cent per share, <u>provided</u> that any adjustments which are not required to be made by reason of this sentence shall be carried forward and shall be either taken into account in any subsequent adjustment made prior to three years from the date of the event giving rise to the adjustment being carried forward, or shall be made at the end of three years from the date of the event giving rise to the adjustment being carried forward.
- (C) Determination of Consideration. In the case of the issuance of Ordinary Shares for cash, the consideration shall be deemed to be the net amount of cash paid therefor before deducting any reasonable discounts or commissions payable by the Company for any underwriting or placement agents in connection with the issuance and sale thereof. In the case of the issuance of Ordinary Shares for a consideration in whole or in part other than cash, the consideration other than cash shall be deemed to be the fair value thereof as determined by the Board of Directors irrespective of any accounting treatment, subject to the written consent of the holders of a majority of the issued and outstanding Series A Preference Shares, which written consent shall not be unreasonably withheld, conditioned or delayed.
- (D) <u>Deemed Issuances of Ordinary Shares</u>. In the case of the issuance (whether before, on or after the applicable Purchase Date) of securities or rights convertible into (including upon an automatic conversion pursuant to Article 10.4(b)), or entitling the holder thereof to receive directly or indirectly, additional Ordinary Shares (the "Ordinary Shares Equivalents"), the following provisions shall apply for all purposes of this Article 10.4(d)(i):
  - (1) The aggregate maximum number of Ordinary Shares deliverable upon conversion, exchange or exercise (assuming the satisfaction of any conditions to convertibility, exchangeability or exercisability, including, without limitation, the passage of time, but without taking into account potential antidilution adjustments) of any Ordinary Shares Equivalents and subsequent conversion, exchange or exercise thereof shall be deemed to have been issued at the time such securities were issued or such Ordinary Shares Equivalents were issued and for a consideration

equal to the net consideration, if any, received by the Company for any such securities and related Ordinary Shares Equivalents (excluding any cash received on account of accrued interest or accrued Dividends), plus the minimum additional net consideration, if any, to be received by the Company (without taking into account potential anti-dilution adjustments) upon the conversion, exchange or exercise of any Ordinary Shares Equivalents (the consideration in each case to be determined in the manner provided in Article 10.4(d)(i)(C)).

- (2) In the event of any change in the number of Ordinary Shares deliverable or in the consideration payable to the Company upon conversion, exchange or exercise of any Ordinary Shares Equivalents, other than a change resulting from the anti-dilution provisions thereof, the Conversion Price of a series of Preference Shares, to the extent in any way affected by or computed using such Ordinary Shares Equivalents, shall be recomputed to reflect such change, but no further adjustment shall be made for the actual issuance of Ordinary Shares or any payment of such consideration upon the conversion, exchange or exercise of such Ordinary Shares Equivalents.
- (3) Upon the termination or expiration of the convertibility, exchangeability or exercisability of any Ordinary Shares Equivalents, the Conversion Price of any series of the Preference Shares, to the extent in any way affected by or computed using such Ordinary Shares Equivalents, shall be recomputed to reflect the issuance of only the number of Ordinary Shares (and Ordinary Shares Equivalents that remain convertible, exchangeable or exercisable) actually issued upon the conversion, exchange or exercise of such Ordinary Shares Equivalents.
- (4) The number of Ordinary Shares deemed issued and the consideration deemed paid therefor pursuant to Article 10.4(d) (i)(D)(1) shall be appropriately adjusted to reflect any change, termination or expiration of the type described in either Article 10.4(d)(i)(D)(2) or Article 10.4(d)(i)(D)(3).
- (E) <u>No Increased Conversion Price</u>. Notwithstanding any other provisions of this Article 10.4(d)(i), except to the limited extent provided for in Article 10.4(d)(i)(D)(2) and Article 10.4(d)(i)(D)(3), no adjustment of the Conversion Price pursuant to this Article 10.4(d)(i) shall have the effect of increasing the Conversion Price above the Conversion Price in effect immediately prior to such adjustment.
- (ii) <u>Share Splits and Dividends</u>. In the event the Company should at any time after the Purchase Date fix a record date for the effectuation of a split or subdivision of the issued and outstanding Ordinary Shares or the determination of holders of Ordinary Shares entitled to receive a Dividend or other distribution payable in additional Ordinary Shares or Ordinary Shares Equivalents without payment of any consideration by such holders for the additional Ordinary Shares or the

Ordinary Shares Equivalents (including the additional Ordinary Shares issuable upon conversion or exercise thereof), then, as of such record date (or the date of such Dividend distribution, split or subdivision if no record date is fixed), the Conversion Price of each series of Preference Shares shall be appropriately decreased so that the number of Ordinary Shares issuable on conversion of each share of such series shall be increased in proportion to such increase of the aggregate of Ordinary Shares outstanding and those issuable with respect to such Ordinary Shares Equivalents with the number of shares issuable with respect to Ordinary Shares Equivalents determined from time to time in the manner provided for deemed issuances in Article 10.4(d)(i)(D).

- (iii) <u>Reverse Share Splits</u>. If the number of Ordinary Shares issued and outstanding at any time after the Purchase Date is decreased by a combination or consolidation of the issued and outstanding Ordinary Shares, then, following the record date of such combination or consolidation, the Conversion Price for a series of Preference Shares shall be appropriately increased so that the number of Ordinary Shares issuable on conversion of each share of such series shall be decreased in proportion to such decrease in outstanding shares.
- (e) <u>Other Distributions</u>. In the event the Company shall declare a distribution payable in securities of other persons, evidences of indebtedness issued by the Company or other persons, assets (excluding cash Dividends) or options or rights not referred to in Articles 10.4(d)(i) or 10.4(d)(ii), then, in each such case for the purpose of this Article 10.4(e), the holders of Preference Shares shall be entitled to a proportionate share of any such distribution as though they were the holders of the number of Ordinary Shares of the Company into which their Preference Shares are convertible as of the record date fixed for the determination of the holders of Ordinary Shares of the Company entitled to receive such distribution.
- (f) <u>Recapitalisations</u>. If at any time or from time to time there shall be a recapitalisation of the Ordinary Shares (other than a subdivision, combination or merger or sale of assets transaction provided for elsewhere in this Article 10.4 or in Article 46) provision shall be made so that the holders of the Preference Shares shall thereafter be entitled to receive upon conversion of such Preference Shares the number of shares or other securities or property of the Company or otherwise, to which a holder of Ordinary Shares deliverable upon conversion would have been entitled on such recapitalisation. In any such case, appropriate adjustment shall be made in the application of the provisions of this Article 10.4 with respect to the rights of the holders of such Preference Shares after the recapitalisation to the end that the provisions of this Article 10.4 (including, with respect to the Preference Shares) shall be applicable after that event and be as nearly equivalent as practicable.

#### (g) <u>No Fractional Shares and Certificate as to Adjustments</u>.

- (i) No fractional shares shall be issued upon the conversion of any Preference Shares and the number of Ordinary Shares to be issued shall be rounded down to the nearest whole share. In lieu of fractional shares, the Company will pay cash in an amount equal to the fair value of such fractional shares, based on their fair market value of the Ordinary Shares, as determined in good faith by the Board of Directors, as of the time when those who would otherwise be entitled to receive such fractional shares is determined. The number of shares issuable upon such conversion shall be determined on the basis of the total number of Preference Shares the holder is at the time converting into Ordinary Shares and the number of Ordinary Shares issuable upon such aggregate conversion.
- (ii) Upon the occurrence of each adjustment or readjustment of the Conversion Price of Preference Shares pursuant to this Article 10.4, the Company, at its expense, shall promptly compute such adjustment or readjustment in accordance with the terms hereof and prepare and furnish to each holder of such Preference Shares a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Company shall, upon the written request at any time of any holder of Preference Shares, furnish or cause to be furnished to such holder a like certificate setting forth (A) such adjustment and readjustment, (B) the Conversion Price for such series of Preference Shares at the time in effect, (C) the number of Ordinary Shares and the amount, if any, of other property which at the time would be received upon the conversion of such series of Preference Shares, and (D) if a cash payment is to be made pursuant to Article 10.4(g)(i), the amount of such cash payment.
- (h) <u>Notices of Record Date</u>. In the event of any taking by the Company of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any Dividend (other than a cash Dividend) or other distribution, any right to subscribe for, purchase or otherwise acquire any shares of any class or any other securities or property, or to receive any other right, the Company shall mail to each holder of Preference Shares, at least ten days prior to the date specified therein, a notice specifying the date on which any such record is to be taken for the purpose of such Dividend, distribution or right, and the amount and character of such Dividend, distribution or right.
- (i) <u>Reservation of Shares Issuable Upon Conversion</u>. The Company shall at all times reserve and keep available out of its authorised but unissued Ordinary Shares, solely for the purpose of effecting the conversion of the Preference Shares, such number of its Ordinary Shares as shall from time to time be sufficient to effect the conversion of all issued and outstanding shares of such series of Preference Shares; and if at any time the number of authorised but unissued Ordinary Shares shall not be sufficient to effect the conversion of all then issued and outstanding shares of such series of Preference Shares, in addition to such other remedies as shall be available to the holder of such Preference Shares, the Company and the Members will take such corporate action as may, in the opinion of the Company's counsel, be necessary to increase the Company's authorised but unissued Ordinary Shares to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite shareholder approval of any necessary increase in the authorised share capital of the Company and any necessary amendment to these Articles.

- (j) <u>Notices</u>. Any notice required by the provisions of this Article 10.4 to be given to the holders of Preference Shares shall be deemed given if deposited in the United States mail, postage prepaid, or sent by email, and addressed to each holder of record at his address or email address appearing on the books of the Company, or as subsequently modified by written notice.
- (k) <u>Status of Converted Shares</u>. In the event any Preference Shares shall be converted pursuant to this Article 10.4, the shares so redeemed upon such conversion shall be cancelled and shall not be reissued by the Company.

#### **11. Treasury Shares**

- 11.1 The Directors may, prior to the purchase, redemption or surrender of any Share, determine that such Share shall be held as a Treasury Share.
- 11.2 The Directors may determine to cancel a Treasury Share or transfer a Treasury Share on such terms as they think proper (including, without limitation, for nil consideration); provided, however, any cancelled Treasury Shares shall not be reissued, sold or transferred.

#### 12. Variation of Rights of Shares

#### 12.1 Protective Provisions.

- (a) For so long as any Series A Preference Shares remain issued and outstanding, in addition to any other vote or consent required herein (including any consent required pursuant to Article 9.3(g)) or by law, the vote or written consent of the holders of a majority of the then issued and outstanding Series A Preference Shares, voting as a separate class, shall be necessary for effecting or validating the following actions (whether by merger, recapitalisation or otherwise):
  - effect any amendment, alteration, or waiver of any provision of the Memorandum, Articles or Shareholder Agreements, or take any action that adversely alters, changes or otherwise has any other adverse effect on the voting or any powers, preferences, or other special rights, preferences or privileges of the Series A Preference Shares;
  - (ii) issue, authorize or designate, whether by reclassification or otherwise, any new class or series of shares or any other securities convertible into equity securities of the Company ranking on a parity with or senior to the Series A Preference Shares in right of redemption, liquidation preference, voting, Dividend rights, or otherwise;
  - (iii) purchase or redeem or pay or declare any Dividend or make any other distribution with respect to Ordinary Shares or Preference Shares other than (A) repurchases of, or Dividends or distributions on, the Series A Preference Shares as expressly authorized herein (including, without limitation, any redemption of the Series A Preference Shares in accordance with Article 9.3), (B) Dividends or other distributions payable on the Ordinary Shares solely in the form of additional shares of Ordinary Shares and (C) repurchases of shares from former employees, officers, directors, consultants or other persons who performed services for the Company or any direct or indirect subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then-current fair market value thereof;

- (iv) consummate a Liquidation Event (as defined in Article 46) or a transaction or series of related transactions in which a Person, or a group of related Persons, acquires from shareholders of the Company shares representing more than fifty percent (50%) of the outstanding voting power of the Company (a "Share Sale");
- (v) create, or authorize the creation of, or issue, or authorized the issuance of, any debt security, or create any lien or security interest (except for purchase money liens or statutory liens of landlords, mechanics, materialmen, workmen, warehousemen and other similar persons arising or incurred in the ordinary course of business), or incur other indebtedness for borrowed money;
- (vi) create or hold capital stock in any subsidiary that is not a wholly-owned subsidiary, dispose of shares of any subsidiary or all or substantially all of any subsidiary assets;
- (vii) make any loans, advances, guarantees or investments, other than (A) to direct or indirect wholly-owned subsidiaries and (B) advances of expenses made in the ordinary course of business;
- (viii) sell, lease or otherwise dispose of any interest in any assets of the Company or its subsidiaries, other than in the ordinary course of business;
- (ix) acquire any equity interest in any company or business (which is not a direct or indirect wholly owned subsidiary), or enter into any joint venture;
- (x) enter into, amend, modify or supplement any agreement, commitment or understanding with any officer, director, senior vice president or higher employee or affiliate of the Company or any of its subsidiaries, or with any person related by blood, marriage or adoption to any such person or any entity in which any such person owns more than 5% of the equity; <u>provided</u> that the foregoing will not limit any bona fide employee compensation terms entered into on arm's length terms, and approved by the Board of Directors;
- (xi) amend or modify any equity incentive plan as in existence as of Purchase Date, adopt any new equity incentive plan or increase the number of Ordinary Shares available under any equity incentive plan, except with respect to an equity incentive plan that would become effective only in connection with the Qualified IPO; or
- (xii) sell, issue, sponsor, create, or distribute any digital tokens, cryptocurrency or other block-based assets (collectively, "Tokens"), or cause any subsidiary to do the same, including through a pre-sale, initial coin offering, token distribution event or crowdfunding, or through the issuance of any instrument convertible into or exchangeable for Tokens.
- 12.2 The rights conferred upon the holders of the Shares of any class issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the Shares of that class, be deemed to be varied by the creation or issue of further Shares ranking pari passu therewith.

## 13. Commission on Sale of Shares

13.1 The Company may, in so far as the Law permits, pay a commission to any person in consideration of his subscribing or agreeing to subscribe (whether absolutely or conditionally) or procuring or agreeing to procure subscriptions (whether absolutely or conditionally) for any Shares. Such commissions may be satisfied by the payment of cash and/or the issue of fully or partly paid-up Shares. The Company may also on any issue of Shares pay such brokerage as may be lawful.

#### 14. Non Recognition of Trusts

14.1 The Company shall not be bound by or compelled to recognise in any way (even when notified) any equitable, contingent, future or partial interest in any Share, or (except only as is otherwise provided by the Articles or the Law) any other rights in respect of any Share other than an absolute right to the entirety thereof in the holder.

#### 15. Lien on Shares

- 15.1 The Company shall have a first and paramount lien on all Shares (whether fully paid-up or not) registered in the name of a Member (whether solely or jointly with others) for all debts, liabilities or engagements to or with the Company (whether presently payable or not) by such Member or his estate, either alone or jointly with any other person, whether a Member or not, but the Directors may at any time declare any Share to be wholly or in part exempt from the provisions of this Article. The registration of a transfer of any such Share shall operate as a waiver of the Company's lien thereon. The Company's lien on a Share shall also extend to any amount payable in respect of that Share.
- 15.2 The Company may sell, in such manner as the Directors think fit, any Shares on which the Company has a lien, if a sum in respect of which the lien exists is presently payable, and is not paid within fourteen clear days after notice has been received or deemed to have been received by the holder of the Shares, or to the person entitled to it in consequence of the death or bankruptcy of the holder, demanding payment and stating that if the notice is not complied with the Shares may be sold.
- 15.3 To give effect to any such sale the Directors may authorise any person to execute an instrument of transfer of the Shares sold to, or in accordance with the directions of, the purchaser. The purchaser or his nominee shall be registered as the holder of the Shares comprised in any such transfer, and he shall not be bound to see to the application of the purchase money, nor shall his title to the Shares be affected by any irregularity or invalidity in the sale or the exercise of the Company's power of sale under the Articles.
- 15.4 The net proceeds of such sale after payment of costs, shall be applied in payment of such part of the amount in respect of which the lien exists as is presently payable and any balance shall (subject to a like lien for sums not presently payable as existed upon the Shares before the sale) be paid to the person entitled to the Shares at the date of the sale.
- 15.5 The terms of this Article 15 shall not apply, under any circumstances, to any Series A Preference Shares.

# 16. [Reserved]

17. [Reserved]

#### 18. Transmission of Shares

- 18.1 If a Member dies the survivor or survivors (where he was a joint holder) or his legal personal representatives (where he was a sole holder), shall be the only persons recognised by the Company as having any title to his Shares. The estate of a deceased Member is not thereby released from any liability in respect of any Share, for which he was a joint or sole holder.
- 18.2 Any person becoming entitled to a Share in consequence of the death or bankruptcy or liquidation or dissolution of a Member (or in any other way than by transfer) may, upon such evidence being produced as may be required by the Directors, elect by a notice in writing sent by him to the Company, either to become the holder of such Share or to have some person nominated by him registered as the holder of such Share. If he elects to have another person registered as the holder of such Share he shall sign an instrument of transfer of that Share to that person. The Directors shall, in either case, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by the relevant Member before his death or bankruptcy or liquidation or dissolution, as the case may be.
- 18.3 A person becoming entitled to a Share by reason of the death or bankruptcy or liquidation or dissolution of a Member (or in any other case than by transfer) shall be entitled to the same Dividends, other distributions and other advantages to which he would be entitled if he were the holder of such Share. However, he shall not, before becoming a Member in respect of a Share, be entitled in respect of it to exercise any right conferred by membership in relation to general meetings of the Company and the Directors may at any time give notice requiring any such person to elect either to be registered himself or to have some person nominated by him be registered as the holder of the Share (but the Directors shall, in either case, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by the relevant Member before his death or bankruptcy or liquidation or dissolution or any other case than by transfer, as the case may be). If the notice is not complied with within 90 days of being received or deemed to be received (as determined pursuant to the Articles) the Directors may thereafter withhold payment of all Dividends, other distributions, bonuses or other monies payable in respect of the Share until the requirements of the notice have been complied with.

## 19. Amendments of Memorandum and Articles of Association and Alteration of Capital

- 19.1 Subject to the other provisions of these Articles (including the protective provisions set forth in Article 12) and after providing the holders of Series A Preference Shares five (5) business days' prior written notice, the Company may by Ordinary Resolution:
  - (a) increase its share capital by such sum as the Ordinary Resolution shall prescribe and with such rights, priorities and privileges annexed thereto, as the Company in general meeting may determine;
  - (b) consolidate and divide all or any of its share capital into Shares of larger amount than its existing Shares;
  - (c) convert all or any of its paid up Shares into stock, and reconvert that stock into paid up Shares of any denomination;

- (d) by subdivision of its existing Shares or any of them divide the whole or any part of its share capital into Shares of smaller amount than is fixed by the Memorandum or into Shares without par value; and
- (e) cancel any Shares that at the date of the passing of the Ordinary Resolution have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the Shares so cancelled.
- 19.2 All new Shares created in accordance with the provisions of the preceding Article shall be subject to the same provisions of the Articles with reference to the payment of calls, liens, transfer, transmission, forfeiture and otherwise as the Shares in the original share capital.
- 19.3 Subject to the provisions of the Law and the provisions of the Articles as regards the matters to be dealt with by Ordinary Resolution, and the protective provisions set forth in Article 12 of these Articles, the Company may by Special Resolution:
  - (a) change its name;
  - (b) alter or add to the Articles;
  - (c) alter or add to the Memorandum with respect to any objects, powers or other matters specified therein; and
  - (d) reduce its share capital or any capital redemption reserve fund.

### 20. Offices and Places of Business

20.1 Subject to the provisions of the Law, the Company may by resolution of the Directors change the location of its Registered Office. The Company may, in addition to its Registered Office, maintain such other offices or places of business as the Directors determine.

#### 21. General Meetings

- 21.1 All general meetings other than annual general meetings shall be called extraordinary general meetings.
- 21.2 The Company may, but shall not (unless required by the Law) be obliged to, in each year hold a general meeting as its annual general meeting, and shall specify the meeting as such in the notices calling it. Any annual general meeting shall be held at such time and place as the Directors shall appoint and if no other time and place is prescribed by them, it shall be held at the Registered Office on the second Wednesday in December of each year at ten o'clock in the morning. At these meetings the report of the Directors (if any) shall be presented.
- 21.3 The Directors may call general meetings, and they shall on a Members requisition forthwith proceed to convene an extraordinary general meeting of the Company.
- 21.4 A Members' requisition is a requisition of Members holding at the date of deposit of the requisition not less than ten per cent in par value of the issued Shares which as at that date carry the right to vote at general meetings of the Company.
- 21.5 The Members' requisition must state the objects of the meeting and must be signed by the requisitionists and deposited at the Registered Office, and may consist of several documents in like form each signed by one or more requisitionists.

- 21.6 If there are no Directors as at the date of the deposit of the Members' requisition or if the Directors do not within 21 days from the date of the deposit of the Members' requisition duly proceed to convene a general meeting to be held within a further 21 days, the requisitionists, or any of them representing more than one-half of the total voting rights of all of the requisitionists, may themselves convene a general meeting, but any meeting so convened shall be held no later than the day which falls three months after the expiration of the said 21-day period.
- 21.7 A general meeting convened as aforesaid by requisitionists shall be convened in the same manner as nearly as possible as that in which general meetings are to be convened by Directors.

# 22. Notice of General Meetings

- 22.1 At least ten clear days' prior written notice shall be given to all Members of any general meeting. Every notice shall specify the place, the day and the hour of the meeting and the general nature of the business to be conducted at the general meeting and shall be given in the manner hereinafter mentioned or in such other manner if any as may be prescribed by the Company, <u>provided</u> that a general meeting of the Company shall, whether or not the notice specified in this Article has been given and whether or not the provisions of the Articles regarding general meetings have been complied with, be deemed to have been duly convened if it is so agreed:
  - (a) in the case of an annual general meeting, by all of the Members entitled to attend and vote thereat; and
  - (b) in the case of an extraordinary general meeting, by Members having a right to attend and vote at the meeting together holding not less than 90% in par value of the Shares giving that right.

# 23. Proceedings at General Meetings

- 23.1 No business shall be transacted at any general meeting unless a quorum is present. The quorum being Members, if individuals present in person or by proxy, or if a corporation or other non-natural person, by its duly authorised representative, holding a majority of Shares carrying the right to vote; <u>provided</u> that the quorum for any general meeting at which a resolution for an action set forth in Article 12 is to be considered shall also require the presence, in person or by proxy, of Members holding at least a majority of the Preference Shares.
- 23.2 A person may participate at a general meeting by conference telephone or other communications equipment by means of which all the persons participating in the meeting can communicate with each other. Participation by a person in a general meeting in this manner is treated as presence in person at that meeting.
- 23.3 A resolution (including a Special Resolution) in writing (in one or more counterparts) signed by or on behalf of all of the Members for the time being entitled to receive notice of and to attend and vote at general meetings (or, being corporations or other non-natural persons, signed by their duly authorised representatives) shall be as valid and effective as if the resolution had been passed at a general meeting of the Company duly convened and held.
- 23.4 If a quorum is not present within half an hour from the time appointed for the meeting to commence or if during such a meeting a quorum ceases to be present, the meeting, if convened upon a Members' requisition, shall be dissolved and in any other case it shall stand adjourned to the same day in the next week at the same time and/or place or to such other day, time and/or place as the Directors may determine, and if at the adjourned meeting a quorum is not present within half an hour from the time appointed for the meeting to commence, the Members present shall be a quorum.

- 23.5 The Directors may, at any time prior to the time appointed for the meeting to commence, appoint any person to act as chairman of a general meeting of the Company or, if the Directors do not make any such appointment, the chairman, if any, of the Board of Directors shall preside as chairman at such general meeting. If there is no such chairman, or if he shall not be present within 15 minutes after the time appointed for the meeting to commence, or is unwilling to act, the Directors present shall elect one of their number to be chairman of the meeting.
- 23.6 If no Director is willing to act as chairman or if no Director is present within 15 minutes after the time appointed for the meeting to commence, the Members present shall choose one of their number to be chairman of the meeting.
- 23.7 The chairman may, with the consent of a meeting at which a quorum is present (and shall if so directed by the meeting) adjourn the meeting from time to time and from place to place, but no business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place.
- 23.8 When a general meeting is adjourned for 30 days or more, notice of the adjourned meeting shall be given as in the case of an original meeting. Otherwise it shall not be necessary to give any such notice of an adjourned meeting.
- 23.9 A resolution put to the vote of the meeting shall be decided on a show of hands unless before, or on the declaration of the result of, the show of hands, the chairman demands a poll, or any other Member or Members collectively present in person or by proxy (or in the case of a corporation or other non-natural person, by its duly authorised representative or proxy) and holding at least ten per cent in par value of the Shares giving a right to attend and vote at the meeting demand a poll. Except on a poll demanded on the election of a chairman or on a question of adjournment, a poll shall be taken as the chairman directs, and the result of the poll shall be deemed to be the resolution of the general meeting at which the poll was demanded.
- 23.10 Unless a poll is duly demanded and the demand is not withdrawn a declaration by the chairman that a resolution has been carried or carried unanimously, or by a particular majority, or lost or not carried by a particular majority, an entry to that effect in the minutes of the proceedings of the meeting shall be conclusive evidence of that fact without proof of the number or proportion of the votes recorded in favour of or against such resolution.
- 23.11 The demand for a poll may be withdrawn.
- 23.12 Except on a poll demanded on the election of a chairman or on a question of adjournment, a poll shall be taken as the chairman directs, and the result of the poll shall be deemed to be the resolution of the general meeting at which the poll was demanded.
- 23.13 A poll demanded on the election of a chairman or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such date, time and place as the chairman of the general meeting directs, and any business other than that upon which a poll has been demanded or is contingent thereon may proceed pending the taking of the poll.
- 23.14 In the case of an equality of votes, whether on a show of hands or on a poll, the chairman shall be entitled to a second or casting vote.

#### 24. Votes of Members

- 24.1 Except as otherwise provided herein, and subject to any rights or restrictions attached to any Shares, on a show of hands every Member who (being an individual) is a holder of: (i) Ordinary Shares and is present in person or by proxy or, if a corporation or other non-natural person is present by its duly authorised representative or by proxy, shall have one vote, and on a poll, shall have one vote for every Ordinary Share of which he is the holder, or (ii) Preference Shares and is present in person or by proxy, or if a corporation or other non-natural person is present by its duly authorised representative or by proxy, shall be entitled to the number of votes equal to the number of Ordinary Shares into which such Preference Shares could be converted at the time of the vote, and on a poll, shall have that number of votes equal to the number of Ordinary Shares into which such Preference Shares could be converted at the time of the poll.
- 24.2 In the case of joint holders the vote of the senior holder who tenders a vote, whether in person or by proxy (or, in the case of a corporation or other non-natural person, by its duly authorised representative or proxy), shall be accepted to the exclusion of the votes of the other joint holders, and seniority shall be determined by the order in which the names of the holders stand in the Register of Members.
- 24.3 A Member of unsound mind, or in respect of whom an order has been made by any court, having jurisdiction in lunacy, may vote, whether on a show of hands or on a poll, by his committee, receiver, curator bonis, or other person on such Member's behalf appointed by that court, and any such committee, receiver, curator bonis or other person may vote by proxy.
- 24.4 No person shall be entitled to vote at any general meeting or at any separate meeting of the holders of a class of Shares unless he is registered as a Member on the record date for such meeting nor unless all calls or other monies then payable by him in respect of Shares have been paid.
- 24.5 No objection shall be raised as to the qualification of any voter except at the general meeting or adjourned general meeting at which the vote objected to is given or tendered and every vote not disallowed at the meeting shall be valid. Any objection made in due time in accordance with this Article shall be referred to the chairman whose decision shall be final and conclusive.
- 24.6 On a poll or on a show of hands votes may be cast either personally or by proxy (or in the case of a corporation or other non-natural person by its duly authorised representative or proxy). A Member may appoint more than one proxy or the same proxy under one or more instruments to attend and vote at a meeting. Where a Member appoints more than one proxy the instrument of proxy shall state which proxy is entitled to vote on a show of hands and shall specify the number of Shares in respect of which each proxy is entitled to exercise the related votes.
- 24.7 On a poll, a Member holding more than one Share need not cast the votes in respect of his Shares in the same way on any resolution and therefore may vote a Share or some or all such Shares either for or against a resolution and/or abstain from voting a Share or some or all of the Shares and, subject to the terms of the instrument appointing him, a proxy appointed under one or more instruments may vote a Share or some or all of the Shares in respect of which he is appointed either for or against a resolution and/or abstain from voting a Share or some or all of the Shares in respect of which he is appointed.

# 25. Proxies

25.1 The instrument appointing a proxy shall be in writing and shall be executed under the hand of the appointor or of his attorney duly authorised in writing, or, if the appointor is a corporation or other non natural person, under the hand of its duly authorised representative. A proxy need not be a Member.

- 25.2 The Directors may in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, specify the manner by which the instrument appointing a proxy shall be deposited and the place and the time (being not later than the time appointed for the commencement of the meeting or adjourned meeting to which the proxy relates) at which the instrument appointing a proxy shall be deposited. In the absence of any such direction from the Directors in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, the instrument appointing a proxy shall be deposited physically at the Registered Office not less than 48 hours before the time appointed for the meeting or adjourned meeting to commence at which the person named in the instrument proposes to vote.
- 25.3 The chairman may in any event at his reasonable discretion declare that an instrument of proxy shall be deemed to have been duly deposited. An instrument of proxy that is not deposited in the manner permitted, or which has not been declared to have been duly deposited by the chairman, shall be invalid.
- 25.4 The instrument appointing a proxy may be in any usual or common form (or such other form as the Directors may approve) and may be expressed to be for a particular meeting or any adjournment thereof or generally until revoked. An instrument appointing a proxy shall be deemed to include the power to demand or join or concur in demanding a poll.
- 25.5 Votes given in accordance with the terms of an instrument of proxy shall be valid notwithstanding the previous death or insanity of the principal or revocation of the proxy or of the authority under which the proxy was executed, or the transfer of the Share in respect of which the proxy is given unless notice in writing of such death, insanity, revocation or transfer was received by the Company at the Registered Office before the commencement of the general meeting, or adjourned meeting at which it is sought to use the proxy.

#### 26. Corporate Members

26.1 Any corporation or other non-natural person which is a Member may in accordance with its constitutional documents, or in the absence of such provision by resolution of its directors or other governing body, authorise such person as it thinks fit to act as its representative at any meeting of the Company or of any class of Members, and the person so authorised shall be entitled to exercise the same powers on behalf of the corporation which he represents as the corporation could exercise if it were an individual Member.

#### 27. Shares that May Not be Voted

27.1 Shares in the Company that are beneficially owned by the Company shall not be voted, directly or indirectly, at any meeting and shall not be counted in determining the total number of outstanding Shares at any given time.

#### 28. Directors

28.1 The number of Directors shall be not less than one and, if as of September 30, 2021 the Company has not consummated a Qualified IPO, not more than (a) seven or (b) such greater number as may be approved by a majority of the Directors then in office (which majority must include the Series A Director, if then in office), and subject to the provisions of Article 10 and Article 12, the Company may by Ordinary Resolution increase or reduce the limits in the number of Directors. The first Directors of the Company shall be determined in writing by the subscriber of the Memorandum. Thereafter, the Directors shall be appointed in accordance with the terms of Article 10.

## 29. Powers of Directors

- 29.1 Subject to the provisions of the Law, the Memorandum and the Articles and to any directions given by Special Resolution, the business of the Company shall be managed by the Directors who may exercise all the powers of the Company. No alteration of the Memorandum or Articles and no such direction shall invalidate any prior act of the Directors which would have been valid if that alteration had not been made or that direction had not been given. A duly convened meeting of Directors at which a quorum is present may exercise all powers exercisable by the Directors.
- 29.2 All cheques, promissory notes, drafts, bills of exchange and other negotiable or transferable instruments and all receipts for monies paid to the Company shall be signed, drawn, accepted, endorsed or otherwise executed as the case may be in such manner as the Directors shall determine by resolution.
- 29.3 Subject to other provisions of these Articles (including, but not limited to Article 12.1), the Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof and to issue debentures, debenture stock, mortgages, bonds and other such securities whether outright or as security for any debt, liability or obligation of the Company or of any third party.

#### 30. Appointment, Resignation and Removal of Directors

- 30.1 Any Director may resign effective on giving written notice to the Board of Directors, unless the notice specifies a later time for that resignation to become effective.
- 30.2 Vacancies in the Board of Directors shall be filled by the vote of the holders of that class or series of shares originally entitled to elect the Director whose absence or resignation created such vacancy.
  - (a) A vacancy or vacancies in the Board of Directors shall be deemed to exist (i) in the event of the death, resignation or removal of any Director, (ii) if the Board of Directors by resolution declares vacant the office of a Director who has been declared of unsound mind by an order of court or convicted of a criminal offense punishable by imprisonment, (iii) if the authorised number of Directors is increased or (iv) if the Members fail, at any meeting of Members at which any Director or Directors are elected, to elect the number of directors to be elected at that meeting. Upon any vacancy arising as a result of paragraph (i) or (ii) above the Director concerned shall cease to be a Director.
  - (b) The Board of Directors shall have power by vote of a majority of the remaining Directors, even if less than a quorum, from time to time to (i) appoint any person to be a Director at any time to fill any vacancy or vacancies not filled by the Members in accordance with Article 28 and (ii) designate and appoint any person to be any of the Directors specified in Article 10.2 prior to the appointment or election of such Director by the Members in accordance with Article 10.2. Each Director so elected shall hold office until the next annual meeting of the Members or until a successor has been elected and qualified.

## 31. Vacation of Office of Director

- 31.1 Notwithstanding anything to the contrary in these Articles, the office of a Director shall be vacated if:
  - (a) the Director gives notice in writing to the Company that he resigns the office of Director;
  - (b) the Director absents himself (for the avoidance of doubt, without being represented by proxy or an alternate Director appointed by him) from three consecutive meetings of the Board of Directors without special leave of absence from the Directors, and the Directors pass a resolution that he has by reason of such absence vacated office;
  - (c) the Director dies, becomes bankrupt or makes any arrangement or composition with his creditors generally;
  - (d) the Director is found to be or becomes of unsound mind; or
  - (e) all of the other Directors (being not less than two in number) determine that he should be removed as a Director, either by a resolution passed by all of the other Directors at a meeting of the Directors duly convened and held in accordance with the Articles or by a resolution in writing signed by all of the other Directors.

#### 32. Proceedings of Directors

- 32.1 The quorum for the transaction of the business of the Directors may be fixed by the Directors, and unless so fixed shall be a majority of the then elected or appointed Directors, and shall be one if there is only one Director. A person who holds office as an alternate Director shall, if his appointor is not present, be counted in the quorum. A Director who also acts as an alternate Director shall, if his appointor is not present, count twice towards the quorum.
- 32.2 Subject to the provisions of the Articles, the Directors may regulate their proceedings as they think fit. Questions arising at any meeting shall be decided by a majority of votes. In the case of an equality of votes, the chairman shall have a second or casting vote. A Director who is also an alternate Director shall be entitled in the absence of his appointor to a separate vote on behalf of his appointor in addition to his own vote.
- 32.3 A person may participate in a meeting of the Directors or committee of Directors by conference telephone or other communications equipment by means of which all the persons participating in the meeting can communicate with each other at the same time. Participation by a person in a meeting in this manner is treated as presence in person at that meeting. Unless otherwise determined by the Directors the meeting shall be deemed to be held at the place where the chairman is located at the start of the meeting.
- 32.4 A resolution in writing (in one or more counterparts) signed by all the Directors or all the members of a committee of the Directors or, in the case of a resolution in writing relating to the removal of any Director or the vacation of office by any Director, all of the Directors other than the Director who is the subject of such resolution (an alternate Director being entitled to sign such a resolution on behalf of his appointor and if such alternate Director is also a Director, being entitled to sign such resolution both on behalf of his appointer and in his capacity as a Director) shall be as valid and effectual as if it had been passed at a meeting of the Directors, or committee of Directors as the case may be, duly convened and held.

- 32.5 A Director or alternate Director may, or other officer of the Company on the direction of a Director or alternate Director shall, call a meeting of the Directors by at least two days' notice in writing to every Director and alternate Director which notice shall set forth the general nature of the business to be considered unless notice is waived by all the Directors (or their alternates) either at, before or after the meeting is held. To any such notice of a meeting of the Directors all the provisions of the Articles relating to the giving of notices by the Company to the Members shall apply *mutatis mutandis*.
- 32.6 The continuing Directors (or a sole continuing Director, as the case may be) may act notwithstanding any vacancy in their body, but if and so long as their number is reduced below the number fixed by or pursuant to the Articles as the necessary quorum of Directors the continuing Directors or Director may act for the purpose of increasing the number of Directors to be equal to such fixed number, or of summoning a general meeting of the Company, but for no other purpose.
- 32.7 The Directors may elect a chairman of the Board of Directors and determine the period for which he is to hold office; but if no such chairman is elected, or if at any meeting the chairman is not present within five minutes after the time appointed for the meeting to commence, the Directors present may choose one of their number to be chairman of the meeting.
- 32.8 All acts done by any meeting of the Directors or of a committee of the Directors (including any person acting as an alternate Director) shall, notwithstanding that it is afterwards discovered that there was some defect in the appointment of any Director or alternate Director, and/or that they or any of them were disqualified, and/or had vacated their office and/or were not entitled to vote, be as valid as if every such person had been duly appointed and/or not disqualified to be a Director or alternate Director and/or had not vacated their office and/or had been entitled to vote, as the case may be.
- 32.9 A Director but not an alternate Director may be represented at any meetings of the Board of Directors by a proxy appointed in writing by him. The proxy shall count towards the quorum and the vote of the proxy shall for all purposes be deemed to be that of the appointing Director.

#### 33. Presumption of Assent

33.1 A Director or alternate Director who is present at a meeting of the Board of Directors at which action on any Company matter is taken shall be presumed to have assented to the action taken unless his dissent shall be entered in the minutes of the meeting or unless he shall file his written dissent from such action with the person acting as the chairman or secretary of the meeting before the adjournment thereof or shall forward such dissent by registered post to such person immediately after the adjournment of the meeting. Such right to dissent shall not apply to a Director or alternate Director who voted in favour of such action.

# 34. Directors' Interests

- 34.1 A Director or alternate Director may hold any other office or place of profit under the Company (other than the office of Auditor) in conjunction with his office of Director for such period and on such terms as to remuneration and otherwise as the Directors may determine, subject to the terms of Article 12.1.
- 34.2 A Director or alternate Director may act by himself or by, through or on behalf of his firm in a professional capacity for the Company and he or his firm shall be entitled to remuneration for professional services as if he were not a Director or alternate Director, subject to the terms of Article 12.1.

- 34.3 A Director or alternate Director may be or become a director or other officer of or otherwise interested in any company promoted by the Company or in which the Company may be interested as a shareholder, a contracting party or otherwise, and no such Director or alternate Director shall be accountable to the Company for any remuneration or other benefits received by him as a director or officer of, or from his interest in, such other company, subject to the terms of Article 12.1.
- 34.4 No person shall be disqualified from the office of Director or alternate Director or prevented by such office from contracting with the Company, either as vendor, purchaser or otherwise, nor shall any such contract or any contract or transaction entered into by or on behalf of the Company in which any Director or alternate Director shall be in any way interested be or be liable to be avoided, nor shall any Director or alternate Director so contracting or being so interested be liable to account to the Company for any profit realised by or arising in connection with any such contract or transaction by reason of such Director or alternate Director holding office or of the fiduciary relationship thereby established. A Director (or his alternate Director in his absence) shall be at liberty to vote in respect of any contract or transaction shall be disclosed by him in writing at or prior to its consideration and any vote thereon and the foregoing shall be subject to the terms of Article 12.1.
- 34.5 Subject to Article 12.1, a general notice that a Director or alternate Director is a shareholder, director, officer or employee of any specified firm or company and is to be regarded as interested in any transaction with such firm or company shall be sufficient disclosure for the purposes of voting on a resolution in respect of a contract or transaction in which such Director has an interest, and after such general notice it shall not be necessary to give special notice relating to any particular transaction.

## 35. Minutes

35.1 The Directors shall cause minutes to be made in books kept for the purpose of all appointments of officers made by the Directors, all proceedings at meetings of the Company or the holders of any class of Shares and of the Directors, and of committees of the Directors including the names of the Directors or alternate Directors present at each meeting.

# 36. Delegation of Directors' Powers

- 36.1 The Directors may delegate any of their powers, authorities and discretions, including the power to sub-delegate, to any committee consisting of one or more Directors. They may also delegate to any managing director or any Director holding any other executive office such of their powers, authorities and discretions as they consider desirable to be exercised by him <u>provided</u> that an alternate Director may not act as managing director and the appointment of a managing director shall be revoked forthwith if he ceases to be a Director. Any such delegation may be made subject to any conditions the Directors may impose and either collaterally with or to the exclusion of their own powers and any such delegation may be revoked or altered by the Directors. Subject to any such conditions, the proceedings of a committee of Directors shall be governed by the Articles regulating the proceedings of Directors, so far as they are capable of applying.
- 36.2 The Directors may establish any committees, local boards or agencies or appoint any person to be a manager or agent for managing the affairs of the Company and may appoint any person to be a member of such committees, local boards or agencies. Any such appointment may be made subject to any conditions the Directors may impose, and either collaterally with or to the exclusion of their own powers and any such appointment may be revoked or altered by the Directors. Subject to any such conditions, the proceedings of any such committee, local board or agency shall be governed by the Articles regulating the proceedings of Directors, so far as they are capable of applying.

- 36.3 The Directors may by power of attorney or otherwise appoint any person to be the agent of the Company on such conditions as the Directors may determine, <u>provided</u> that the delegation is not to the exclusion of their own powers and may be revoked by the Directors at any time.
- 36.4 The Directors may by power of attorney or otherwise appoint any company, firm, person or body of persons, whether nominated directly or indirectly by the Directors, to be the attorney or authorised signatory of the Company for such purpose and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Directors under the Articles) and for such period and subject to such conditions as they may think fit, and any such powers of attorney or other appointment may contain such provisions for the protection and convenience of persons dealing with any such attorneys or authorised signatories as the Directors may think fit and may also authorise any such attorney or authorised signatory to delegate all or any of the powers, authorities and discretions vested in him.
- 36.5 The Directors may appoint such officers of the Company (including, for the avoidance of doubt and without limitation, any secretary) as they consider necessary on such terms, at such remuneration and to perform such duties, and subject to such provisions as to disqualification and removal as the Directors may think fit. Unless otherwise specified in the terms of his appointment an officer of the Company may be removed by resolution of the Directors or Members. An officer of the Company may vacate his office at any time if he gives notice in writing to the Company that he resigns his office.

#### 37. Alternate Directors

- 37.1 Any Director (but not an alternate Director) may by writing appoint any other Director, or any other person willing to act, to be an alternate Director and by writing may remove from office an alternate Director so appointed by him.
- 37.2 An alternate Director shall be entitled to receive notice of all meetings of Directors and of all meetings of committees of Directors of which his appointor is a member, to attend and vote at every such meeting at which the Director appointing him is not personally present, to sign any written resolution of the Directors, and generally to perform all the functions of his appointor as a Director in his absence.
- 37.3 An alternate Director shall cease to be an alternate Director if his appointor ceases to be a Director.
- 37.4 Any appointment or removal of an alternate Director shall be by notice to the Company signed by the Director making or revoking the appointment or in any other manner approved by the Directors.
- 37.5 Subject to the provisions of the Articles, an alternate Director shall be deemed for all purposes to be a Director and shall alone be responsible for his own acts and defaults and shall not be deemed to be the agent of the Director appointing him.

#### 38. No Minimum Shareholding

38.1 A Director is not required to hold Shares.

#### 39. Remuneration of Directors

- 39.1 The remuneration to be paid to the Directors, if any, shall be determined by the Company in general meeting or, in the absence of such a determination, by the Directors, but in any case, shall be subject to the terms of Article 12.1.
- 39.2 Each Director shall also be entitled to be paid his reasonable travelling, hotel and other expenses properly incurred by him in connection with his attendance at meetings of the Directors, committees of the Directors or general meetings of the Company, or otherwise in connection with the business of the Company, or, subject to Article 12.1, to receive a fixed allowance in respect thereof as may be determined by the Directors, or a combination partly of one such method and partly the other.

#### 40. Seals and Deeds

- 40.1 The Directors may determine that the Company shall have a Seal, and if they so determine, shall provide for the safe custody of the Seal. The Seal shall only be used by the authority of the Directors and in the presence of a Director or the Chief Executive Officer of the Company or such other person as the Directors may by resolution appoint for this purpose, and every instrument to which the Seal affixed shall be signed by the relevant person. Notwithstanding the above, annual returns and notices filed under the Law may be executed either as a deed or under Seal and in either case without the need for the authority of a resolution of the Directors.
- 40.2 The Company may maintain in any place or places outside the Cayman Islands a facsimile of any Seal and such facsimile seal shall be affixed in the same way as if it were the Seal.
- 40.3 In accordance with the Law, the Company may execute any deed or other instrument (which would otherwise be required to be executed under Seal) by the signature of such deed or instrument as a deed by a Director or by the Chief Executive Officer of the Company or by such other person as the Directors may appoint or by any other person or attorney on behalf of the Company appointed by a deed or other instrument executed as a deed by a Director or the Secretary or such other person as aforesaid.

## 41. Dividends, Distributions and Reserve

- 41.1 Subject to the Law and this Article and except as otherwise provided by the rights attached to any Shares, the Directors may resolve to pay Dividends and other distributions on Shares in issue and authorise payment of the Dividends or other distributions out of the funds of the Company lawfully available therefor. A Dividend shall be deemed to be an interim Dividend unless the terms of the resolution pursuant to which the Directors resolve to pay such Dividend specifically state that such Dividend shall be a final Dividend. No Dividend or other distribution shall be paid except out of the realised or unrealised profits of the Company, out of the share premium account or as otherwise permitted by the Law.
- 41.2 Except as otherwise provided by the rights attached to any Shares and as provided in Article 10 hereof, all Dividends and other distributions shall be paid according to the par value of the Shares that a Member holds. If any Share is issued on terms providing that it shall rank for Dividend as from a particular date, that Share shall rank for Dividend accordingly.
- 41.3 The Directors may deduct from any Dividend or other distribution payable to any Member, other than a holder of Series A Preference Shares, all sums of money (if any) then payable by him to the Company on account of calls or otherwise.

- 41.4 Except as otherwise provided by the rights attached to any Shares and as provided in Article 10 hereof, the Directors may resolve that any Dividend or other distribution be paid wholly or partly by the distribution of specific assets and in particular (but without limitation) by the distribution of shares, debentures, or securities of any other company or in any one or more of such ways and where any difficulty arises in regard to such distribution of such specific assets or any part thereof and may determine that cash payments shall be made to any Members upon the basis of the value so fixed in order to adjust the rights of all Members and may vest any such specific assets in trustees in such manner as may seem expedient to the Directors.
- 41.5 Any amounts payable with respect to any Dividend or other distribution with respect to the Series A Preference Shares shall be paid in U.S. dollars. Otherwise, except as otherwise provided by the rights attached to any Shares, Dividends and other distributions with respect to any other series or class of securities may be paid in any currency. The Directors may determine the basis of conversion for any currency conversions that may be required and how any costs involved are to be met.
- 41.6 The Directors may, before resolving to pay any Dividend or other distribution, set aside such sums as they think proper as a reserve or reserves which shall, at the discretion of the Directors, be applicable for any purpose of the Company and pending such application may, at the discretion of the Directors, be employed in the business of the Company.
- 41.7 Any Dividend, other distribution, interest or other monies payable in cash in respect of Shares may be paid by wire transfer to the holder or by cheque or warrant sent through the post directed to the registered address of the holder or, in the case of joint holders, to the registered address of the holder who is first named on the Register of Members or to such person and to such address as such holder or joint holders may in writing direct. Every such cheque or warrant shall be made payable to the order of the person to whom it is sent. Any one of two or more joint holders may give effectual receipts for any Dividends, other distributions, bonuses, or other monies payable in respect of the Share held by them as joint holders.
- 41.8 No Dividend or other distribution shall bear interest against the Company.
- 41.9 Any Dividend or other distribution which cannot be paid to a Member and/or which remains unclaimed after six months from the date on which such Dividend or other distribution becomes payable may, in the discretion of the Directors, be paid into a separate account in the Company's name, <u>provided</u> that the Company shall not be constituted as a trustee in respect of that account and the Dividend or other distribution shall remain as a debt due to the Member. Any Dividend or other distribution which remains unclaimed after a period of six years from the date on which such Dividend or other distribution becomes payable shall be forfeited and shall revert to the Company.

## 42. Capitalisation

42.1 The Directors may at any time capitalise any sum standing to the credit of any of the Company's reserve accounts or funds (including the share premium account and capital redemption reserve fund) or any sum standing to the credit of the profit and loss account or otherwise available for distribution; appropriate such sum to Members in the proportions in which such sum would have been divisible amongst such Members had the same been a distribution of profits by way of Dividend or other distribution; and apply such sum on their behalf in paying up in full unissued Shares for allotment and distribution credited as fully paid-up to and amongst them in the

proportion aforesaid. In such event the Directors shall do all acts and things required to give effect to such capitalisation, with full power given to the Directors to make such provisions as they think fit in the case of Shares becoming distributable in fractions (including provisions whereby the benefit of fractional entitlements accrue to the Company rather than to the Members concerned). The Directors may authorise any person to enter on behalf of all of the Members interested into an agreement with the Company providing for such capitalisation and matters incidental or relating thereto and any agreement made under such authority shall be effective and binding on all such Members and the Company, except as otherwise provided by the rights attached to any Shares.

# 43. Books of Account

- 43.1 The Directors shall cause proper books of account (including, where applicable, material underlying documentation including contracts and invoices) to be kept with respect to all sums of money received and expended by the Company and the matters in respect of which the receipt or expenditure takes place, all sales and purchases of goods by the Company and the assets and liabilities of the Company. Such books of account must be retained for a minimum period of five years from the date on which they are prepared. Proper books shall not be deemed to be kept if there are not kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions.
- 43.2 The Directors shall determine whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of Members not being Directors and no Member (not being a Director) shall have any right of inspecting any account or book or document of the Company except as conferred by Law or authorised by the Directors or by the Company in general meeting.
- 43.3 The Directors may cause to be prepared and to be laid before the Company in general meeting profit and loss accounts, balance sheets, group accounts (if any) and such other reports and accounts as may be required by Law.

# 44. Audit

- 44.1 The Directors may appoint an Auditor of the Company who shall hold office on such terms as the Directors determine.
- 44.2 Every Auditor of the Company shall have a right of access at all times to the books and accounts and vouchers of the Company and shall be entitled to require from the Directors and officers of the Company such information and explanation as may be necessary for the performance of the duties of the Auditor.
- 44.3 Auditors shall, if so required by the Directors, make a report on the accounts of the Company during their tenure of office at the next annual general meeting following their appointment in the case of a company which is registered with the Registrar of Companies as an ordinary company, and at the next extraordinary general meeting following their appointment in the case of a company which is registered with the Registrar of Companies as an exempted company, and at any other time during their term of office, upon request of the Directors or any general meeting of the Members.

#### 45. Notices

- 45.1 Notices shall be in writing and may be given by the Company to any Member either personally or by sending it by courier, post, cable, or e-mail to him or to his address as shown in the Register of Members (or where the notice is given by e-mail by sending it to the e-mail address provided by such Member). Any notice, if posted from one country to another, is to be sent by airmail.
- 45.2 Where a notice is sent by courier, service of the notice shall be deemed to be effected by delivery of the notice to a courier company, and shall be deemed to have been received on the third day (not including Saturdays or Sundays or public holidays) following the day on which the notice was delivered to the courier. Where a notice is sent by post, service of the notice shall be deemed to be effected by properly addressing, pre paying and posting a letter containing the notice, and shall be deemed to have been received on the fifth day (not including Saturdays or Sundays or public holidays in the Cayman Islands) following the day on which the notice was posted. Where a notice is given by e-mail service shall be deemed to be effected by transmitting the e-mail to the e-mail address provided by the intended recipient and shall be deemed to have been received on the same day that it was sent, and it shall not be necessary for the receipt of the e-mail to be acknowledged by the recipient.
- 45.3 A notice may be given by the Company to the person or persons which the Company has been advised are entitled to a Share or Shares in consequence of the death or bankruptcy of a Member in the same manner as other notices which are required to be given under the Articles and shall be addressed to them by name, or by the title of representatives of the deceased, or trustee of the bankrupt, or by any like description at the address supplied for that purpose by the persons claiming to be so entitled, or at the option of the Company by giving the notice in any manner in which the same might have been given if the death or bankruptcy had not occurred.
- 45.4 Notice of every general meeting shall be given in any manner authorised by the Articles to every holder of Shares carrying an entitlement to receive such notice on the record date for such meeting except that in the case of joint holders the notice shall be sufficient if given to the joint holder first named in the Register of Members and every person upon whom the ownership of a Share devolves by reason of his being a legal personal representative or a trustee in bankruptcy of a Member where the Member but for his death or bankruptcy would be entitled to receive notice of the meeting, and no other person shall be entitled to receive notices of general meetings.

# 46. Winding Up

# 46.1 Liquidation, Dissolution or Winding Up.

(a) Series A Liquidation Preference. Upon any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or any Share Sale (as defined in Article 12.1), Asset Transfer or Acquisition (each as defined below) (collectively, a "Liquidation Event"), before any distribution or payment shall be made to the holders of any Ordinary Shares, the holders of Series A Preference Shares shall be entitled to be paid out of the assets of the Company legally available for distribution (or the consideration received by the Company or its Members in an Acquisition) for each Series A Preference Share held by them, an amount per Series A Preference Share equal to the sum of (i) the Series A Original Issue Price, plus (ii) any accrued but unpaid Dividends on each Series A Preference Share. If, upon any such Liquidation Event, the assets of the Company shall be insufficient to make payment in full to all holders of Series A Preference Shares of the liquidation preference set forth in this Article 46.1(a), then such assets (or consideration) shall be distributed among the holders of Series A Preference Shares at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

- (b) Allocation of Escrow and Contingent Consideration. In the event of a Liquidation Event pursuant to Article 46.1, if any portion of the consideration payable to the shareholders of the Company is payable only upon satisfaction of contingencies (the "Additional Consideration"), the agreement effecting the Liquidation Event shall provide that (i) the portion of such consideration that is not Additional Consideration (such portion, the "Initial Consideration") shall be allocated among the shareholders of the Company in accordance with Article 46.1(a) as if the Initial Consideration were the only consideration payable in connection with such Liquidation Event; and (ii) any Additional Consideration which becomes payable to the shareholders of the Company upon satisfaction of such contingencies shall be allocated among the shareholders of the Company in accordance with Article 46.1(a) after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Article 46.1(b), consideration placed into escrow or retained as a holdback to be available for satisfaction of indemnification or similar obligations in connection with such Liquidation Event shall be deemed to be Additional Consideration.
- (c) <u>Remaining Assets</u>. After the payment of the full liquidation preference of the Series A Preference Shares as set forth in Article 46.1(a) above, the remaining assets of the Company legally available for distribution (or the consideration received by the Company or its Members in an Acquisition), if any, shall be distributed to the holders of Series A Preference Shares and Ordinary Shares, pro rata based on the number of Shares held by each such holder, treating for this purpose all such Shares as if they had been converted to Ordinary Shares pursuant to these Articles immediately prior to such Liquidation Event.
- (d) <u>Certain Acquisitions</u>.
  - (i) <u>Asset Transfer or Acquisition</u>. For the purposes of this Article 46.1:
    - (A) "Acquisition" shall mean any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganisation, other than any such consolidation, merger or reorganisation in which the Shares of the Company immediately prior to such consolidation, merger or reorganisation, continue to represent a majority of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganisation, (provided that, for the purpose of this Article 46.1(c), all Ordinary Shares issuable upon exercise of options outstanding immediately prior to such consolidation or merger or upon conversion of Convertible Securities (as defined below) issued and outstanding immediately prior to such merger or consolidation shall be deemed to be issued and outstanding immediately prior to such merger or consolidation and, if applicable, converted or exchanged in such merger or consolidation on the same terms as the actual issued and outstanding Shares are converted or exchanged); provided that an Acquisition shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof.
    - (B) "Asset Transfer" shall mean a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company (as determined on a consolidated basis with the assets of all direct and indirect subsidiaries of the Company).

- (ii) <u>Valuation of Consideration</u>. In any Acquisition or Asset Transfer, if the consideration to be received is securities of a corporation or other property other than cash, its value will be deemed its fair market value as determined in good faith by the Board of Directors on the date such determination is made, subject to the consent of the holders of a majority of the outstanding Series A Preference Shares, which consent shall not be unreasonably withheld, conditioned or delayed.
- (iii) The Company shall not have the power to effect an Acquisition or Asset Transfer unless the definitive agreement for such transaction provides that the consideration payable to the Members in connection therewith shall be allocated among the holders of Shares of the Company in accordance with this Article 46.1.
- 46.2 Subject to Article 46.1, if the Company shall be wound up, the liquidator may, with the sanction of a Special Resolution of the Company and any other sanction required by the Law, divide amongst the Members in kind the whole or any part of the assets of the Company (whether such assets shall consist of property of the same kind or not) and may for that purpose value any assets and determine how the division shall be carried out as between the Members or different classes of Members. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the Members as the liquidator, with the like sanction, shall think fit, but so that no Member shall be compelled to accept any asset upon which there is a liability.

## 47. Indemnity and Insurance

- 47.1 Every Director and officer of the Company (which for the avoidance of doubt, shall not include auditors of the Company), together with every former Director and former officer of the Company (each an "**Indemnified Person**") shall be indemnified out of the assets of the Company against any liability, action, proceeding, claim, demand, costs, damages or expenses, including legal expenses, whatsoever which they or any of them may incur as a result of any act or failure to act in carrying out their functions other than such liability (if any) that they may incur by reason of their own actual fraud, gross negligence, or wilful default. No Indemnified Person shall be liable to the Company for any loss or damage incurred by the Company as a result (whether direct or indirect) of the carrying out of their functions unless that liability arises through the actual fraud, or wilful default of such Indemnified Person. No person shall be found to have committed actual fraud, gross negligence, or wilful default under this Article unless or until a court of competent jurisdiction shall have made a finding to that effect.
- 47.2 The Company shall advance to each Indemnified Person reasonable attorneys' fees and other costs and expenses incurred in connection with the defence of any action, suit, proceeding or investigation involving such Indemnified Person for which indemnity will or could be sought. In connection with any advance of any expenses hereunder, the Indemnified Person shall execute an undertaking to repay the advanced amount to the Company if it shall be determined by final judgment or other final adjudication that such Indemnified Person was not entitled to indemnification pursuant to this Article. If it shall be determined by a final judgment or other final adjudication that such Indemnified Person was not entitled to indemnification with respect to such judgment, costs or expenses, then such party shall not be indemnified with respect to such judgment, costs or expenses and any advancement shall be returned to the Company (without interest) by the Indemnified Person.

47.3 The Directors, on behalf of the Company, may purchase and maintain insurance for the benefit of any Director or other officer of the Company against any liability which, by virtue of any rule of law, would otherwise attach to such person in respect of any negligence, default, breach of duty or breach of trust of which such person may be guilty in relation to the Company.

# 48. Financial Year

48.1 Unless the Directors otherwise prescribe, the financial year of the Company shall end on 31st December in each year and, following the year of incorporation, shall begin on 1st January in each year.

## 49. Transfer by Way of Continuation

49.1 If the Company is exempted as defined in the Law, it shall, subject to the provisions of the Law and with the approval of a Special Resolution, have the power to register by way of continuation as a body corporate under the laws of any jurisdiction outside the Cayman Islands and to be deregistered in the Cayman Islands.

# 50. Excluded Opportunity

50.1 The Company renounces any interest or expectancy of the Company in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "Excluded Opportunity" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, any Series A Preference holder or any director of the Company who is not an employee of the Company or any of its subsidiaries, (collectively, "Covered Persons"), unless in either case such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Company. No amendment or repeal of this Article 50.1 (a "Future Amendment") will apply to or have any effect on the liability or alleged liability of any Covered Person with regards to any opportunities that such Covered Person becomes aware of prior to such Future Amendment.

# SHARE CERTIFICATE

Number

Shares

# LEGEND BIOTECH CORPORATION

**THIS SHARE CERTIFICATE CERTIFIES THAT** as of [DATE], [HOLDER OF SHARES], [ADDRESS OF HOLDER] is the registered holder of [NUMBER OF SHARES] fully paid [CLASS OF SHARES] of [PAR VALUE] par value per share in the above named Company which are held subject to, and transferable in accordance with, the Memorandum and Articles of Association of the Company (as Revised).

In Witness Whereof the Company has authorised this certificate to be issued on [DATE].

Director

By\_\_\_\_

# INVESTORS' RIGHTS AGREEMENT

MARCH 30, 2020

1	Def		Page 1
1 2		initions gistration Rights	1 4
2		Demand Registration	4
	2.1	[Reserved]	5
		Underwriting Requirements	5
		Obligations of the Company	6
		Furnish Information	8
	2.6	Expenses of Registration	8
		Delay of Registration	9
		Indemnification	9
		Reports Under Exchange Act	11
		Limitations on Subsequent Registration Rights	11
		"Market Stand-off" Agreement	11
		Restrictions on Transfer	12
		Termination of Registration Rights	13
3		ormation and Inspection Rights	14
		Delivery of Financial Statements	14
		Inspection	15
	3.3	Termination of Information and Inspection Rights	16
	3.4	Confidentiality	16
4	Right	ts to Future Share Issuances	17
	4.1	Right of First Offer	17
	4.2	Termination	18
5			18
		Employee Agreements	18
		Employee Shares	18
		Accounting Firm	18
		Tax	18
		Foreign Corrupt Practices Act	19
		Export Control Laws	19
		Additional Rights	20
		Termination of Additional Covenants	20
6		scellaneous	20
	6.1	Successors and Assigns	20
	6.2	Governing Law	20
		Counterparts	20
		Titles and Subtitles	21
		Notices	21
		Amendments and Waivers	21
	6.7	Severability	21
		Aggregation of Shares	22
		Entire Agreement	22
		Dispute Resolution	22 22
		Delays or Omissions; Remedies Construction of Terms	22
		Independent Nature of Investors	23
	0.10		25

i

6.12 Construction of Terms6.13 Independent Nature of Investors

Schedule A - Schedule of Investors

ii

#### **INVESTORS' RIGHTS AGREEMENT**

THIS INVESTORS' RIGHTS AGREEMENT is made as of March 30, 2020, by and among Legend Biotech Corporation, a Cayman Islands exempted company (the **"Company"**), and each of the investors listed on <u>Schedule A</u> hereto (each an **"Investor"** and collectively the **"Investors"**).

#### RECITALS

WHEREAS, the Company and the Investors are parties to the Series A Preference Shares Purchase Agreement of even date herewith (the "Purchase Agreement"); and

WHEREAS, in order to induce the Company to enter into the Purchase Agreement and to induce the Investors to invest funds in the Company pursuant to the Purchase Agreement, the Investors and the Company hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register Ordinary Shares (as defined below) issuable to the Investors, to receive certain information from the Company, and to participate in future equity offerings by the Company, and shall govern certain other matters as set forth in this Agreement.

## NOW, THEREFORE, the parties hereby agree as follows:

1 Definitions. For purposes of this Agreement:

"Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund, private equity fund, hedge fund or other private investment fund or registered investment company now or hereafter existing that is controlled by one or more general partners, managing members or investment adviser of, or shares the same management company or investment adviser with, such Person.

"Board of Directors" means the Board of Directors of the Company.

"**Capital Research and Management Company**" means Capital Research and Management Company, as investment adviser to SMALLCAP World Fund, Inc. and its permitted transferees, and its Affiliates.

"**Competitor**" means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in any activity that directly or indirectly competes with the current or planned business or activity of the Company, but shall not include any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than 20% of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the board of directors of any Competitor; <u>provided</u>, <u>however</u>, that none of Hudson Bay, Capital Research and Management Company and any funds or accounts managed by it, JJDC, LAV, Vivo, RA Capital or any of the foregoing's Affiliates shall be deemed a Competitor.

"**Damages**" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any free writing prospectus relating thereto, any amendment or supplement to any such registration statement or prospectus,

or any filing made by the Company under the securities (or "Blue Sky" laws) of any state or other jurisdiction, (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein (in the case of statements in any prospectus, in the light of the circumstances under which such statements were made) not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

"Derivative Securities" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Ordinary Shares, including options and warrants.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Excluded Registration**" means (i) a registration relating to the sale or grant of securities to employees of the Company or a Subsidiary pursuant to a share option, share purchase, equity incentive or similar plan; (ii) a registration on Form S-4, Form F-4 or their then equivalents relating solely to the issuance of equity securities in connection with an acquisition of any entity or business; or (iii) a registration in which the only Ordinary Shares being registered are Ordinary Shares issuable upon conversion of debt securities that are also being registered.

"FOIA Party" means a Person that, in the reasonable determination of the Board of Directors, may be subject to, and thereby required to disclose non-public information furnished by or relating to the Company under, the Freedom of Information Act, 5 U.S.C. 552 ("FOIA"), any state public records access law, any state or other jurisdiction's laws similar in intent or effect to FOIA, or any other similar statutory or regulatory requirement; <u>provided</u>, <u>however</u>, that none of Hudson Bay, Capital Research and Management Company and any funds or accounts managed by it, JJDC, LAV, Vivo, RA Capital or any of the foregoing's Affiliates shall be deemed a FOIA Party.

"Form F-1" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

"Form F-3" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

"**Form S-1**" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

"Form S-3" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

"GAAP" means generally accepted accounting principles in the United States as in effect from time to time.

"Holder" means any holder of Registrable Securities who is a party to this Agreement.

"Hudson Bay" means HBC Asia Healthcare Opportunities III and its Affiliates and permitted transferees.

"Immediate Family Member" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

"Initiating Holders" means, collectively, Holders who properly initiate a registration request under this Agreement.

"IPO" means the Company's first underwritten public offering of its Ordinary Shares under the Securities Act.

"JJDC" means Johnson & Johnson Innovation – JJDC, Inc.

"Key Employee" means each of Yuan Xu and Ying Huang.

"LAV" means LAV Biosciences Fund V, L.P. and its Affiliates and permitted transferees.

"New Securities" means, collectively, equity securities of the Company, whether or not currently authorised, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

"Ordinary Shares" means shares of the Company's Ordinary Shares, par value US\$0.0001 each.

"Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

"RA Capital" means RA Capital Management, L.P. and its Affiliates and permitted transferees.

"**Registrable Securities**" means (i) the Ordinary Shares issuable pursuant to any Series A Preference Shares then outstanding or issued upon conversion of the Series A Preference Shares and (ii) any Ordinary Shares or other shares of capital stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, any of the shares referenced in clause (<u>i</u>) above, and (iii) any securities issued upon any stock split, dividend, recapitalization or similar event with respect to any of the foregoing; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to <u>Subsection 6.1</u>, and excluding for purposes of <u>Section 2</u> any shares for which registration rights have terminated pursuant to <u>Subsection 2.13</u> of this Agreement.

"**Registrable Securities then outstanding**" means the number of shares determined by adding the number of outstanding Registrable Securities and the number of Registrable Securities issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities.

"**Restated Articles**" means the Second Amended and Restated Memorandum and Articles of Association of the Company, as amended and/or restated from time to time.

"Restricted Securities" means the securities of the Company required to be notated with the legend set forth in Subsection 2.12(b) hereof.

"Rule 415" means Rule 415 under the Securities Act or any successor rule providing for the offering of securities on a continuous basis.

"SEC" means the Securities and Exchange Commission.

"SEC Rule 144" means Rule 144 promulgated by the SEC under the Securities Act.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Selling Expenses" means all underwriting discounts, selling commissions, and share transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in <u>Subsection 2.6.</u>

"Series A Preference Shares" means the Company's Series A Preference Shares, par value US\$0.0001 each.

"Vivo" means Vivo Capital Fund IX, L.P. and its Affiliates and permitted transferees.

2 <u>Registration Rights</u>. The Company covenants and agrees as follows:

#### 2.1 Demand Registration.

(a) Form F-1 Demand. If at any time after the earlier of (i) four years after the date of this Agreement or (ii) 180 days after the effective date of the registration statement for the IPO, the Company receives a request from Holders of a majority of the Registrable Securities then outstanding that the Company file a Form F-1 registration statement (or, if the Company is not then eligible to use Form F-1, a Form S-1 registration statement) with respect to at least 40% of the Registrable Securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of Selling Expenses, would exceed US\$30,000,000), then the Company shall (i) within ten days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders and (ii) as soon as practicable, and in any event within 60 days after the date such request is given by the Initiating Holders, file a Form F-1 registration statement (or, if the Company is not then eligible to use Form F-1, Form S-1) under the Securities Act covering all Registrable Securities that the Initiating Holders, as specified by notice given by each such Holder to the Company within 20 days of the date the Demand Notice is given, and in each case, subject to the limitations of <u>Subsection 2.1(c)</u> and <u>Subsection 2.3</u>. A registration statement filed pursuant to this <u>Subsection 2.1</u> shall, unless otherwise directed by a majority of the Registrable Securities to be included in such registration statement, and no Holder shall be named as an "underwriter" in the registration statement without such Holder's prior written consent.

If the Company files a registration statement for the IPO in a jurisdiction other than the U.S., then for purposes of the rights described in <u>Subsection</u> <u>2.1(a)(ii)</u> only, all references to the registration of securities under the Securities Act shall be deemed to mean the equivalent registration in such non-U.S. jurisdiction, and all applicable references to the Securities Act and rules, forms of registration statements and registration of securities thereunder, U.S. law and the SEC shall be deemed to refer to the equivalent statutes, rules, forms of registration statements, registration of securities and laws of and equivalent government authority in the applicable non-U.S. jurisdiction.

(b) Form F-3 Demand. If at any time when it is eligible to use a Form F-3 registration statement (or, if the Company is not then eligible to use Form F-3 but is eligible to use Form S-3, a Form S-3 registration statement), the Company receives a request from Holders of at least 20% of the Registrable Securities then outstanding that the Company file a Form F-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least US\$10,000,000, then the Company shall (i) within ten days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders and (ii) as soon as practicable, and in any event within 45 days after the date such request is given by the Initiating Holders, file a Form F-3 registration statement (or, if the Company is not then eligible to use Form F-3 but is eligible to use Form S-3, a Form S-3 registration statement) under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within 20 days of the date the Demand Notice is given, and in each case, subject to the limitations of <u>Subsection 2.1(c)</u> and <u>Subsection 2.3</u>.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this <u>Subsection 2.1</u> a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board of Directors it would be materially detrimental to the Company and its shareholders for such registration statement to become effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company, (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than 60 days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any 12-month period; and provided further that the Company shall not register any securities for its own account or that of any other shareholder during such 60-day period other than pursuant to an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(a)</u> (i) during the period that is 30 days before the Company's good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration, <u>provided</u>, that the Company actively employs in good faith commercially reasonable efforts to cause such registration statement to become effective and complies with its obligations hereunder in respect of such registration, (ii) after the Company has effected two registrations pursuant to <u>Subsection 2.1(a)</u> or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form F-3 or Form S-3 pursuant to a request made pursuant to <u>Subsection 2.1(b)</u>. The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(b)</u> (i) during the period that is 30 days before the Company's good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration, <u>provided</u>, that the Company actively employs in good faith commercially reasonable efforts to cause such registrations subsection 2.1(b) within the 12 month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this <u>Subsection 2.1(d)</u> until such time as the applicable registration expenses therefor, and forfeit their right to one demand registration statement pursuant to <u>Subsection 2.1(d)</u>.

2.2 [Reserved]

2.3 Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding the foregoing or anything else to the contrary contained here, no holder of Registrable Securities included in any underwritten offering (under this Section 2.3 or any other section hereof) shall be required to make any representations or warranties to the Company or the underwriters other than representations and warranties regarding such holder, such holder's ownership of its Registrable Securities to be sold in the offering and such holder's intended method of distribution, or to undertake any indemnification or contribution obligations to the Company or the underwriters or other investment banks with respect thereto, except as provided in Section 2.8. Notwithstanding any other provision of this Subsection 2.3, if the underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities requested to be included therein by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares.

(b) For purposes of <u>Subsection 2.1</u>, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in <u>Subsection 2.3(a)</u>, fewer than 50% of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4 <u>Obligations of the Company</u>. Whenever required under this <u>Section 2</u> to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to 180 days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such 180-day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Ordinary Shares (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form F-3 or Form S-3 that are intended to be offered on a continuous or delayed basis pursuant to Rule 415, subject to compliance with applicable SEC rules, such 180-day period shall be extended for up to 90 days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) promptly prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement, including any amendments and supplements (i) as may be requested by the SEC or (ii) as may be reasonably requested by a majority in interest of the Holders of the Registrable Securities included in the registration statement, including to change the plan of distribution set forth in the registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; <u>provided</u> that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange and to be listed or quoted (as applicable) on each securities exchange and trading market (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration and ensure that all Registrable Securities shall be eligible for clearing through The Depository Trust Company ("**DTC**"), through its Deposit/Withdrawal At Custodian ("**DWAC**") or applicable successor system, and that the Company shall be eligible and participating in the Direct Registration System of DTC with respect to the Ordinary Shares;

(h) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed;

7

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus;

(k) cooperate with each Holder that holds Registrable Securities being offered and the managing underwriter or underwriters with respect to an applicable Registration Statement, if any, to facilitate the timely (i) preparation and delivery of certificates (not bearing any restrictive legends) representing Registrable Securities to be offered pursuant to such Registration Statement, and enable such certificates to be registered in such names and in such denominations or amounts, as the case may be, or (ii) crediting of the Registrable Securities to be offered pursuant to a Registration Statement to the applicable account (or accounts) with DTC through its DWAC system, in any such case as such Holder or the managing underwriter or underwriters, if any, may reasonably request;

(l) use its commercially reasonable best efforts to prevent the issuance of any stop order or other suspension of effectiveness of the registration statement, and, if such an order is issued, to obtain the withdrawal of such order as soon as possible and notify each Holder (and, in the event of an underwritten offering, the managing underwriters) of the issuance of any such order and the resolution thereof;

(m) permit Selling Holder Counsel (as defined below) to review the registration statement and all amendments and supplements thereto (as well as all requests for acceleration or effectiveness thereof), a reasonable period of time prior to their filing with the SEC (not less than five (5) business days);

(n) hold in confidence and not make any disclosure of information concerning a Holder provided to the Company unless (i) disclosure of such information is necessary to comply with federal or state securities laws, (ii) the disclosure of such information is necessary to avoid or correct a misstatement or omission in the registration statement, (iii) the release of such information is ordered pursuant to a subpoena or other order from a court or governmental body of competent jurisdiction, or (iv) such information has been made generally available to the public other than by disclosure in violation of this or any other agreement; and

(o) take such other actions as are reasonably required in order to expedite or facilitate the disposition of the Registrable Securities.

(p) In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors (and, for the avoidance of doubt, any Person employing or designating any such director) may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5 <u>Furnish Information</u>. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this <u>Section 2</u> with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6 <u>Expenses of Registration</u>. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to <u>Section 2</u>, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed US\$80,000 per registration, of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; <u>provided</u>, <u>however</u>, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to <u>Subsection 2.1</u> if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling

Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to <u>Subsection 2.1(a)</u> or <u>Subsection 2.1(b)</u>, as the case may be; <u>provided further</u> that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to <u>Subsection 2.1(a)</u> or <u>Subsection 2.1(b)</u>. Each Holder shall bear all Selling Expenses relating to such Holder's Registrable Securities that are registered pursuant to this <u>Section 2</u>.

2.7 <u>Delay of Registration</u>. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this <u>Section 2</u>.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, managers, officers, directors, and equityholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; <u>provided</u>, <u>however</u>, that the indemnity agreement contained in this <u>Subsection 2.8(a)</u> shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, conditioned or delayed, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon misstatements or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, , any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon misstatements or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; <u>provided</u>, <u>however</u>, that the indemnity agreement contained in this <u>Subsection 2.8(b)</u> shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld, conditioned or delayed; and <u>provided further</u> that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under <u>Subsections 2.8(b)</u> and <u>2.8(d)</u> exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder).

(c) Promptly after receipt by an indemnified party under this <u>Subsection 2.8</u> of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this <u>Subsection 2.8</u>, give the indemnifying party notice of the commencement thereof. The indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; <u>provided</u>, <u>however</u>, that an indemnified party (together with all other indemnifying party so be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall not relieve such indemnifying party of any liability to the indemnified party under this <u>Subsection 2.8</u>, except to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnified party under this <u>Subsection 2.8</u>, except to the extent that such failure materially prejudices the indemnifying party otherwise than under this <u>Subsection 2.8</u>.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this <u>Subsection 2.8</u> but it is judicially determined that such indemnification may not be enforced in such case, notwithstanding the fact that this <u>Subsection 2.8</u> provides for indemnification in such case or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this <u>Subsection 2.8</u>, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; <u>provided, however</u>, that, in any such case, no Person guilty of such fraudulent misrepresentation; and <u>provided further</u> that in no event shall a Holder's contribution from any Person who was not guilty of such fraudulent misrepresentation; and <u>provided further</u> that in no event shall a Holder's contribution (pursuant to this <u>Subsection 2.8(d)</u>) when combined with the amounts paid or payable by such Holder pursuant to <u>Subsection 2.8(b</u>), exceed the proce

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this <u>Subsection 2.8</u> shall survive the completion of any offering of Registrable Securities in a registration under this <u>Section 2</u>, and otherwise shall survive the termination of this Agreement.

2.9 <u>Reports Under Exchange Act</u>. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form F-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) file with the SEC in a timely manner (without giving effect to any extensions pursuant to Rule 12b-25 of the Exchange Act) all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements) and not terminate the registration of the Ordinary Shares under the Exchange Act or otherwise terminate its status as an issuer required to file reports under the Exchange Act, even if the securities laws would otherwise permit any such termination; and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after 90 days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form F-3 and/or Form S-3 (at any time after the Company so qualifies) and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form F-3 or Form S-3 (at any time after the Company so qualifies to use such form).

2.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that would allow such holder or prospective holder (i) to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder; provided that this limitation shall not apply Registrable Securities acquired by any additional Investor that becomes a party to this Agreement in accordance with <u>Subsection 6.9</u>.

2.11 <u>"Market Stand-off" Agreement</u>. Each Holder hereby agrees that, upon the request of the managing underwriter(s) for the IPO, enter into a lock-up agreement with the managing underwriter(s) of the IPO in substantially the form attached hereto as <u>Exhibit A</u> (the "Lock-up Agreement"), provided that (a) the Lock-Up Agreement is not more restrictive in any respect than any similar agreement entered into with any other shareholder of the Company and (b) all officers and directors are subject to the same restrictions as those contained in the Lock-up Agreement and the Company uses commercially reasonable efforts to obtain a similar agreement from all shareholders individually owning more than 1% of the Company's outstanding Ordinary Shares (after giving effect to conversion into Ordinary Shares of all outstanding Series A Preference Shares). If a managing underwriter of the IPO notifies the Company (the "**Release Notice**") that any Person has requested to be released from a lock-up agreement entered into in connection with the IPO (the "**Requested Release**"), the Company shall provide the Investors written notice of the Requested Release within one business day of receiving the Release Notice. The foregoing provisions

of this <u>Subsection 2.11</u> shall apply only to the IPO. The managing underwriter(s) in connection with the IPO are intended third-party beneficiaries of this <u>Subsection 2.11</u> and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements or the provisions of this <u>Subsection 2.11</u> by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

# 2.12 Restrictions on Transfer.

(a) The Series A Preference Shares and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognise and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Series A Preference Shares and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement. For the avoidance of doubt, a Series A Preference Share Holder may freely sell, pledge or otherwise transfer such Holder's Series A Preference Shares without the Company's prior written consent if such sale, pledge, or transfer complies with the provisions of this Agreement and all applicable securities laws.

(b) Each certificate, instrument or book entry representing (i) the Series A Preference Shares, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any share split, share dividend, recapitalisation, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of <u>Subsection 2.12(c)</u>) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE SHAREHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this <u>Subsection 2.12</u>.

(c) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this <u>Section 2</u>. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal

counsel (which can be an opinion of the in-house counsel of the Holder) who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act, (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate, member, partner or equityholder of such Holder; provided that each transferee agrees in writing to be subject to the terms of this <u>Subsection 2.12</u>. Each certificate, instrument or book entry representing the Restricted Securities transferred as above provided shall be notated with, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in <u>Subsection 2.12(b)</u>, except that such certificate, instrument or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

(d) Notwithstanding the foregoing, with respect to each Holder, the certificates (or electronic book entries, if applicable) evidencing each Holder's Registrable Securities and any other shares or other securities subject to restriction under this <u>Subsection 2.12</u> or otherwise hereunder shall not contain or be subject to (and such Holder shall be entitled to immediate removal of) (A) the legends set forth in <u>Subsection 2.12(b)</u> or any other restrictive legend with respect to registration requirements under the Securities Act and U.S. state securities laws, nor shall be subject to any stop transfer instructions imposed by the Company or its transfer agent with respect to any restrictions under <u>Subsection 2.11</u>, this <u>Subsection 2.12</u> or any U.S. federal or state securities laws, while a registration statement covering the resale of such Registrable Securities is effective, (B) if such Holder provides customary paperwork to the effect that (I) it has sold or is selling such Registrable Securities or other shares or securities may then be sold without limitation pursuant to Rule 144, (C) if such Holder certifies that it is not an affiliate of the Company (within the meaning of Rule 144) and that such Holder's holding period for purposes of Rule 144 with respect to such Registrable Securities or other shares or securities is at least six months (or, prior to an IPO, 12 months), or (D) if no legend is required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC), as set forth in a legal opinion, in form and substance reasonably acceptable to the Company, delivered by counsel to such Holder.

2.13 <u>Termination of Registration Rights</u>. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to <u>Subsection 2.1</u> shall terminate upon the earliest to occur of:

(a) the closing of a Liquidation Event, as such term is defined in the Restated Articles;

(b) such time as Rule 144 is available for the sale of all of such Holder's Registrable Securities without limitation during a threemonth period without registration and without compliance with any current public information requirement; and

(c) the five-year anniversary of the date of the IPO.

## 3 Information and Inspection Rights.

3.1 <u>Delivery of Financial Statements</u>. Upon the written request of any Investor, the Company shall deliver to such Investor, provided that the Board of Directors has not reasonably determined that such Investor is a Competitor:

(a) as soon as practicable, but in any event within 120 days after the end of each fiscal year of the Company, including the fiscal year ended December 31, 2019, (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of shareholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants of nationally recognised standing selected by the Company;

(b) as soon as practicable, but in any event within 45 days after the end of each of the first three quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of shareholders' equity as of the end of such fiscal quarter;

(c) as soon as practicable, but in any event 30 days before the end of each fiscal year, a budget and business plan for the next fiscal year, approved by the Board of Directors and prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company; and

(d) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Investor may from time to time reasonably request; <u>provided</u>, <u>however</u>, that the Company shall not be obligated under this <u>Subsection 3.1</u> to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

Notwithstanding the foregoing, each of the Investors set forth on <u>Exhibit B</u> (the "<u>Automatic Recipients</u>") have advised the Company of their desire to receive the financial statements described in Subsections 3.1(a)-(c) without having to provide a written request and the Company covenants and agrees to deliver such financial statements to the Automatic Recipients without requiring a prior written request from such Automatic Recipients.

If, for any period, the Company has any Subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated Subsidiaries.

Not later than the third business day after the date of this Agreement, the Company shall publicly disclose, or cause GenScript Biotech Corporation to publicly disclose, any material non-public information in respect of GenScript Biotech Corporation disclosed or made available to any Investor on prior to the date of this Agreement, including, as applicable, any information regarding the Purchase Agreement and related transaction documents that constitutes such material non-public information (the "GenScript Announcement"). Notwithstanding anything else in this Agreement or any other agreement or instrument to the contrary, (a) no Investor, and no Investor's agents or representatives ("Representatives"), shall at any time after the date of this Agreement be given, or be provided access to, any material nonpublic information concerning the Company, the Company's Affiliates, any other public company or Person, or

any of their respective securities, unless such Investor requests such information from the Company in writing, and (b) the Company may cease providing the information set forth in this Subsection 3.1 during the period starting with the date 60 days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants to provide information under this Subsection 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective. Upon the effective date of the registration statement in respect of the IPO or when the Company otherwise first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, the Company shall certify to each Investor that such Investor is then not in possession of any material nonpublic information concerning the Company, the Company's Affiliates or any of their respective securities, regardless of whether such Investor received or had access to any material non-public information concerning the Company prior to such date. Without limiting the foregoing, the Company acknowledges that following the effective date of the registration statement in respect of the IPO or when the Company otherwise first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, no Investor desires to receive any material nonpublic information relating to any company with any publicly-traded securities, and the Company agrees that it shall not disclose any such information to any Investor, except as otherwise expressly requested in writing by such Investor. Notwithstanding anything to the contrary contained in Section 3.4 or elsewhere in this Agreement, no Investor, nor any of such Investor's Representatives, shall at any time have any duty of trust or confidence with respect to, or any obligation not to trade in any securities on the basis of, any material nonpublic information concerning the Company, the Company's Affiliates, any other public company or Person, or any of their respective securities, that is (X) provided or made available to such Investor in violation of any of the provisions of this paragraph or (Y) otherwise possessed (or continued to be possessed) by such Investor as a result of a violation of any of the provisions of this paragraph.

In the event of a breach of any of the foregoing covenants by the Company or any of its Subsidiaries or Affiliates, or any of its or their respective officers, directors (or equivalent persons), employees, attorneys, representatives or agents, in addition to any other remedies provided in this Agreement or otherwise available at law or in equity, the Investors shall have the right (i) to require the Company to make a public disclosure immediately (but in any case, within one business day) in the form of a press release, public advertisement or otherwise, of the applicable material nonpublic information regarding the Company or its Subsidiaries or Affiliates, or (ii) notwithstanding anything to the contrary contained in Section 3.4 or elsewhere in this Agreement, if the Company fails to make such public disclosure within one business day, to make a public disclosure in the form of a press release, public advertisement or otherwise, of the applicable material nonpublic information regarding the Company or its Subsidiaries or Affiliates, or any of its or their respective officers, directors (or equivalent persons), employees, attorneys, representatives or agents. With regards to the foregoing, no Investor shall have any liability to the Company, any Subsidiaries or Affiliates or any of its or their respective officers, directors (or equivalent persons), employees, equityholders, attorneys, representatives or agents for any such disclosure.

3.2 <u>Inspection</u>. The Company shall permit each Investor provided that the Board of Directors has not reasonably determined that such Investor is a Competitor, at such Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Investor; <u>provided, however</u>, that the Company shall not be obligated pursuant to this <u>Subsection 3.2</u> to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3 <u>Termination of Information and Inspection Rights</u>. The covenants set forth in <u>Subsection 3.1</u> (other than the last two paragraphs in <u>Section 3.1</u>) and <u>Subsection 3.2</u> shall terminate and be of no further force or effect (a) immediately before the consummation of the IPO, (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act or (c) upon a Liquidation Event, as such term is defined in the Restated Articles, whichever event occurs first.

#### 3.4 Confidentiality.

(a) Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement) ("Confidential Information"), unless such Confidential Information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection 3.4 by such Investor), (b) is or has been independently developed or conceived by such Investor without use of the Company's confidential information, (c) is or has been made known or disclosed to such Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company, or (d) or is provided or made available to such Investor or any of its Representatives in violation of any of the provisions of the last paragraph of Subsection 3.1; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company, (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Subsection 3.4, (iii) to any existing or prospective Affiliate, partner, member, shareholder, investment advisers and such investment adviser's Affiliates or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information or (iv) as may otherwise be required by law, regulation, rule, court order or subpoena or as otherwise requested by a regulatory or self-regulatory authority or in a proceeding, regulatory, self-regulatory or judicial inquiry, provided that the Investor promptly notifies the Company of such disclosure (to the extent legally permitted) and takes reasonable steps to minimize the extent of any such required disclosure. Notwithstanding the foregoing, an Investor shall not be required to provide notice to the Company in connection with any disclosures by or on behalf of such Investor pursuant to a regulatory, self-regulatory or judicial request or requirement that is not specifically related to the Company or the Confidential Information.

(b) The Company acknowledges that (1) certain of the Investors and their respective Affiliates are investment funds that are engaged in the business of public market and private equity investing or strategic corporate investors and may from time to time invest in entities that develop and utilize technologies, products or services that are similar to or competitive with those of the Company, and (2) except insofar as this Agreement restricts the disclosure of Confidential Information, this Agreement shall not prevent any of such Investors and their Affiliates from (x) engaging in or operating any business, (y) entering into any agreement or business relationship with any third party, or (z) evaluating or engaging in investment discussions with, or investing in, any third party, whether or not competitive with the Company or its affiliates. The Company acknowledges that each such Investor's review of Confidential Information will inevitably enhance its knowledge and understanding of the business of the Company in a way that cannot be separated from such Investor's other knowledge, and the Company agrees that this Agreement shall not restrict any of such Investors and their Affiliates in connection with the purchase, sale, consideration of, and decisions related to other investments, that may compete with the Company and serving on the boards of such investments in such industries or developing internal programs that may compete with the Company; *provided however*, subject to the other provisions of this Subsection 3.4, each such Investor acknowledges that its review, use and disclosure of Confidential Information received pursuant to this Agreement is subject to the confidentiality obligations set forth in Section 3.4(a) and is not

a license to exploit such Confidential Information, use such Confidential Information to compete with the Company, or actively share such Confidential Information with portfolio companies of such Investor or its Affiliates. Furthermore, nothing in this Agreement will be construed as a representation or agreement that any of such Investors and their Affiliates will not develop, receive or otherwise possess ideas, plans or other information which may be similar to that embodied in the Confidential Information, provided that such information has not been prepared in reliance upon or in reference to the Confidential Information.

#### 4 Rights to Future Share Issuances.

4.1 <u>Right of First Offer</u>. Subject to the terms and conditions of this <u>Subsection 4.1</u> and applicable securities laws, if the Company proposes to offer or sell any New Securities or debt securities (excluding indebtedness obtained pursuant to a credit facility, line of credit or other similar arrangement from a regulated banking institution) (the "**Offered Securities**"), the Company shall first offer such Offered Securities to the Investors. An Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (a) itself, (b) its Affiliates and (c) its beneficial interest holders, such as limited partners, members or any other Person having "beneficial ownership," as such term is defined in Rule 13d-3 promulgated under the Exchange Act, of such Investor ("**Investor Beneficial Owners**"); <u>provided</u> that, each such Affiliate or Investor Beneficial Owner: (i) is not a Competitor or FOIA Party, unless such party's purchase of Offered Securities is otherwise consented to by the Board of Directors, and (ii) agrees to enter into this Agreement and the Right of First Refusal and Co-Sale Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an "**Investor**" under each such agreement (provided that, any Competitor or FOIA Party shall not be entitled to any rights as an Investor under <u>Subsections 3.1, 3.2</u> and <u>4.1</u> hereof).

(a) The Company shall give notice (the "**Offer Notice**") to each Investor, stating (i) its bona fide intention to offer such Offered Securities, (ii) the number of such Offered Securities to be offered and (iii) the price and terms, if any, upon which it proposes to offer such Offered Securities.

(b) By notification to the Company within 20 days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such Offered Securities which equals the proportion that the Ordinary Shares issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Series A Preference Shares and any other Derivative Securities then held, by such Investor bears to the total Ordinary Shares of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Series A Preference Shares and other Derivative Securities). At the expiration of such twenty (20) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares available to it (each, a "**Fully Exercising Investor**") of any other Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of Offered Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the proportion that the Ordinary Shares issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable of the Series A Preference Shares and any other Derivative Securities then held, by Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Subsection 4.1(c).

(c) If all Offered Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in <u>Subsection</u> <u>4.1(b)</u>, the Company may, during the 90 day period following the expiration of the periods provided in <u>Subsection 4.1(b)</u>, offer and sell the remaining unsubscribed portion of such Offered Securities to any Person or Persons at a price not less than, and upon

terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the Offered Securities within such period, or if such agreement is not consummated within 30 days of the execution thereof, the right provided hereunder shall be deemed to be revived and such Offered Securities shall not be offered unless first reoffered to the Investors in accordance with this <u>Subsection 4.1</u>.

(d) The right of first offer in this <u>Subsection 4.1</u> shall not be applicable to (i) shares excepted from the definition of "Additional Shares" in the Restated Articles and (ii) Ordinary Shares issued in the Qualified IPO, as such term is defined in the Restated Articles.

4.2 <u>Termination</u>. The covenants set forth in <u>Subsection 4.1</u> shall terminate and be of no further force or effect (a) immediately before the consummation of an IPO that results in the Series A Preference Shares being converted into Ordinary Shares, or (b) upon a Liquidation Event, as such term is defined in the Restated Articles, whichever event occurs first.

#### 5 Additional Covenants.

5.1 <u>Employee Agreements</u>. The Company will cause (a) each Person now or hereafter employed by it or by any Subsidiary (or engaged by the Company or any Subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement, substantially in the form approved by the Board of Directors.

5.2 <u>Employee Shares</u>. Unless otherwise approved by the Board of Directors, all future employees and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's share capital after the date hereof shall be required to execute restricted share or option agreements, as applicable, providing for (a) vesting of shares over a five-year period with 20% vesting after each year of service and (b) a market stand-off provision substantially similar to that in <u>Subsection 2.11</u>.

5.3 <u>Accounting Firm</u>. The Company shall engage a nationally recognized, top four accounting firm (a "**Top Four Firm**") to audit the annual financial statements provided for in this Agreement.

5.4 <u>Tax</u>.

(a) Not later than 45 days after the end of Company's fiscal year (the "**Reporting Deadline**"), the Company will make due inquiry with the Company's tax advisors or accountants regarding whether it or any of its Subsidiaries is, may be, or is likely to become (i) a "passive foreign investment company" as defined in Section 1297 of the U.S. Internal Revenue Code of 1986, as amended (the "**Code**") (a "**PFIC**"), and (ii) a "controlled foreign corporation" as defined in Section 957 of the Code (a "**CFC**") and whether the Automatic Recipients are, may be, or are likely to be treated as a "United States shareholder" thereof, as defined in Section 951(b) of the Code, in each case of clause (i) and (ii), for such fiscal year and will so advise the Automatic Recipients. Each Investor agrees to cooperate with the Company in connection with any inquiry pursuant to this Section 5.4 and to provide information reasonably requested by the Company.

(b) To the extent notification is provided pursuant to Subsection 5.4(a) above that the Company is a PFIC, the Company shall, and shall cause each of its Subsidiaries to, no later than 90 days after the end of such fiscal year, furnish the Automatic Recipients with all information necessary for the Automatic Recipients to timely make and maintain a qualified electing fund ("**QEF**") election in respect thereof, including (i) a PFIC Annual Information Statement under Section 1295(b) of the Code, which is

described in Treasury Regulation 1.1295-1(g), and containing all the information in Treasury Regulation 1.1295-1(g)(1)(i), 1.1295-1(g)(1)(ii)(A), 1.1295-1(g)(1)(iii) and 1.1295-1(g)(1)(iv)(A) and (ii) all information necessary for it to complete IRS Form 8621 (or successor form). All such information shall be provided in English.

(c) To the extent notification is provided pursuant to Subsection 5.4(a), that the Company is a CFC, the Company shall, and shall cause each of its Subsidiaries to, no later than 90 days after the end of each fiscal year (i) provide sufficient information to enable the Automatic Recipients to accurately and timely complete their annual U.S. tax reporting obligations, including filing IRS Form 5471 (or successor form) and including such information as is necessary for the Automatic Recipients to calculate any amounts with respect to a deemed paid foreign tax credit, Subpart F or GILTI inclusions, if any, (ii) if necessary, permit the Automatic Recipients (or their authorized representatives) to examine and copy the books of account, records, and other documentation of the Company and each of its Subsidiaries in order to verify the required information, and (iii) use commercially reasonable best efforts to mitigate any adverse or potentially adverse consequences to the Automatic Recipients so long as such mitigation can be achieved without material cost or disruption of the business of the Company or its Subsidiaries. In addition, the Company shall, and shall cause each of its Subsidiaries to, covenant to retain all records relevant for calculating the earnings and profits of and taxes paid by the Company and its Subsidiaries for as long each of the Automatic Recipients is a "United States shareholder" in respect of the Company or its Subsidiaries. All such information shall be provided in English.

(d) The Company is treated as an association taxable as a corporation for U.S. federal income tax purposes and no election to the contrary shall be made without the Investors' prior written consent.

5.5 Foreign Corrupt Practices Act. By the Reporting Deadline, the Company will determine whether: (i) it, its Subsidiaries, or any of their respective directors, officers, employees or agents have, directly or indirectly, made, offered, promised or authorized any payment or gift of any money or anything of value to or for the benefit of any "foreign official" (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**")), foreign political party or official thereof or candidate for foreign political office for the purpose of (x) influencing any official act or decision of such official, party or candidate, (y) inducing such official, party or candidate to use his, her or its influence to affect any act or decision of a foreign governmental authority, or (z) securing any improper advantage, in the case of (x), (y) and (z) above in order to assist the Company or any of its affiliates in obtaining or retaining business for or with, or directing business to, any person; (ii) it, its Subsidiaries, or any of their respective directors, officers, employees or agents have made or authorized any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of funds or received or retained any funds in violation of any law, rule or regulation; (iii) it has maintained, and has caused each of its Subsidiaries and affiliates to maintain, systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) and written policies to ensure compliance with the FCPA or any other applicable anti-bribery or anti-corruption law, and to ensure that all books and records of the Company and its Subsidiaries accurately and fairly reflect, in reasonable detail, all transactions and dispositions of funds and assets; and (iv) it, or any of its officers, directors or employees are the subject of any allegation, voluntary disclosure, investigation, prosecution or other enforcement action related to the FCPA or any other anti-corruption

5.6 <u>Export Control Laws</u>. By the Reporting Deadline, the Company will determine whether: (i) it has conducted all export transactions in accordance with applicable provisions of United States export control laws and regulations, including the Export Administration Regulations, the International Traffic in Arms Regulations, the regulations administered by the Office of Foreign Assets Control of the U.S.

Treasury Department, and the export control laws and regulations of any other Applicable Jurisdiction; (ii) it has obtained all export licenses and other approvals, timely filed all required filings and has assigned the appropriate export classifications to all products, in each case as required for its exports of products, software and technologies from the United States and any other Applicable Jurisdiction; (iii) it is in compliance with the terms of all applicable export licenses, classifications, filing requirements or other approvals; (iv) there are any pending or, to the knowledge of the Company, threatened claims against the Company with respect to such exports, classifications, or circumstances pertaining to the Company's export transactions that would reasonably be expected to give rise to any material future claims. The Company covenants and agrees to, by the Reporting Deadline, deliver to the Automatic Recipients an annual report attesting to the foregoing.

5.7 <u>Additional Rights</u>. For so long as any Series A Preference Shares remain outstanding, the Company shall not, directly or indirectly, enter into, amend, modify or supplement any agreement, commitment, understanding or any offer or proposal of any additional or beneficial consideration, offers, terms, options, rights, warrants, instruments or settlements with any Investor, or with any Affiliate of any Investor, relating to the Series A Preference Shares (including any agreement made on the date the Purchase Agreement is entered into), without offering the same terms and conditions to all Investors, other than any commercial arrangements that arise in the ordinary course of business and on arm's length terms; <u>provided</u>, <u>however</u>, that this Section 5.7 shall not apply in any respect to that certain letter agreement by and between the Company and RA Capital, dated on or about the date hereof, in the form previously circulated to the Investors.

5.8 <u>Termination of Additional Covenants</u>. The covenants set forth in this Section 5 shall terminate and be of no further force or effect (a) immediately before the consummation of the IPO, (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act or (c) upon a Liquidation Event, as such term is defined in the Restated Articles, whichever event occurs first.

#### 6 Miscellaneous.

6.1 <u>Successors and Assigns</u>. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities; <u>provided</u> that (i) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred and (ii) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of <u>Subsection 2.11</u>. The Company may not assign its right or obligations hereunder. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein (including in <u>Subsection 2.7</u>).

6.2 <u>Governing Law</u>. This Agreement shall be governed by the internal law of the State of New York, without regard to conflict of law principles that would result in the application of any law other than the law of the State of New York.

6.3 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (a) personal delivery to the party to be notified, (b) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day, (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid or (d) one business day after the business day of deposit with a nationally recognised overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on <u>Schedule A</u> or <u>Schedule B</u> (as applicable) hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this <u>Subsection 6.5</u>. If notice is given to the Company, a copy (which shall not constitute notice) shall also be given to Katten Muchin Rosenman LLP, 525 W. Monroe Street, Chicago, IL 60661-3693, Attn: Jeffrey R. Patt.

6.6 <u>Amendments and Waivers</u>. Any term of this Agreement may be amended, modified or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of a majority of the Registrable Securities then outstanding; provided that the Company may in its sole discretion waive compliance with <u>Subsection 2.12(c)</u>; and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (a) Subsection 3.1 and 3.4 may not be amended, modified or terminated and the observance of any term thereof may not be waived with respect to any Investor without the written consent of such Investor, (b) Subsection 2.11 and this Subsection 6.6 may not be amended, modified or terminated and the observance of any term thereof may not be waived without the written consent of all of the Investors and (c) any other provision of this Agreement may not be amended, modified or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, modification, termination, or waiver applies to all Investors in the same fashion. No consideration shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement unless the same consideration also is offered to all of the Investors. The Company shall give prompt notice of any amendment, modification or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, modification, termination, or waiver. Any amendment, modification, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7 <u>Severability</u>. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 <u>Aggregation of Shares</u>. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9 <u>Entire Agreement</u>. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

#### 6.10 Dispute Resolution.

(a) The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of New York and to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of New York or the United States District Court for the Southern District of New York and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

(b) WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

The prevailing party shall be entitled to reasonable attorney's fees, costs, and necessary disbursements in addition to any other relief to which such party may be entitled.

6.11 <u>Delays or Omissions; Remedies</u>. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default thereafter occurring. All remedies, whether under this Agreement or by law, at equity or otherwise afforded to any party, shall be cumulative and not alternative. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Investors by vitiating the intent and purpose of the transactions contemplated hereby. Accordingly, the

Company acknowledges that the remedy at law for breach of its obligations hereunder will be inadequate and agrees, in the event of a breach or threatened breach by the Company of any of the provisions hereunder, that the Investors shall be entitled, in addition to all other available remedies under this Agreement or by law or otherwise, to an injunction or injunctions to prevent or cure breaches of the provisions of this Agreement and to enforce specifically the terms and provisions hereof, without the necessity of showing economic loss and without any bond or other security being required.

6.12 <u>Construction of Terms</u>. Common nouns and pronouns shall be deemed to refer to the masculine, feminine, neuter, singular or plural, as the identity of the Person may in the context require. Any reference to statutes or laws shall include all amendments, modifications or replacements of the specific sections or provisions concerned. Whenever the term "include" or "including" is used in this Agreement, it shall mean "including, without limitation," (whether or not such language is specifically set forth) and shall not be deeded to limit the range of possibilities to those items specifically enumerated. A Person is deemed to hold, and be a holder of, Ordinary Shares or other Registrable Securities whenever such Person owns of record or beneficially through a "street name" holder such Ordinary Shares or other Registrable Securities (or the other securities upon exercise, conversion or exchange of which such Registrable Securities are directly or indirectly issuable, without giving effect to any limitations on exercise, conversion or exchange of other securities), and solely for purposes hereof, Registrable Securities, Registrable Securities (without giving effect to any limits on exercise, conversion or exchange of other securities). If the Company receives conflicting instructions, notices or elections from two or more Persons with respect to the same Registrable Securities, the Company shall act upon the basis of instructions, notice or election received from the registered owner of such Registrable Securities are directly or indirectly issuable).

6.13 <u>Independent Nature of Investors</u>. The obligations of each Investor under this Agreement are several and not joint with the obligations of any other Investor, and no Investor shall be responsible in any way for the performance of the obligations of any other Investor under this Agreement. Each Investor shall be responsible only for its own representations, warranties, agreements and covenants hereunder. Nothing contained in this Agreement, and no action taken by any Investor pursuant hereto, shall be deemed to constitute the Investors as, and the Company acknowledges and agrees that the Investors do not thereby constitute, a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Investors are in any way acting in concert or as a group with respect to the obligations under, or the transactions contemplated by, this Agreement, and the Company shall not assert any contrary position.

[Signature Pages Follow]

# COMPANY:

# LEGEND BIOTECH CORPORATION

By: /s/ Yuan Xu

Name: Dr. Yuan Xu

Title: Chief Executive Officer

Address: 2101 Cottontail Lane Somerset, NJ 08873, USA

**INVESTORS:** 

#### HBC ASIA HEALTHCARE OPPORTUNITIES III

By: /s/ Sander Gerber

Name: Sander Gerber

Title: Authorized Signatory

Address: 777 3rd Avenue New York, NY 10017

# **INVESTORS:**

## LAV BIOSCIENCES FUND V, L.P.

By: LAV GP V, L.P. Its General Partner By: LAV Corporate V GP, Ltd. Its General Partner

By: /s/ Yu Luo

Name: Yu Luo

Title: Authorized Signatory

Address: Attn: Jieyu Zou Unit 902-904, Two Chinachem Central, 26 Des Voeux Road Central, Hong Kong

## **INVESTORS:**

## JOHNSON & JOHNSON INNOVATION – JJDC, INC.

By: /s/ Asish K. Xavier

Name: Asish K. Xavier

Title: Vice President, Venture Investments

Address: Johnson & Johnson Innovation – JJDC, Inc. 410 George Street New Brunswick, New Jersey 08901 Attention: Asish K. Xavier, Vice President, Venture Investments

> With a copy to: Johnson & Johnson Law Department Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 Attention: JJDC Board Lawyer

# **INVESTORS:**

## VIVO CAPITAL FUND IX, L.P.

By: Vivo Capital IX, LLC, General Partner

By: /s/ Frank Kung

Name: Frank Kung

Title: Managing Member

Address: C/O Vivo Capital LLC 192 Lytton Avenue Palo Alto, CA 94301 Attn: General Counsel

#### **INVESTORS:**

## SMALLCAP WORLD FUND, INC.

- By: Capital Research and Management Company, as investment adviser for and on behalf of SMALLCAP World Fund, Inc.
- By: /s/ Walter R. Burkley

Name: Walter R. Burkley

- Title: Authorized Signatory
- Address: Capital Research and Management Company 333 South Hope Street, 55th Floor Los Angeles, CA 90071 Attn: Casey Solomon

**INVESTORS:** 

## RA CAPITAL HEALTHCARE FUND, L.P.

By: RA Capital Healthcare Fund GP, LLC Its General Partner

By: /s/ Peter Kolchinsky

Name: Peter Kolchinsky

Title: Manager

Address: RA Capital Management, L.P. 200 Berkeley Street 18th Floor Boston, MA 02116 Attn: General Counsel

**INVESTORS:** 

# **BLACKWELL PARTNERS LLC – SERIES A**

By: /s/ Abayomi A. Adigun

Name: Abayomi A. Adigun

Title: Investment Manager DUMAC, Inc., Authorized Agent

By: /s/ Jannine M. Lall

Name: Jannine M. Lall

Title: Head of Finance & Controller DUMAC, Inc., Authorized Agent

Address: Blackwell Partners LLC – Series A 280 S. Mangum Street Suite 210 Durham, NC 27701 Attn: Jannine Lall

**INVESTORS:** 

## RA CAPITAL NEXUS FUND, L.P.

By: RA Capital Nexus Fund GP, LLC Its General Partner

By: /s/ Peter Kolchinsky

Name: Peter Kolchinsky

Title: Manager

Address: RA Capital Management, L.P. 200 Berkeley Street 18th Floor Boston, MA 02116 Attn: General Counsel

# **INVESTORS:**

## **RISING ARROW ENTERPRISE LTD**

By: /s/ Da Liu

Name: Da Liu Title: Director

Address: Portcullis Chambers 4th Floor Ellen Skelton Building 3076 Sir Francis Drake Highway Road Town, Tortola British Virgin Islands VG1110 Attention: Mr. Da Liu

#### SCHEDULE A

#### INVESTORS

HBC Asia Healthcare Opportunities III 777 3rd Avenue NY NY 10017 Email: Jo-Wen <u>Lin-Jlin@hudsonbaycapital.com;</u> <u>treasury@hudsonbaycapital.com</u>

#### LAV Biosciences Fund V, L.P.

Attn: Jieyu Zou Unit 902-904, Two Chinachem Central, 26 Des Voeux Road Central, Hong Kong Email: Jieyu.zou@lavfund.com

# Johnson & Johnson Innovation – JJDC, Inc.

410 George Street New Brunswick, New Jersey 08901 Attention: Asish K. Xavier, Vice President, Venture Investments

> With a copy to: Johnson & Johnson Law Department Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 Attention: JJDC Board Lawyer

#### SMALLCAP World Fund, Inc.

Capital Research and Management Company 333 South Hope Street, 55<sup>th</sup> Floor Los Angeles, CA 90071 Attn: Casey Solomon Email: <u>cazs@capgroup.com</u>

# Vivo Capital Fund IX, L.P.

C/O Vivo Capital LLC 192 Lytton Avenue Palo Alto, CA 94301 Attn: General Counsel Email: <u>legal@vivocapital.com</u>

## RA Capital Healthcare Fund, L.P.

RA Capital Management, L.P. 200 Berkeley Street 18<sup>th</sup> Floor Boston, MA 02116 Attn: General Counsel Email: <u>legal@racap.com</u>

## Blackwell Partners LLC – Series A

280 S. Mangum Street Suite 210 Durham, NC 27701 Attn: Jannine Lall Email: <u>legal@racap.com</u>

## RA Capital Nexus Fund, L.P.

RA Capital Management, L.P. 200 Berkeley Street 18th Floor Boston, MA 02116 Attn: General Counsel Email: <u>legal@racap.com</u>

## **Rising Arrow Enterprise Ltd**

Portcullis Chambers 4th Floor Ellen Skelton Building 3076 Sir Francis Drake Highway Road Town, Tortola British Virgin Islands VG1110 Email: <u>liuda@crcplsf.com</u>

# EXHIBIT A

# FORM OF LOCK-UP AGREEMENT

#### EXHIBIT B

# AUTOMATIC RECIPIENTS

#### LAV Biosciences Fund V, L.P. Attn: Jieyu Zou

Unit 902-904, Two Chinachem Central, 26 Des Voeux Road Central, Hong Kong Email: Jieyu.zou@lavfund.com

#### Johnson & Johnson Innovation – JJDC, Inc.

410 George Street New Brunswick, New Jersey 08901 Attention: Asish K. Xavier, Vice President, Venture Investments

> With a copy to: Johnson & Johnson Law Department Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 Attention: JJDC Board Lawyer

# SMALLCAP World Fund, Inc.

Capital Research and Management Company 333 South Hope Street, 55<sup>th</sup> Floor Los Angeles, CA 90071 Attn: Casey Solomon Email: <u>cazs@capgroup.com</u>

#### IMPORTANT NOTE: INFORMATION SHOULD ONLY BE PROVIDED TO ERIK VAYNTRUB (ERV@CAPGROUP.COM) AND CASEY SOLOMON (CAZS@CAPGROUP.COM)

## Vivo Capital Fund IX, L.P.

C/O Vivo Capital LLC 192 Lytton Avenue Palo Alto, CA 94301 Attn: General Counsel Email: <u>legal@vivocapital.com</u>

## RA Capital Healthcare Fund, L.P.

RA Capital Management, L.P. 200 Berkeley Street 18<sup>th</sup> Floor Boston, MA 02116 Attn: General Counsel Email: <u>legal@racap.com</u>

## Blackwell Partners LLC – Series A

280 S. Mangum Street Suite 210 Durham, NC 27701 Attn: Jannine Lall Email: <u>legal@racap.com</u>

## RA Capital Nexus Fund, L.P.

RA Capital Management, L.P. 200 Berkeley Street 18th Floor Boston, MA 02116 Attn: General Counsel Email: <u>legal@racap.com</u>

## **Rising Arrow Enterprise Ltd**

Portcullis Chambers 4th Floor Ellen Skelton Building 3076 Sir Francis Drake Highway Road Town, Tortola British Virgin Islands VG1110 Email: <u>liuda@crcplsf.com</u>

# COLLABORATION AND LICENSE AGREEMENT

### **BY AND AMONG**

# LEGEND BIOTECH USA, INC.,

### LEGEND BIOTECH IRELAND LIMITED

AND

### JANSSEN BIOTECH, INC.

[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

# TABLE OF CONTENTS

ARTICLE I DEFINITIONS				
ARTICLE II MANAGEMENT OF COLLABORATIVE ACTIVITIES				
2.1	Joint Steering Committee	17		
2.2	Joint Development Committee	17		
2.3	U.S. Commercialization Committee	18		
2.4	Greater China Commercialization Committee	18		
2.5	Joint Manufacturing Committee	18		
2.6	Working Groups	18		
2.7	Membership of Committees, Subcommittees and Working Groups	19		
	Decision-Making	23		
	Meetings of the Committees and Working Groups	23		
	Disbandment	23		
	Alliance Managers	24		
2.12	Collaboration Activities	24		
ARTICLE III LICENSE GRANTS		24		
3.1	Legend Grant to Janssen	24		
3.2	Janssen Grant to Legend	24		
3.3	Sublicensing; Licensing	24		
3.4	Reciprocal Non-Exclusive Licenses for Disclosed Know-How	25		
3.5	Reciprocal Non-Exclusive Licenses for Collaboration Intellectual Property	25		
3.6	Exclusivity	26		
3.7	Combination Products	27		
3.8	Section 365(n) of the Bankruptcy Code	27		
3.9	Joint Patent Rights	28		
	No Other Rights	28		
3.11	Technical Assistance	28		
ARTICLE IV DEVELOPMENT				
4.1	GDP and Development Budget	28		
	Conduct of Development Activities	30		
4.3	Independent Development Activities	34		
4.4	Clinical Studies of Combination Regimens	36		
4.5	Companion Diagnostics	36		
	Regulatory Matters	36		
	Pricing and Reimbursement Approvals	39		
4.8	Pharmacovigilance	39		
	Patient Samples	39		
4.10	[***] Products	40		

-i-

ARTICLE V COMMERCIALIZATION				
5.2 5.3 5.4	Global Commercialization Strategy Commercialization in the U.S. Commercialization in Janssen Territory Commercialization in Greater China General Commercialization Provisions	42 43 46 48 51		
ARTICL	E VI MANUFACTURE AND SUPPLY	52		
6.2 6.3 6.4	Overview Supply for U.S. and Janssen Territories Greater China No Liability for Failure to Supply JMC Authority	52 54 63 66 66		
ARTICLE VII FINANCIAL PROVISIONS 6				
7.2 7.3 7.4 7.5 7.6 7.7 7.8 7.9	Upfront Payments Milestone Payments Shared Costs Pre-Tax Profit or Loss Third Party Intellectual Property Audits Tax Matters Tax Returns Currency Exchange Late Payments	66 66 70 72 74 75 76 77 78 78		
ARTICL	E VIII INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS	78		
8.2 8.3 8.4 8.5	Ownership of Inventions Prosecution and Maintenance of Patent Rights Globally Third Party Infringement Patent Invalidity Claims Claimed Infringement Patent Term Extensions Trademarks	78 79 80 82 83 83 83		
ARTICL	E IX CONFIDENTIALITY AND PUBLICITY	84		
9.2 9.3 9.4 9.5 9.6 9.7	Non-Disclosure and Non-Use Exceptions Authorized Disclosure Confidential Terms Publicity Prior Non-Disclosure Agreement Equitable Relief Publications	84 85 86 87 87 88 88		
ARTICLE X REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS				
10.2 10.3	Representations of Authority Consents No Conflict Enforceability	89 89 89 89		

E

# -ii-

	10.5 10.6 10.7 10.8 10.9	Additional Representations and Warranties of Legend No Warranties No Debarment or Exclusion Compliance with Anti-Corruption Laws Insurance	89 92 92 92 94
ART	ICLE	XI INDEMNIFICATION	95
	11.3 11.4		95 95 95 96 96
ART	ICLE	XII TERM AND TERMINATION	97
	12.1 12.2 12.3 12.4	Term Termination for Material Breach Termination by Janssen Unilaterally Effects of Termination or Expiration	97 97 98 98
ART	ICLE	XIII DISPUTE RESOLUTION	104
	13.1 13.2 13.3	Exclusive Dispute Resolution Mechanism Resolution by Executive Officers Arbitration	104 104 104
ART	ICLE	XIV MISCELLANEOUS	106
	14.2 Choic 14.3 14.4 14.5 14.6 14.7 14.8	Assignment; Successors Legend Change of Control te of Law Notices Severability Force Majeure Captions Integration Independent Contractors; No Agency	106 107 108 108 109 109 109 109
	14.9 14 10	Submission to Jurisdiction Execution in Counterparts; Facsimile Signatures	110 110
	14.11 14.12	No Consequential or Punitive Damages Performance by Affiliates Construction	110 110 110 110

-iii-

#### **COLLABORATION AND LICENSE AGREEMENT**

This Collaboration and License Agreement (the "**Agreement**") is made and effective as of December 21, 2017 (the "**Effective Date**") by and among Legend Biotech USA, Inc., a Delaware corporation ("Legend U.S."), Legend Biotech Ireland Limited, an Irish entity ("Legend Ireland"; together with Legend U.S., "Legend") and Janssen Biotech, Inc., a Pennsylvania corporation ("Janssen").

#### INTRODUCTION

1. Legend is developing LCAR-B38M and controls certain patents, know-how and other rights related to Products based on LCAR-

B38M;

2. Janssen has considerable knowledge and experience in developing and commercializing products in the oncology field throughout the world;

3. Legend and Janssen believe that a collaboration and license arrangement between the Parties regarding Products incorporating LCAR-B38M and potential [\*\*\*] Products would be desirable;

4. Legend desires to establish itself as an international pharmaceutical company with capabilities in all major functional areas, and the Parties desire that the collaboration under this Agreement will help Legend gain experience and infrastructure in connection with manufacturing and commercializing, and, to a lesser degree for the Initial Product, developing the Products hereunder; and

5. Legend and Janssen therefore desire to provide for the development, manufacture and commercialization of Products in the Field on and subject to the terms and conditions set forth herein;

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, Legend and Janssen hereby agree as follows:

#### ARTICLE I DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth below:

1.1 "Acquirer" means any Third Party that is an acquirer in any Change of Control transaction and any of such Third Party's Affiliates.

1.2 "Action" means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.3 "Affiliate" means, with respect to a Person, any Person directly or indirectly controlling, controlled by, or under common control with, such first Person at the time the determination of affiliation is being made. For purposes of this definition, the term "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), as used with respect to any Person, means (i) in the case of a Person that is a corporate entity, direct or indirect ownership of 50% or more of the stock or shares having the right to vote for the election of directors of such Person and (ii) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by contract, or otherwise.

1.4 "BCMA" means B-cell maturation antigen.

1.5 "**Binding Domain**" means the region of a CAR that binds to the antigen targeted by such CAR (or if such CAR is multivalent, binds to one of the epitopes targeted by such CAR), such region comprised of one or more CDRs, and most commonly consisting of CDRH1, CDRH2 and CDRH3.

1.6 "**Blocking Third Party Patent Rights**" means, with respect to any country, Patent Rights in such country Controlled by a Third Party that Cover a Product.

1.7 "Business Day" means a day on which banking institutions in New York, New York and Hong Kong are open for business.

1.8 "**Calendar Quarter**" means a quarter based on the Johnson & Johnson Universal Calendar for that quarter (a copy of which is attached hereto as <u>Exhibit A</u>).

1.9 "**Calendar Year**" means a year based on the Johnson & Johnson Universal Calendar for that year (a copy of which is attached hereto as <u>Exhibit A</u>).

1.10 "CAR" means a chimeric antigen receptor.

1.11 "CAR-T" means a T-Cell incorporating a CAR.

1.12 "**CAR T-Cell Therapy**" means a therapy comprising a T-Cell, whether or not autologous, that has been transfected or engineered (*in vivo* or *ex vivo*) to express a chimeric antigen receptor directed to an antigen.

1.13 "**CDR**" means the complementarity-determining region of an antigen binding region of an antibody as defined by the Kabat numbering scheme (Kabat *et al.*, Sequences of Proteins of Immunological Interest (1991)).

1.14 "Change of Control" means, with respect to a Party (which with respect to Legend, shall include Legend U.S. and Legend Ireland):

(a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other similar transaction involving such Party as a result of which either (i) the stockholders of such Party immediately preceding such transaction hold immediately following such transaction (when combined with the holdings of the Affiliates of

-2-

such stockholders and such Party) less than 50% of the Beneficial Ownership (defined below) of the outstanding shares or less than 50% of the Beneficial Ownership of the outstanding voting power of the ultimate company or entity resulting from such transaction immediately after consummation thereof, or (ii) any single Third Party person or group of Third Parties (with "group" being defined within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect) acquires 50.1% or more of the Beneficial Ownership of the outstanding shares or 50.1% or more of the Beneficial Ownership of the voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof;

(b) the direct or indirect acquisition in a single or series of related transactions (including by means of a tender offer or an exchange offer) by any Third Party person or Third Party Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, it being understood that a pending transaction shall not result in a change in beneficial ownership until such transaction is consummated, "**Beneficial Ownership**") of 50.1% or more of the outstanding voting power or outstanding shares of such Party, in each case on a fully diluted basis;

(c) the adoption of a plan relating to the liquidation or dissolution of such Party, other than in connection with a corporate reorganization (without limitation of clause (a), above);

(d) the sale or disposition to a Third Party of all or substantially all the assets of such Party (determined on a consolidated basis, with assets being valued at fair market value), including such Party's assets related to the Products; or

(e) the sale or disposition to a Third Party of assets or businesses that generate 50.1% or more of the total revenue of such Party (determined on a consolidated basis), including such Party's assets or business related to the Products;

*provided, however*, that the following transactions, and any security issuance in connection therewith, shall not constitute or be taken into account in determining whether a "Change of Control" has occurred: any distribution or transfer of securities or related rights (including a rights offering or exchange offer) of any Party or any of its Affiliates to the securityholders of such Party or its Affiliates;

[\*\*\*]

1.15 "Clinical Study" means any study in which human subjects are dosed or treated with a drug, biological product, cell therapy or gene therapy, whether approved or investigational.

#### 1.16 [\*\*\*].

1.17 "**CMC Development**" means test method development and stability testing, process development, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, technology transfer and other related activities directed to establishing Manufacturing for a Product.

-3-

1.18 "Code" means the U.S. Internal Revenue Code of 1986, as amended.

1.19 "Combination Product" means [\*\*\*].

1.20 "**Combination Regimen**" means the administration of two or more drugs, biological products, cell therapies or gene therapies contemporaneously to a patient for the treatment, diagnosis or prophylaxis of any indication in the Field, including a Product and at least one other distinct drug, biological product, cell therapy or gene therapy that is not a Product, where such Product and other drug, biological product, cell therapy or gene therapy the administration of a drug, biological product, cell therapy or gene therapy as an induction therapy prior to the administration of a Product (or vice versa), shall not be treated as a Combination Regimen.

1.21 "**Commercialization**" or "**Commercialize**" means marketing, promoting, detailing, distributing, importing, exporting, offering for sale or selling a product, including Medical Affairs Activities, regulatory activities directed to obtaining pricing and reimbursement approvals, price calculations and related reporting to Governmental Authorities, and interacting with Regulatory Authorities with respect to the foregoing. Commercialization shall not include any activities related to Development, CMC Development or Manufacturing.

1.22 "**Commercialization Approval**" means any and all Regulatory Licenses that are necessary to market and/or sell a drug, biological product, cell therapy or gene therapy in a country or jurisdiction for one or more uses, including any pricing and reimbursement approvals that are necessary to conduct a launch of such drug, biological product, cell therapy or gene therapy in such country or jurisdiction (even if such pricing and reimbursement approvals are not legally required to launch such drug, biological product, cell therapy or gene therapy in such country or jurisdiction). For purposes of illustration with respect to the Major European Countries, the following pricing and reimbursement approvals are examples of those that are necessary to conduct a launch of a drug, biological product, cell therapy or gene therapy: in France, publication of the reimbursed price level in the official journal and registration on a reimbursement list by or on behalf of Comité Economique des Produits de Santé or Haute Autorité de Santé (or a successor agency); in Italy, publication of reimbursement in the Government's Official Gazette (by Agenzia Italiana del Farmaco or a successor agency); in Germany, execution of contract with the head association of sick funds (GKV-Spitzenverband, Gesetzlichen Krankenversicherung, or a successor agency); in Spain, authorization by La Comisión Interministerial de Precios de los Medicamentos or La Comisión Nacional para el Uso Racional de los Medicamentos (or a successor agency) for national patient access to reimbursement by or on behalf of a Governmental Authority; and in the United Kingdom, a recommendation by the National Institute for Health and Care Excellence (or a successor agency) to obtain mandatory funding to enable broad market access. For clarity, as of the Effective Date, no pricing or reimbursement approval as described above is required to launch a drug, biological product, cell therapy or gene therapy in the United States.

1.23 "**Commercialization Budget**" means the Global Commercialization Strategy Budget, U.S. Commercialization Budget, Greater China Commercialization Budget or Janssen Territory Commercialization Budget, as applicable.

1.24 "**Commercialization Plan**" means the Global Commercialization Strategy Plan, U.S. Commercialization Plan, Greater China Commercialization Plan or Janssen Territory Commercialization Plan, as applicable.

-4-

1.25 "**Control**" or "**Controlled**" means, with respect to any intellectual property right or other intangible property and subject to Section 14.2, the possession (whether by license or ownership, or by control over an Affiliate having possession by license or ownership) by a Party or its Affiliate of the ability to grant to the other Party access or a license or sublicense as provided herein without violating the terms of any agreement with any Third Party in existence as of the Effective Date or pursuant to which a Party first develop or acquired rights to such subject matter.

1.26 **"Cooperative Group"** means any cooperative group that is funded by the U.S. National Cancer Institute Clinical Trials Cooperative Group Program or any similar cooperative group in the U.S. or any country outside the U.S.

1.27 "**Cover**," "**Covering**" or "**Covered**" means, with respect to a Product or with respect to technology, that, in the absence of a license granted under or ownership of a Valid Claim, the making, use, offering for sale, sale, or importation of such Product or the practice of such technology would or is reasonably likely to infringe such Valid Claim.

#### 1.28 "Currency Hedge Rate" means [\*\*\*].

1.29 "**Data**" means any and all research data, results, pharmacology data, preclinical data, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws) and the like, in each case directed to, or used in the Exploitation of any Product hereunder.

#### 1.30 "Development" or "Develop" means:

(a) non-clinical and clinical research and drug development activities, including assay development, toxicology, pharmacology and other discovery efforts, data collection and management, statistical analysis and Clinical Studies (including post-approval commitments and post-marketing requirements mandated by or undertaken at the request of Governmental Authorities and IISs and Cooperative Group Studies that are designed to generate data to support Marketing Approval), but excluding CMC Development activities;

(b) regulatory activities relating to Clinical Studies;

(c) regulatory activities in support of obtaining and maintaining Commercialization Approval, including the preparation and submission of Drug Approval Applications, regulatory affairs, project management, drug safety surveillance and REMS programs as required by the FDA or other Regulatory Authorities;

(d) Early Access Programs; and

(e) Medical Affairs Studies.

1.31 "**Development Costs**" means FTE Costs and Out-of-Pocket Costs incurred by the Parties and their Affiliates in Developing the Products in the Field to the extent incurred in accordance with the GDP (including the Development Budget contained therein), including the following:

-5-

(a) all Out-of-Pocket Costs and FTE Costs incurred for activities specified in the GDP;

(b) the [\*\*\*] Development activities under the GDP [\*\*\*], which costs shall be determined based on [\*\*\*] is otherwise agreed in advance by the Parties in writing; <u>provided</u>, <u>however</u>, if a [\*\*\*] of a Party or Affiliate [\*\*\*] (as provided in the GDP), on a [\*\*\*] activities under the GDP [\*\*\*], then the applicable portion of such [\*\*\*] may be included in Development Costs;

(c) the Clinical Supply Costs of clinical supplies for activities set forth in the GDP, including those [\*\*\*];

(d) Out-of-Pocket Costs that are fees incurred in connection with [\*\*\*] with respect to Products in the Field in accordance with this Agreement;

(e) all Out-of-Pocket Costs and FTE Costs associated with [\*\*\*], to the extent incurred with respect to Products, in accordance with this Agreement;

(f) Out-of-Pocket Costs and FTE Costs associated with [\*\*\*] for Products in accordance with this Agreement;

(g) Out-of-Pocket Costs and FTE Costs associated with [\*\*\*]; and

(h) any other Out-of-Pocket Costs and FTE Costs incurred that are expressly included in the Development Budget included in

the GDP.

Development Costs shall exclude all of the payments set forth in Sections 7.1 and 7.2, all payments pursuant to Section 7.3 and [\*\*\*], and costs attributable to [\*\*\*]. It is understood that Development Costs shall also exclude [\*\*\*].

## 1.32 "Diligent Efforts" means[\*\*\*].

1.33 "**Drug Approval Application**" means (i) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder, including all amendments and Supplemental Applications with respect thereto ("**BLA**"); (ii) an application for authorization to market and/or sell a biological product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including all amendments with respect thereto, including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure ("**MAA**"); or (iii) with respect to any biological product for which a BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional indication ("**Supplemental Application**").

1.34 "**Drug Regulation Laws**" means Laws regulating drugs, biological products, cell therapies and gene therapies, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, the Public Health Service Act and regulations issued by the FDA, each as in effect and as amended from time to time.

-6-

1.35 "Early Access Program" or "EAP" means any program to provide patients with a Product prior to receipt of Marketing Approval and prior to First Commercial Sale in the country in which the use of the Product is not primarily intended to obtain information about the safety or effectiveness of such Product, including Treatment INDs / Protocols, Named Patient Programs and Compassionate Use programs in other countries. For clarity, an EAP with respect to a Product may continue to be performed following receipt of Marketing Approval of such Product and costs may continue to be incurred in accordance with the performance of such EAP after Marketing Approval.

1.36 "EMA" means the European Medicines Agency or any successor agency thereto.

1.37 **"Equivalent**" means:

(a) with respect to a particular CAR ("**Subject CAR**") and a given comparator CAR ("**Reference CAR**"), that the Subject CAR contains [\*\*\*] in the Reference CAR; and

(b) with respect to a particular Product ("**Subject Product**") and a given comparator Product ("**Reference Product**"), that the Subject Product [\*\*\*] the Reference Product.

1.38 "**European Union**" or "**EU**" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be expanded from time to time after the Effective Date. For clarity, any country that is a member of the EU as of the Effective Date, including the United Kingdom, shall be deemed within the EU for all purposes of this Agreement.

1.39 "Executive Officers" means [\*\*\*].

1.40 "**Exploitation**" or "**Exploit**" means to make, have made, use, have used, import, export, sell, have sold or offer for sale and otherwise practice or exploit, including to conduct Development and CMC Development, to Manufacture, and to Commercialize.

1.41 "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.42 "Field" means all diagnostic, prophylactic and therapeutic uses in multiple myeloma.

1.43 "Financial Exhibit" means Exhibit B attached hereto, as the same may be amended from time to time by the Parties.

1.44 "**First Commercial Sale**" means, with respect to a Product in a country, the first commercial sale of such Product in the Field in such country. Sales for Clinical Study purposes, Early Access Programs or similar uses shall not constitute a First Commercial Sale. In addition, sales of a Product by and between a Party and its Affiliates, Licensees and Sublicensees, or between the Parties (or their respective Affiliates, Licensees or permitted Sublicensees) shall not constitute a First Commercial Sale.

-7-

1.45 "Force Majeure Event" means acts of God, fires, floods, pandemics, earthquakes, labor strikes, acts of war, terrorism or civil unrest.

1.46 "**FTE**" means a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [\*\*\*].

1.47 "**FTE Costs**" means the product of: (a) that number of FTEs (proportionally, on a per FTE basis) used by a Party or its Affiliates in directly performing activities assigned to such Party [\*\*\*], multiplied by (b) the applicable FTE Rate (as defined below), with such costs calculated on a pro-rated basis based on time spent performing the applicable activity. [\*\*\*].

1.48 "FTE Rate" means [\*\*\*].

1.49 "GAAP" means U.S. generally accepted accounting principles or in the case of Legend, International Financial Reporting Standards, in each case applied on a consistent basis. Unless otherwise defined or stated, financial terms shall be calculated by the accrual method under GAAP.

1.50 "**Global Development Plan**" or "**GDP**" means the plan for the Parties' Development of the Products in the Field in the U.S., Greater China and Janssen Territory, including the Development Budget, Registration Plan and Development Budget Forecast, as amended from time to time in accordance with the terms of this Agreement. The initial GDP is attached hereto as <u>Exhibit C</u>.

1.51 "Global Commercialization Strategy Budget Benchmark Amount" means, with respect to each of the following Calendar Years, the following amounts (where "launch year" means the Calendar Year during which the Parties expect the First Commercial Sale of a Product to occur [\*\*\*]):

[\*\*\*]

1.52 "**Good Clinical Practice**" means the current standards for clinical trials for pharmaceuticals, as set forth in the applicable regulations and ICH guidance, including ICH E6, as amended from time to time, and such standards of good clinical practice as are required by the European Union and other organizations and governmental agencies in countries in which a Product is intended to be tested to the extent such standards are not less stringent than United States Good Clinical Practice.

1.53 "**Good Laboratory Practice**" means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations at 21 C.F.R. Part 58 or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.54 "**Good Manufacturing Practice**" means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. Parts 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable United States, European Union, Canadian and ICH Guidance and/or regulatory requirements for a product.

-8-

1.55 "**Governmental Authority**" means any U.S. federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.56 "**Government Health Care Programs**" means the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), TRICARE, the Federal Employee Health Benefits Program, and other foreign, federal, state and local governmental health care plans and programs.

1.57 "**Government Order**" means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority.

1.58 "Greater China" means Mainland China, Hong Kong, Macau and Taiwan.

1.59 "**Greater China Commercialization Budget Benchmark Amount**" means, with respect to each of the following Calendar Years, the following amounts (where "launch year" means the Calendar Year during which the Parties expect the First Commercial Sale of a Product to occur in Greater China):

[\*\*\*]

1.60 **"Greater China-Specific Development Activity**" means any Development activity for a Product that is intended to support Marketing Approval and Commercialization of such Product in Greater China and not in any other country.

1.61 "**Greater China-Specific Development Costs**" means any Development Costs incurred in performing a Greater China-Specific Development Activity, in each case that is not included in a Development Budget for the U.S. or Janssen Territory.

1.62 "**Health Care Laws**" means Laws relating to Government Health Care Programs, Private Health Care Plans, privacy and confidentiality of patient health information and human biological materials, including, in the United States, federal and state Laws pertaining to the federal Medicare and Medicaid programs (including the Medicaid rebate program); federal Laws pertaining to the Federal Employees Health Benefit Program, the TRICARE program and other Government Health Care Programs; federal and state Laws applicable to health care fraud and abuse, kickbacks, physician self-referral and false claims (including 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1320a-7b, 42 U.S.C. § 1395nn and the federal Civil False Claims Act, 31 U.S.C. § 3729 *et. seq.*); the Health Insurance Portability and Accountability Act of 1996; and 45 C.F.R. Part 46, as well as similar Laws in the Janssen Territory, each as in effect and as amended from time to time.

1.63 "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.64 "**IND**" means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application, a clinical trial notification or a clinical trial exemption, or any other equivalent or related regulatory submission, license or authorization.

-9-

1.65 "**Initial Product**" means any autologous T-Cell incorporating LCAR-B38M[\*\*\*] together with the CAR T-Cell Therapy being developed by Legend as of the Effective Date using any such CAR-T.

1.66 "Janssen Intellectual Property" means Janssen Know-How and Janssen Patent Rights, collectively.

1.67 "**Janssen Know-How**" means any Know-How that is Controlled by Janssen or any of its Affiliates during the Term that relates to the Exploitation of a Product.

1.68 "Janssen Patent Rights" means any Patent Rights Controlled by Janssen or any of its Affiliates during the Term that relate to the Exploitation of a Product. [\*\*\*]

1.69 "**Janssen Territory**" means the entire world and all countries, territories and possessions therein, excluding the U.S. and Greater China.

1.70 "**Janssen Territory Commercialization Budget Benchmark Amount**" means, with respect to each of the following Calendar Years, the following amounts (where "launch year" means the Calendar Year during which the Parties expect the First Commercial Sale of a Product to occur in any Major Market Country other than the U.S.):

[\*\*\*]

1.71 "Joint Patent Rights" means Patent Rights in Joint Inventions.

1.72 **"Know-How"** means any information and materials, whether patentable or not, including ideas, concepts, formulas, methods, procedures, designs, compositions, plans, documents, Data, inventions, discoveries, works of authorship, compounds and tangible materials, in each case to the extent not generally known or available to the public.

1.73 "**Law**" means any federal, state, local, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any court, regulatory agency or other Governmental Authority, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.74 "LCAR-B38M" means that certain CAR that binds to two specific epitopes on BCMA and is designated by Legend as "LCAR-B38M."

1.75 "Legend Intellectual Property" means Legend Know-How and Legend Patent Rights, collectively.

1.76 "**Legend Know-How**" means any Know-How that is Controlled by Legend or any of its Affiliates during the Term that relates to the Exploitation of a Product.

1.77 "Legend Patent Rights" means any Patent Rights Controlled by Legend or any of its Affiliates during the Term that relate to the Exploitation of Products, including the Patent Rights set forth on <u>Schedule 1.77</u>. [\*\*\*]

1.78 "Licensed CAR" means (a) LCAR-B38M and its Equivalents, [\*\*\*].

-10-

1.79 "**Licensee**" means a Third Party to which a license or other right is granted under the Legend Intellectual Property, Janssen Intellectual Property or Joint Inventions to use, Develop, have Developed, make, have made, otherwise Manufacture, sell, offer to sell, have sold, import, or otherwise Commercialize or Exploit a Product in the Field, excluding any contractors working under the direction of a Party.

# 1.80 "Major European Countries" means [\*\*\*].

# 1.81 "Major Market Countries" means the U.S., [\*\*\*].

1.82 "**Manufacturing**" or "**Manufacture**" means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product, including shipping from and to treatment sites (such as shipment of patient specimens after apheresis and delivery of the product to the treatment site).

1.83 "Marketing Approval" means approval of a Drug Approval Application by the applicable Regulatory Authority.

1.84 "**Medical Affairs Activities**" or "**MAF Activities**" means activities directed to interacting with physicians and other healthcare professionals who utilize or conduct research related to a drug, biological product, cell therapy or gene therapy, including: medical and scientific information; responding to external inquiries or complaints; pharmacovigilance activities; medical education; Health Economics and Outcomes Research (HECOR, HEMAR); speaker programs; advisory boards; grants, fellowships and sponsorships; drug safety; local country government affairs; deployment of field-based medical science liaisons (MSLs); MD's in the field (separate from medical science liaisons); publications; medical communications; field medical education; registries; advocacy support; and slide libraries/kits, reprints and publication planning, but excluding activities directed toward the conduct or support of Medical Affairs Studies.

1.85 "Medical Affairs Study" means any of the following:

(a) any Clinical Study that is sponsored and conducted by a Cooperative Group as sponsor-investigator (a "**Cooperative Group Study**") that is supported or enabled by a Party or one of its Affiliates;

(b) any Clinical Study that is sponsored and conducted by a Third Party as a sponsor-investigator, other than a Cooperative Group Study (an "**Investigator Initiated Study**" or "**IIS**") that is supported or enabled by a Party or one of its Affiliates; or

(c) any Clinical Study that: (i) is sponsored and conducted by a Party or one of its Affiliates as a sponsor; (ii) is not intended for use as a basis for obtaining Marketing Approval (e.g., for a further indication, label expansion or otherwise); and (iii) is not being conducted as a commitment made to or a requirement imposed by a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Marketing Approval (a "**Post-Approval Commercialization Study**"), including any Real World Evidence (RWE) study that is intended to support commercial efforts to secure and retain reimbursement.

-11-

1.86 "**Modification**" means with respect to a particular CAR ("**Subject CAR**") and a given comparator CAR ("**Reference CAR**"), that the Subject CAR is a modification of the Reference CAR [\*\*\*]. For clarification, an [\*\*\*].

1.87 "**Out-of-Pocket Costs**" means amounts paid to Third Party vendors or contractors for services or materials provided by them directly in the performance of activities under the [\*\*\*], to the extent such services or materials apply directly to the Product (or such amounts paid to Third Parties for other activities [\*\*\*], but for which sharing of Out-of-Pocket Costs is otherwise specified in this Agreement). For clarity, Out-of-Pocket Costs do not include payments for the Parties' or their Affiliates' salaries or benefits, facilities, utilities, general office or facility supplies, insurance, information technology, capital expenditures or the like.

1.88 "Parties" means Legend and Janssen.

1.89 "**Party**" means either Legend or Janssen.

1.90 "**Patent Costs**" means all reasonable Out-of-Pocket Costs incurred by a Party or its Affiliate in preparing, filing, prosecuting, validating, extending or maintaining Patent Rights.

1.91 "**Patent Rights**" means all original (priority establishing) patent applications claiming one or more inventions filed anywhere in the world, including provisionals and nonprovisionals, and all related applications thereafter filed, including any continuations, continuations-in-part, divisions, or substitute applications, any patents issued or granted from any such patent applications, and any reissues, reexaminations, renewals or extensions (including by virtue of any supplementary protection certificates) of any such patents, and any confirmation patents or registration patents or patents of addition based on any such patents, and all foreign counterparts or equivalents of any of the foregoing.

1.92 "**Person**" means any individual, corporation (including not-for-profit), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, Governmental Authority or other entity of any kind or nature.

1.93 **"Phase 1 Clinical Study**" means, in reference to a clinical study of a Product, a trial conducted in the U.S. or Janssen Territory under the GDP, the principal purpose of which is preliminary determination of safety in patients, including (a) a Phase 1 study as defined in 21 C.F.R. § 312.21(a) or (b) a Phase 1 study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.94 "**Phase 2 Clinical Study**" means a Clinical Study of a Product (a) with the endpoint of evaluating its effectiveness for a particular indication or indications, its short term tolerance and safety, as well as its pharmacokinetic and pharmacodynamic information in patients with the indications under study and is not intended to be pivotal to support Marketing Approval for the Product; or (b) that meets the definition in 21 C.F.R. §312.21(b) or any of its foreign equivalents.

1.95 **"Phase 2/3 Clinical Study**" means a Phase 2 Clinical Study involving a sufficient number of subjects that, prior to commencement of the trial or at any other defined point in the trial, satisfies both of the following ((a) and (b)):

-12-

(a) such trial is intended to (i) establish that the Product is safe and efficacious for its intended use, and (ii) generate such data as is necessary to define and determine warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Product or a similar clinical study prescribed by the Regulatory Authority in the applicable country or jurisdiction; and

(b) such trial is or becomes a registration trial sufficient for filing a Drug Approval Application for such Product in the applicable country or jurisdiction, as evidenced by (i) an agreement with or statement from the Regulatory Authority in such country or jurisdiction, for such registration trial.

1.96 **"Phase 3 Clinical Study**" means a Clinical Study of the Product (a) on a sufficient number of patients, which trial (i) is designed to establish that the Product is safe and efficacious for its intended use, (ii) is designed to define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed, and (iii) is pivotal to support Marketing Approval for the Product; or (b) that meets the definition in 21 C.F.R. §312.21(c) or any of its foreign equivalents.

1.97 "**Private Health Care Plans**" means non-governmental Third Party health care payors and plans, including insurance companies, health maintenance organizations and other managed care organizations, Blue Cross and Blue Shield plans and self-funded employers.

1.98 "**Product**" means (a) a T-Cell incorporating LCAR-B38M or an Equivalent of LCAR-B38M, and any CAR T-Cell Therapy using any such CAR-T, including the Initial Product, [\*\*\*].

1.99 "**Product Liability Costs**" means Out-of-Pocket Costs (including reasonable attorneys' and experts' fees and expenses paid to Third Parties), damages paid to Third Parties and other amounts paid in settlement to Third Parties, and FTE Costs associated with Third Party Products Liability Actions resulting from the Exploitation of the Products pursuant to this Agreement.

1.100 "**Promotional Materials**" means all written, printed, graphic, electronic, audio or video presentations of information, including journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, disease awareness materials, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items, if appropriate), that, in each case, are permitted under applicable Law and intended for use or used by or on behalf of a Party or its Affiliates for promotion of a Product in the Field.

1.101 "**Registration Study**" means a Phase 2/3 Clinical Study or Phase 3 Clinical Study. For purposes of Section 7.2, if a Clinical Study becomes a Phase 2/3 Clinical Study after the dosing of the fifth (5<sup>th</sup>) patient, the applicable Milestone Event shall be deemed to occur on the date that the Party conducting such Clinical Study receives the evidence described in clause (b) of the definition of Phase 2/3 Clinical Study from the applicable Regulatory Authority or, if earlier, on filing of a Drug Approval Application based on the results of such Clinical Study.

1.102 "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country, including FDA in the United States and EMA in the EU.

-13-

1.103 "**Regulatory Documentation**" means any documentation comprising or relating to or supporting any Regulatory License with respect to a drug, biological product, cell therapy or gene therapy, or its use or potential use in humans, including any documents or reports submitted to any Regulatory Authority and all supporting Data, including INDs, Drug Approval Applications and all correspondence with any Regulatory Authority with respect to any drug, biological product, cell therapy or gene therapy (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.104 "**Regulatory License**" means any approval (including a Marketing Approval), license (including an import license), registration or authorization from any Regulatory Authority that is required under applicable Law or reasonably necessary to Exploit a drug, biological product, cell therapy or gene therapy in any country or jurisdiction for one or more uses, and all amendments and supplements thereto.

1.105 "**Right of Reference**" shall have the meaning set forth in 21 C.F.R. §314.3(b) or equivalents thereto under applicable Law in countries or jurisdictions outside the U.S.

1.106 "Segregate" means, with respect to any given product or program, to use Diligent Efforts to segregate activities directed to the Exploitation of such product or program from activities directed to the Exploitation of Products under this Agreement[\*\*\*].

1.107 **"T-Cell**" means any lymphocytes that have the ability to recognize specific peptide antigens presented by major histocompatibility complex antigens through the receptors on their cell surface.

1.108 "Third Party" means any Person other than a Party or any of its Affiliates.

1.109 "U.S." means the United States of America and its territories and possessions.

1.110 **"U.S. Commercialization Budget Benchmark Amount**" means, with respect to each of the following Calendar Years, the following amounts (where "launch year" means the Calendar Year during which the Parties expect the First Commercial Sale of a Product to occur in the U.S.):

# [\*\*\*]

1.111 "**Valid Claim**" means a claim (i) of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (ii) of any patent application that has not been cancelled, withdrawn or abandoned or has not been pending or filed more than [\*\*\*].

## -14-

1.112 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>Definition</u> 1974 Convention	Section 14.4	<u>Definition</u> Development Reconciliation Procedures	Section 7.3.3
Acquiring Party	3.6.4	Disbandment Notice	2.10
[***]	5.0.4	Disclosing Party	9.1
Additional Development Events	7.2.2	Dispute	13.1
Additional Milestone Events	7.2.2	Distribution Costs	Financial Exhibit
Agreement	Preamble	[***]	I manetai Exmon
Agreement Wind-Down Period	12.4.2(b)	Effective Date	Preamble
Alliance Manager	2.11	[***]	1 icumbic
Allowable Expenses	Financial Exhibit	[ ***]	
Anti-Corruption Laws	10.8.1(a)	[***]	
Assigning Party	4.6.3(e)	EU Commercialization Approval Event	7.2.1
Bankruptcy Code	4.0.5(e)	EU Regulatory Filing Event	7.2.1
Biosimilar Application	8.3.2	[***]	7.2.1
BLA	1.33	[ ] [***]	
Breaching Party	1.55	Exclusivity Period	3.6.5
Charitable Contribution Costs	Financial Exhibit	[***]	5.0.5
		[ ] [***]	
	6.2.1(a)	[ ] [***]	
China Manufacturing Facilities [***]	6.3.1(a)	Ex-U.S. Territory Activities	7.8.2
[***] Plan	5.4.3(b)	Facilities	6.1.3(b)
China Product Quality Agreement	6.3.4		
	6.3.4	Facilities Use Agreement [***]	6.2.2(b)(vii)(1)
China Product Supply Agreement Claim	11.4.1	Filing Party	4,10.6
Claim Amount	11.4.1	Fining Faity Finance Working Group	2.6.2
Claim Basis	11.4.1	[***]	2.0.2
Clinical Supply Costs	6.1.3(e)	[ ] [***]	
CMC Development Costs	6.1.3(a)	First Position Detail	Financial Exhibit
CMC Development Plan	6.1.3(a)	[***]	
CMO	6.2.3(c)	[ ] [***]	
COGS	7.2.2	[ ] [***]	
Collaboration Activities	3.5.4	[ ] [***]	
[***]	5.5.4	GCCC	2.4
Collaboration Intellectual Property	3.5.4	Global Commercialization Strategy Budget	5.1.2
Collaboration Losses	Financial Exhibit	Global Commercialization Strategy Dudget	Financial Exhibit
Commercialization Approval Events	7.2.2	Global Commercialization Strategy Plan	5.1.1
Commercial Supply Costs	6.2.3(c)(ii)	Global CQAs	6.1.4
Committee Matters	2.8.2(a)	Global Publication Strategy	9.8.1
Committees	2.5	Global Product Specifications	6.1.4
Comparator	6.1.3(e)	Greater China Commercialization Budget	5.4.2
Competing BCMA CAR-T	3.6.5	Greater China Commercialization Dudget	5.4.2(a)
Confidential Information	9.1	Greater China Pricing and Discounting Plan	5.4.6
Cooperative Group Study	1.85	Greater China Reconciliation Procedures	7.4.2
Cost Report	7.3.3	Greater China Regulatory Submissions	4.6.4
CPR	13.3.1	Group	1.14(a)
Designated China Equipment	6.3.1(c)	Health Care Reform Fees	Financial Exhibit
Designated Equipment	6.2.2(b)(v)	Incumbent Board	1.14(c)
Detail or Detailing	Financial Exhibit		
Development Budget	4.1.1(b)		
Development Budgeted Period	4.1.1(b)		
Development Budget Forecast	4.1.1(c)		
	(0)		

-15-

ŀ			
Indemnified Party	11.4.1	Net Trade Sales	Financial Exhibit
Indemnifying Party	11.4.1	[***]	
Independent Development Activities	4.3	Non-Acquiring Party	3.6.4
Independent Safety Board	4.2.7(a)	Non-Breaching Party	12.2
Infringement	8.3	Non-Filing Party	4.10.6
Infringement Action	8.3.1(b)	[***]	
Infringement Claim	8.5	Non-Specific Legend Patent Rights	8.3.1(a)
Initial Development Budget	4.1.2(b)	On-Going Clinical Study	12.4.2(a)
Initial Development Budget Forecast	4.1.2(c)	Opt-In Date	4.3.3
Initial GDP	4.1.2(c) 4.1.2(a)	Opt-In Date	4.10.3
Initial Milestone Events	7.2.2	Opt-In Period	4.10.3
[***]	1.2.2	Opt-In Right	4.10.3
Initial Phase I Study		[***]	4.10.5
Invalidity Claim	8.4.1	Other Commercialization Costs	Financial Exhibit
	1.85	Other Detail	Financial Exhibit
Investigator Initiated Study or IIS	7.1		
Ireland Upfront Payment		Other Income	Financial Exhibit
Janssen	Preamble	Partnership Audit Procedures	7.8.6
Janssen Indemnified Parties	11.1	Patient Samples	4.9
Janssen Sole Inventions	8.1.1	Payee	7.7.1
Janssen Territory Commercialization		Payor	7.7.1
Budget	5.3.2(a)	PDE	5.2.3
Janssen Territory Commercialization	/ .	Pharmacovigilance Agreement	4.8.1
Plan	5.3.2(c)	[***]	
Janssen Territory Pricing and		Post-Approval Commercialization Study	1.85(c)
Discounting Plan	5.3.7	PPACA	Financial Exhibit
Janssen Territory Reconciliation		Product Quality Agreement	6.2.3(c)
Procedures	7.4.3	Product Supply Agreement	6.2.3(c)
JDC	2.2	Product Trademarks	8.7.1
JMC	2.5	Product Trademark Costs	Financial Exhibit
Joint Inventions	8.1.2	[***]	
JSC	2.1	Proposed Publications	9.8.2
Key Country	4.6.4(b)	Proposing Party	7.5.1
Key Regulatory Submissions	4.6.4(b)	Proposing Party Notice	7.5.1
Launched Products	12.4.2(b)	Public Official	10.8.4
Legend	Preamble	Publishing Party	9.8.2
Legend Change of Control	14.2	[***]	
Legend Indemnified Parties	11.2	[***]	
Legend IDA Plan and Budget	4.3.7	Recall Expenses	Financial Exhibit
Legend Representatives	5.3.3(b)	Receiving Party	9.1
Legend Sole Inventions	8.1.1	Reconciliation Procedures	7.4.3
Lentivirus Supply Price	6.2.3(e)	[***]	
Losses	11.1	Reference CAR	1.86
MAA	1.33	[***]	
Manufacturing Plan	6.1.3(b)	Region	12.3
Manufacturing Plan Costs	6.1.3(b)	Registration Plan	4.1.1(a)
Marketing Expenses	Financial Exhibit	[***]	(1)
Medical Affairs Expenses	Financial Exhibit	Regulatory Maintenance Costs	Financial Exhibit
Milestone Event	7.2.1	[***]	- manetar Emildit
Milestone Payment	7.2.1	L J	
Modified Facility Expiration Date	6.2.4(a)		
internet i territy Expitation Date	0.2. mail		

-16-

-			
Reverted Know-How	12.4.1(d)	Tax Return	7.7.5
Reverted Products	12.4.1(e)	Technology Transfer Plan	3.11
Reviewing Party	9.8.2	Term	12.1
[***]		[***]	
[***]		[***]	
[***]		Third Party Expenditures	6.1.3(e)
[***]		Third Party Intellectual Property	7.5
Second Position Detail	Financial Exhibit	Third Party IP Costs	7.5.3
Securities Authority	9.4.1	Third Party Products Liability Action	11.5.1
Securities Disclosure Obligations	9.4.1	[***]	
Selling Costs	Financial Exhibit	Unprocessed Cells Supply Price	6.2.3(d)
Shared Patent Costs	8.2.3	USCC	2.3
Shared Product Liability Costs	11.3	U.S. Commercialization Approval	
Sole Inventions	8.1.1	Event	7.2.1
Specified Change of Control	14.2.1	U.S. Commercialization Budget	5.2.2(c)
[***]		U.S. Commercialization Plan	5.2.2(a)
Subcommittee	2.6.1	[***]	
Subcontract	4.2.5	U.S. Pricing and Discounting Plan	5.2.6
Subcontractor	4.2.5	U.S. Reconciliation Procedures	7.4.1
Subject CAR	1.86	U.S. Regulatory Filing Event	7.2.1
[***]		U.S. Territory Partnership	7.8.1
Successful Technology Transfer	6.2.4(b)(i)	U.S. Upfront Payment	7.1
Supplemental Application	1.33	Upfront Payment	7.1
Supply Cost	Financial Exhibit	Working Group	2.6.1
[***]		[***]	
Target Bonus Compensation	Financial Exhibit	[***]	
Tax or Taxes	7.7.5		
Tax Representative	7.8.6(b)		
E	(-)		

# ARTICLE II MANAGEMENT OF COLLABORATIVE ACTIVITIES

2.1 **Joint Steering Committee**. Within 10 days after the Effective Date, Legend and Janssen shall establish a joint steering committee (the "JSC"), comprised of senior executives of each Party or their respective Affiliates, to: (i) provide high-level oversight and make decisions with respect to the Parties' Exploitation of the Products in the Field in the U.S., Greater China and Janssen Territory, to the extent provided in this Agreement; (ii) oversee the other Committees and resolve matters on which the Committees do not reach consensus in accordance with Section 2.8; and (iv) perform the other functions that are expressly delegated to the JSC in this Agreement.

2.2 Joint Development Committee. Within 10 days after the Effective Date, Legend and Janssen shall establish a joint development committee (the "JDC"), which shall report to the JSC and shall (i) oversee and make decisions with respect to the Parties' Development of the Products in the Field in the U.S., Greater China and Janssen Territory pursuant to this Agreement, to the extent provided in ARTICLE IV, and (ii) perform the other functions that are expressly delegated to the JDC in this Agreement. The JDC shall include individuals from each Party with reasonable expertise in the areas of product development, clinical research and regulatory matters.

-17-

2.3 **U.S. Commercialization Committee**. [\*\*\*] Legend and Janssen shall establish a U.S. commercialization committee (the "**USCC**"), which shall report to the JSC and shall (i) oversee and make decisions with respect to the Parties' Commercialization of the Products in the Field in the U.S. pursuant to this Agreement, to the extent provided in ARTICLE V, and (ii) perform the other functions that are expressly delegated to the USCC in this Agreement. The USCC shall include individuals from each Party with reasonable expertise in the areas of finance, operations, sales and marketing. If this Agreement requires that any decision be made by the USCC before it is formed, such decision shall be made by the JSC.

2.4 Greater China Commercialization Committee. [\*\*\*] Legend and Janssen shall establish a Greater China commercialization committee (the "GCCC"), which shall report to the JSC and shall (i) oversee and make decisions with respect to the Parties' Commercialization of the Products in the Field in Greater China pursuant to this Agreement, to the extent provided in ARTICLE V, and (ii) perform the other functions that are expressly delegated to the GCCC in this Agreement. The GCCC shall include individuals from each Party with reasonable expertise in the areas of finance, operations, sales and marketing. If this Agreement requires that any decision be made by the GCCC before it is formed, such decision shall be made by the JSC.

2.5 Joint Manufacturing Committee. Within 10 days after the Effective Date, Legend and Janssen shall establish a joint manufacturing committee (the "JMC" and together with the JSC, JDC, GCCC and USCC, the "Committees"), which shall report to the JSC and shall (i) oversee and make decisions with respect to the Parties' CMC Development and Manufacture of Products pursuant to this Agreement, to the extent provided in ARTICLE VI; and (ii) perform the other functions that are expressly delegated to the JMC in this Agreement. The JMC shall include individuals from each Party with reasonable expertise in the areas of CMC Development and Manufacturing.

#### 2.6 Working Groups.

2.6.1 <u>Formation</u>. From time to time, the JSC, JDC, USCC, GCCC and JMC may establish various subcommittees (each, a "**Subcommittee**") and working groups (each, a "**Working Group**") to perform particular tasks and oversee particular projects or activities within the forming Committee's authority. Each such Subcommittee shall operate in the same manner as the forming Committee, as described in Section 2.7, and each such Working Group shall be constituted and shall operate as the forming Committee determines, *provided* that no Subcommittee or Working Group shall have any decision-making authority, but shall instead make recommendations to the forming Committee with respect to such matters within its authority.

2.6.2 <u>Finance Working Group</u>. Within 30 days after the Effective Date, Legend and Janssen shall establish a joint Finance Working Group (the "**Finance Working Group**"), which shall report to the JDC with respect to financial matters relating to the Development of the Products in the Field, to the JMC with respect to the CMC Development or Manufacturing of the Products in the Field and to the USCC, GCCC or JSC, as applicable, with respect to financial matters relating to the Commercialization of the Products in the Field. The Finance Working Group shall (i) coordinate and conduct the budgeting, accounting, reporting, reconciliation and other financial activities set forth in this Agreement to the extent provided in this Agreement and (ii) perform the other functions that are expressly delegated to the Finance Working Group in this Agreement. The Finance Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting.

-18-

## 2.7 Decision-Making.

2.7.1 Working Group Actions and Decision-Making. The Working Groups shall make recommendations to the forming Committees and shall have no formal decision-making authority; provided, however, that the Finance Working Group shall have the authority to determine, approve or resolve those matters that it is expressly authorized to determine, approve or resolve pursuant to this Agreement. The Finance Working Group shall determine, approve or resolve matters within its authority by consensus, with the representatives of each Party collectively having one vote on behalf of such Party. If the Finance Working Group does not reach consensus on any matter within its authority within 30 days after the matter is first presented to the Finance Working Group, then either Party may refer such matter to the JSC, and such matter shall be resolved by the JSC. If the members of the JSC do not reach consensus with respect to such matter within 30 days after such matter is first presented to the JSC, [\*\*\*]. For clarity, neither the Finance Working Group [\*\*\*] shall have authority to: (1) amend this Agreement or a Party's rights or obligations under this Agreement; (2) determine that either Party has fulfilled or breached a Party's obligations under this Agreement, or make any determination as to the terms of this Agreement (including any interpretation thereof) or a Party's rights or obligations hereunder; (3) make any decision that expressly requires Legend's or Janssen's approval or agreement or the approval or agreement of both Parties under this Agreement; (4) resolve any dispute regarding whether a Milestone Event has been achieved or the amount of any payments owed by one Party to the other Party under this Agreement; [\*\*\*] or (5) resolve any dispute regarding whether a matter is a Committee Matter or subject to a Party's final decision-making under this Agreement, or whether a matter is a Dispute hereunder. If the [\*\*\*] is unable or not authorized to make a determination necessary to resolve a matter referred to it under thi

#### 2.7.2 Committee Actions and Decision-Making.

(a) Each Committee shall only have authority to determine, approve or resolve matters that such Committee is expressly authorized to determine, approve or resolve under this Agreement ("**Committee Matters**"). For clarity, no Committee shall have authority to: (1) amend this Agreement or a Party's rights or obligations under this Agreement; (2) determine that either Party has fulfilled or breached a Party's obligations under this Agreement; (3) make any decision that expressly requires Legend's or Janssen's approval or agreement or the approval or agreement of both Parties under this Agreement; (4) resolve any dispute regarding whether a Milestone Event has been achieved or the amount of any payments owed by one Party to the other Party under this Agreement; [\*\*\*] or (5) resolve any dispute regarding whether a matter is a Committee Matter or subject to a Party's final decision-making under this Agreement, or whether a matter is a Dispute hereunder. In conducting its activities, the JSC shall operate and make its decisions consistent with the terms of this Agreement.

(b) The Committees shall determine, approve or resolve Committee Matters by consensus, with the representatives of each Party collectively having one vote on behalf of such Party. If the JDC, USCC, GCCC or JMC does not reach consensus on any Committee Matter within its authority within 15 days after such matter is first presented to such Committee, either Party may refer such Committee Matter to the JSC for resolution. If the members of the JSC do not reach consensus, either with respect to any Committee Matter referred to it by the JDC, USCC, GCCC or JMC or with respect to any Committee Matter within the JSC's authority, within 30 days after such Committee Matter is first presented to the JSC,

-19-

then, unless this Agreement expressly provides otherwise, either Party may refer such Committee Matter to the Executive Officers for resolution. If the Executive Officers do not reach consensus on a Committee Matter within 15 days after such Committee Matter is referred to the Executive Officers, then such Committee Matter will be resolved as set forth in Section 2.8.3 or as otherwise expressly set forth in this Agreement.

#### 2.7.3 Resolution of Certain Committee Matters.

# (a) Development.

(i) *Changes to Study in Current GDP*. If a Party proposes a change to the protocol, design or timing of a Clinical Study in the current GDP and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(ii) Addition of a Clinical Study to GDP for an Indication Included in Current GDP. If a Party proposes an amendment to the GDP to add a Clinical Study of a Product for an indication that is already included in the GDP with respect to such Product and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(iii) *Removal of a Clinical Study from the GDP*. If a Party proposes an amendment to the GDP to remove a Clinical Study in accordance with Section 4.1.3(b) and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(iv) *Addition of a New Indication to GDP.* If a Party proposes an amendment to the GDP to add a Clinical Study of a Product for an indication that is not already included in the GDP with respect to such Product in accordance with Section 4.1.3(b) and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(v) *Changes to Development Budget.* If a Party proposes an amendment to the existing Development Budget in accordance with Section 4.1.3(b) and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(vi) *Initial Development Budget for a Calendar Year*. If the JDC does not reach consensus on an initial Development Budget in accordance with Section 4.1.3(b) and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(vii) *Changes to Registration Plan.* If a Party proposes an amendment to the Registration Plan for a Major Market Country or Greater China in accordance with Section 4.1.3(b) and, after discussion by the JDC and escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

-20-

Allocation of Development Activities. If the JDC does not reach consensus on the determination of which Party will conduct an activity in the GDP in accordance with Section 4.2.2 and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(viii) *Medical Affairs Studies*. If the JDC does not reach consensus on any determination related to Medical Affairs Studies to be made in accordance with Section 4.2.2 and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(ix) *Clinical Study Protocols*. If the JDC does not reach consensus on whether to approve an initial or amended protocol or master informed consent form for a Clinical Study in the GDP proposed by the conducting Party in accordance with Section 4.2.4 and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(x) *Regulatory Submissions and Regulatory Implementation*. If the JDC does not reach consensus on whether to approve a Key Regulatory Submission in a Key Country or a Greater China Regulatory Submission, or with respect to a Committee Matter pertaining to implementing the Registration Plan for obtaining Regulatory Licenses for a Product in a Key Country or Greater China, and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

(xi) *Other Development Matters*. Notwithstanding the foregoing, if the JDC does not reach consensus on a matter regarding Development activities (other than matters described in clause (v) or (vi) above or any other budget matter), and, after escalation to the JSC and Executive Officers, the Executive Officers do not reach consensus on such matter, [\*\*\*].

# (b) Commercial.

(i) *Initial Commercialization Plans*. If the JSC or, after escalation, the Executive Officers, do not reach consensus on a proposed initial Global Commercialization Strategy Plan, U.S. Commercialization Plan, Greater China Commercialization Plan or Janssen Territory Commercialization Plan (including the applicable Global Commercialization Strategy Budget, U.S. Commercialization Budget, Greater China Commercialization Budget and Janssen Territory Commercialization Budget) for a particular Calendar Year submitted to the JSC for approval in accordance with Section 5.1.1, 5.2.2, 5.3.2, or 5.4.2 as applicable, [\*\*\*].

(ii) *Changes to Commercialization Plans.* If JSC, or after escalation the Executive Officers, do not reach consensus on a proposed amendment of the existing Global Commercialization Strategy Plan, U.S. Commercialization Plan, Greater China Commercialization Plan or Janssen Territory Commercialization Plan (including the applicable Global Commercialization Budget, U.S. Commercialization Budget, Greater China Commercialization Budget and Janssen Territory Commercialization Budget) submitted by a Party in accordance with Section 5.1, 5.2.2, 5.3.2 or 5.4.2, as applicable, [\*\*\*].

-21-

(iii) *Pricing and Discount Strategy*. If the JSC, or after escalation the Executive Officers, do not reach consensus on whether to approve U.S. Pricing and Discounting Plan, Greater China Pricing and Discounting Plan or the Janssen Territory Pricing and Discounting Plan for the Products in the Field in the U.S., Greater China or Janssen Territory, as applicable in accordance with Section 5.2.6, 5.3.7 or 5.4.6, as applicable, [\*\*\*].

(iv) *Greater China* [\*\*\*]. If the JDC, or after escalation the JSC or Executive Officers, does not reach consensus on matters pertaining to the [\*\*\*] Plan or the conduct of the [\*\*\*] in accordance with Section 5.4.3(b) below [\*\*\*].

(c) Manufacturing.

(i) If the JMC, or after escalation the JSC or Executive Officers, do not reach consensus on establishing or amending the Manufacturing Plan or any other Committee Matter pertaining to the Manufacture (other than CMC Development) of Product (including the selection or design of the Facilities to the extent that such matters are Committee Matters within the authority of the JMC under ARTICLE VI), [\*\*\*].

(ii) Subject to Section 2.8.3(c)(i), if the JMC or JSC, or after escalation the Executive Officers, do not reach consensus with respect to a Committee Matter pertaining to the CMC Development of a Product or establishing or amending the CMC Development Plan, [\*\*\*].

(iii) If the JMC or the JSC, or after escalation the Executive Officers, do not reach consensus with respect to the Global Product Specifications or Global Critical Quality Attributes for any Product, [\*\*\*].

2.7.4 <u>Other Matters</u>. Unless otherwise expressly set forth in this Agreement, any other Committee Matter for which there is not consensus after escalation to the JSC and Executive Officers (including with respect to Development, CMC Development, Manufacturing or Commercialization matters not specifically addressed in Sections 2.8.2 or 2.8.3 above or elsewhere in this Agreement), [\*\*\*].

2.7.5 Limitations on Final Decision-Making. Neither Party may exercise its final decision-making authority under Section 2.8.2 or 2.8.3 to: (a) substantially increase or modify the nature of the required effort of the other Party under the GDP, CMC Development Plan, Manufacturing Plan or a Commercialization Plan; (b) cause the other Party to violate applicable Law or regulatory requirements; or (c) cause the other Party's activities to violate or not be in compliance with its own health care compliance policies and procedures of general application, consistently applied by such Party and its Affiliates, or any corporate integrity agreement to which such Party is subject.

[\*\*\*]. If Section 2.8.3 or 2.8.4 provides that a Committee Matter will be resolved in accordance with this Section 2.8.6, then either Party may request that such Committee Matter be resolved using the following procedure and thereafter such Committee Matter shall be resolved by [\*\*\*]:

(a) [\*\*\*].

-22-

(b) [\*\*\*].
(c) [\*\*\*].
(d) [\*\*\*].
(e) [\*\*\*].
(f) [\*\*\*].

#### 2.8 Meetings of the Committees and Working Groups. The JSC shall hold meetings at such times as the JSC shall determine, and

the JDC, USCC, GCCC and JMC shall hold meetings at such times as the applicable Committee determines, but in no event shall such meetings of each Committee be held less frequently than once every Calendar Quarter. Each Working Group shall hold meetings at such times as the Working Group agrees or as its forming Committee directs. Each Committee and Working Group may meet in person or by audio or video conference as the Parties may mutually agree or a Party may request, <u>provided</u> that each Committee meet in person at least once per Calendar Year. With respect to in-person meetings of the Committees and Working Groups, the representatives shall meet alternately at a location(s) designated by Janssen or Legend. Employees of the Parties and their Affiliates and, with the consent of the applicable Committee or Working Group, consultants and other Third Parties involved in the Exploitation of the Products may attend such meetings of the Committees or Working Groups as nonvoting observers. No action taken at a meeting of any Committee or Working Group shall be effective unless a representative of each Party is present or participating. Either Party may convene a meeting of a Committee or Working Group for which reasonably withhold attendance of at least one representative of such Party at any meeting of a Committee or Working Group for which reasonable advance notice was provided.

2.9 **Disbandment.** Legend shall have the right to disband all Committees upon prior written notice to Janssen referencing this Section 2.10 ("**Disbandment Notice**"). Following Janssen's receipt of a Disbandment Notice the Committees shall disband and thereafter (a) the Committees shall have no further rights or obligations under this Agreement, (b) all matters to be agreed upon or determined by a Committee will be agreed upon or determined by mutual agreement of the Parties, provided however that any deadlocks between the Parties with respect to such matters shall resolved in the same manner as under the Committees, including with respect to final decision-making authority and Committee Matter resolution and (c) any requirement of either Party to provide information or documents to a Committee or consult with a Committee shall be deemed a requirement to provide such information or document to or consult with the other Party.

2.10 Alliance Managers. Each Party shall designate one of its or its Affiliates' employees to serve as such Party's alliance manager for all of the activities contemplated under this Agreement ("Alliance Manager"). Such Alliance Managers will be responsible for the day-to-day coordination of the Parties' activities under this Agreement and will serve to facilitate communication between the Parties. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.

-23-

2.11 **Collaboration Activities.** For clarity, all Development, CMC Development, Manufacture, and Commercialization of the Products for use in the Field shall be conducted in accordance with the GDP, CMC Development Plan, Manufacturing Plan and the applicable Commercialization Plan, and except as permitted as Independent Development Activities under Section 4.3 below, neither Party (nor its Affiliates) shall Develop, CMC Develop, Manufacture or Commercialization Plan. Notwithstanding the foregoing, it is understood that Legend has independently initiated Clinical Studies and other Development and CMC Development of the Initial Product in Greater China prior to the Effective Date and the Parties agree that the following shall apply with respect to such activities: [\*\*\*].

2.12 **Membership of Committees, Subcommittees and Working Groups**. Each Committee shall be composed of an equal number of representatives appointed by each Party. Each Committee shall be initially comprised of three representatives of each Party. Each Party shall have the right, but not be obligated, to appoint the same number of representatives to the Subcommittees and Working Groups as are appointed by the other Party; however, each Party shall have collectively one vote regardless of the number of representatives from each Party. Each Party is representatives to the Committees, Subcommittees or Working Groups shall be employees or contractors of such Party or its Affiliates. Each Party may replace any Committee, Subcommittee or Working Group representatives at any time upon written notice to the other Party. The Committees and the various Subcommittee and Working Groups shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Committee, Subcommittee or Working Group shall not have any greater authority than any other representative on the Committee, Subcommittee or Working Group shall not have any greater authority than any other representative on the Committee, Subcommittee or Working Group. The co-chairpersons shall be responsible for (i) calling meetings; (ii) preparing and circulating an agenda in advance of each meeting, provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (iii) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (iv) preparing and issuing minutes of each meeting within 30 days thereafter.

## ARTICLE III LICENSE GRANTS

3.1 Legend Grant to Janssen. Subject to the terms and conditions of this Agreement, Legend grants to Janssen a co-exclusive (with Legend), non-royalty bearing, sublicensable (solely to the extent permitted under Section 3.3) license under the Legend Intellectual Property to make, have made, use, sell, offer for sale, import and otherwise Exploit Licensed CARs and Products for all uses in the U.S., Greater China and Janssen Territory.

3.2 Janssen Grant to Legend. Subject to the terms and conditions of this Agreement, Janssen grants to Legend a co-exclusive (with Janssen), non-royalty bearing, sublicensable (solely to the extent permitted under Section 3.3) license under the Janssen Intellectual Property to make, have made, use, sell, offer for sale, import and otherwise Exploit Licensed CARs and Products for all uses in the U.S., Greater China and Janssen Territory.

3.3 **Sublicensing**; **Licensing**. Each Party will have the right to sublicense the rights granted to it under Section 3.1 or 3.2, as applicable, without the consent of the other Party (a) to its Affiliates and (b) to consultants and contractors in performing on such Party's behalf activities conducted in accordance with this Agreement.

-24-

# 3.4 **Reciprocal Non-Exclusive Licenses for Disclosed Know-How**. Subject to the terms of this Agreement and without limiting any other license granted under this Agreement:

3.4.1 <u>To Janssen</u>. Subject to obligations of confidentiality as provided under this Agreement, Legend hereby grants to Janssen a non-exclusive, irrevocable, royalty-free, perpetual license to use for all purposes any Legend Know-How disclosed to Janssen pursuant to this Agreement; provided, however, that (i) such license is not permission for Janssen to use the Know-How for an illegal purpose, (ii) such license shall not include the grant of any rights to Janssen for any exploitation of any Licensed CAR or Product and (iii) such license shall not include the right to practice any Patent Rights owned or Controlled by Legend. For the purposes of this license, Legend Know-How will not include the Know-How described in Schedule 3.4.1.

3.4.2 To Legend. Subject to obligations of confidentiality as provided under this Agreement, Janssen hereby grants to Legend a non-exclusive, irrevocable, royalty-free, perpetual license to use for all purposes any Janssen Know-How disclosed to Legend pursuant to this Agreement; provided, however, that (i) such license is not permission for Legend to use the Know-How for an illegal purpose, (ii) such license shall not include the grant of any rights to Legend for any exploitation of any Licensed CAR or Product and (iii) such license shall not include the right to practice any Patent Rights owned or Controlled by Janssen.

3.5 **Reciprocal Non-Exclusive Licenses for Collaboration Intellectual Property**. Subject to the terms of this Agreement and without limiting any other license granted under this Agreement:

3.5.1 <u>To Janssen</u>. Legend hereby grants to Janssen, and shall cause its Affiliates to grant to Janssen, a world-wide, non-exclusive, irrevocable, royalty-free, perpetual license, with the right to sublicense provided in Section 3.5.3, under Legend's and its Affiliates' interest in all Collaboration Intellectual Property for any and all applications and uses, whether inside or outside the Field; <u>provided</u>, <u>however</u>, that such license to Janssen shall not include the grant of any rights to Janssen for any Exploitation of any Licensed CAR or Product. During the Term, such license shall be subject to the licenses from Janssen to Legend set forth in Section 3.2. The license set forth in this Section shall not be construed as a limitation or exception to the covenants of Janssen set forth in Section 3.6, for so long as the applicable covenants remain in effect.

3.5.2 To Legend. Janssen hereby grants to Legend, and shall cause its Affiliates to grant to Legend, a world-wide, non-exclusive, irrevocable, royalty-free, perpetual license, with the right to sublicense provided in Section 3.5.3, under Janssen's and its Affiliates' interest in all Collaboration Intellectual Property for any and all applications and uses, whether inside or outside the Field; provided, however, that such license to Legend shall not include the grant of any rights to Legend for any Exploitation of any Licensed CAR or Product. During the Term, such license shall be subject to the licenses from Legend to Janssen set forth in Section 3.1. The license set forth in this Section shall not be construed as a limitation or exception to the covenants of Janssen set forth in Section 3.6, for so long as the applicable covenants remain in effect.

-25-

3.5.3 <u>Sublicenses</u>. The licenses granted in Sections 3.5.1 and 3.5.2 to each respective Party shall be sub-licensable to Affiliates and to Third Parties at any time.

3.5.4 <u>Definition</u>. As used herein, "**Collaboration Intellectual Property**" shall mean any and all Data and Know-How, and Patent Rights in and to any inventions, in each case that are made, generated or obtained by either Party (or both Parties) or their Affiliates, or the Subcontractors and other Third Party contractors of any of them (to the extent the applicable Data, Know-How or Patent Right is Controlled by the applicable Party or its Affiliate) in the course of performing activities in the Exploitation of Licensed CARs or Products under this Agreement (such activities collectively referred to as "**Collaboration Activities**"). For clarity, "Collaboration Intellectual Property" does not include Know-How, Data or Patent Rights (a) owned or Controlled by either Party (or their Affiliates) as of the Effective Date or (b) made, generated or obtained by either Party (or their Affiliates or Third Party contractors) outside of, and independently of, Developing, CMC Developing, Manufacturing, Commercializing or otherwise Exploiting a Licensed CAR or Product; provided, the foregoing shall not be construed to limit the inclusion, in accordance with Section 4.9 below, of Know-How or Patent Rights arising from use of the Patient Samples within the definition of Collaboration Intellectual Property.

## 3.6 Exclusivity.

## 3.6.1 Products.

(a) During the Term, neither Party nor any of its Affiliates shall Exploit directly or indirectly any Licensed CAR or Product, including performing on a patient any CAR T-Cell Therapy utilizing a Licensed CAR or Product, in the Field anywhere in the world, except to the extent specifically permitted pursuant to this Agreement. For clarity, subject to Section 12.4.1, this Agreement does not permit any Exploitation of a Licensed CAR other than in (or for incorporation in) a Product.

(b) During the Term, neither Party nor any of its Affiliates shall Exploit directly or indirectly any Licensed CAR or Product, including performing on a patient any CAR T-Cell Therapy utilizing a Licensed CAR or Product, outside the Field anywhere in the world.

(C) [\*\*\*].

3.6.2 Janssen. During the Exclusivity Period, neither Janssen nor any of its Affiliates shall (a) conduct human clinical Development with respect to, conduct CMC Development or Manufacture for commercial purposes, or Commercialize within the Field, directly or indirectly anywhere in the world, any Competing BCMA CAR-T except to the extent specifically permitted pursuant to this Agreement; or (b) subject to the exceptions set forth on Schedule 3.6.2, collaborate with, license or otherwise authorize or grant any rights to any Third Party to conduct any of the activities described in clause (a) of this Section 3.6.2. It is understood that this Section 3.6.2 shall not limit any activities outside the Field.

3.6.3 Legend. During the Exclusivity Period, neither Legend nor any of its Affiliates shall (a) conduct human clinical Development with respect to, conduct CMC Development or Manufacture for commercial purposes, or Commercialize within the Field, directly or indirectly anywhere in the world, any Competing BCMA CAR-T except to the extent specifically permitted pursuant to this Agreement; or (b) collaborate with, license or otherwise authorize or grant any rights to any Third Party to conduct any of the activities described in clause (a) of this Section 3.6.3. It is understood that this Section 3.6.3 shall not limit any activities outside the Field.

-26-

3.6.4 <u>Acquisition of Certain Agents or Products</u>(i). In the event that either Party or any of its Affiliates acquires rights to any Competing BCMA CAR-T as the result of a merger, acquisition, combination, in-license or similar transaction with, of or by a Third Party, and as of the date of consummation of such transaction, there is ongoing Exploitation of such Competing BCMA CAR-T that is prohibited under Section 3.6.2 or 3.6.3 (taking into account Section 14.2 below), then the Party who acquired (or whose Affiliate acquired) such rights to such Competing BCMA CAR-T ("Acquiring Party") shall, [\*\*\*].

[\*\*\*].

3.6.5 Certain Definitions. For purposes of this Agreement:

(a) "**Competing BCMA CAR-T**" means any CAR-T incorporating a CAR that binds to BCMA, and any CAR T-Cell Therapy using any such CAR-T, other than a Product.

(b) "**Exclusivity Period**" means the period beginning on the Effective Date and ending on the earliest of (x) [\*\*\*] anniversary of the Effective Date, (y) the date notice of termination of this Agreement is given pursuant to Section 12.3, or (z) the expiration of this Agreement; provided however, that in the event [\*\*\*], the date referenced in clause (x) shall be the twentieth (20<sup>th</sup>) anniversary instead of the [\*\*\*] anniversary of the Effective Date.

3.7 [\*\*\*].

3.8 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including Section 3.1 hereof, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). Legend and Janssen hereby acknowledge, on behalf of themselves and their respective Affiliates, that (i) copies of research data, (ii) laboratory samples, (iii) product samples and inventory, (iv) formulas, (v) laboratory notes and notebooks, (vi) all Data and results related to Clinical Studies, (vii) Regulatory Documentation and Regulatory Licenses, (viii) rights of reference in respect of Regulatory Documentation and Regulatory Licenses, (vii) and promotional materials, in each case ((i) through (x)), relating to the Licensed CARs or Products, constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code. Each of Legend and Janssen agree not to, and to cause their respective Affiliates not to, interfere with the other Party's or its Affiliate's exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agree to use Diligent Efforts to assist the other Party or its Affiliate to exercise such rights and licenses in accordance with this Agreement, subject to the covenants set forth in Sections 3.6.1(a) (solely with respect to a Licensed CAR and Equivalents of a Product) and Section 3.6.1(b), which for clarity shall continue to apply after any bankruptcy and shall attach to and run with any rights or

-27-

licenses Janssen or its Affiliates obtains to such intellectual property pursuant to the Bankruptcy Code. It shall be deemed for purposes of the Bankruptcy Code, including Bankruptcy Code Sections 1502 and 1517, that the "center of main interests" of Legend U.S. is in the United States and the center of main interests of Legend U.S. shall remain deemed to be in the United States. Legend further acknowledges, agrees and covenants it is intended that Bankruptcy Code Section 365(n) shall apply in any proceeding under Chapter 15 of the Bankruptcy Code involving Legend Ireland and that, in any such proceeding, it is intended Janssen shall be entitled to make the election and exercise the rights described in Section 365(n).

3.9 **Joint Patent Rights**. Subject to the covenants set forth in Section 3.6, and to the extent not already granted herein, each Party hereby grants, and shall cause its Affiliates to grant, to the other Party a worldwide, non-exclusive, royalty-free, fully paid up, freely sublicensable right and license to exploit the Joint Patent Rights in any manner without obtaining the consent of or compensating or accounting to the other Party (or its Affiliates).

3.10 **No Other Rights**. No rights, other than those expressly set forth in this Agreement are granted to either Party hereunder, and no additional rights shall be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other hereunder are reserved.

3.11 **Technical Assistance**. During the Term, Legend shall reasonably cooperate with Janssen to provide all technical assistance, and to transfer to Janssen any Know-How licensed to Janssen under Section 3.1, reasonably requested by Janssen to facilitate the transfer of Development and Manufacturing efforts reasonably necessary for the Development, CMC Development or Manufacture of the Initial Product for the Field pursuant to a technology transfer plan established by the JDC after the Effective Date ("**Technology Transfer Plan**") and from the Effective Date until the establishment of such Technology Transfer Plan use Diligent Efforts to do so. Such cooperation will include providing Janssen with reasonable access by teleconference or in-person at Legend's facilities to any Legend personnel involved in the Development, CMC Development and Manufacturing of the Products to provide Janssen with a reasonable level of technical assistance and consultation in connection with the transfer of such Know-How as described in the Technology Transfer Plan. [\*\*\*]

## ARTICLE IV DEVELOPMENT

#### 4.1 GDP and Development Budget.

4.1.1 Contents.

(a) The GDP shall be prepared in reasonable detail and shall include, with respect to each Product and each indication included therein, all Development activities that are reasonably necessary to support Marketing Approval and Commercialization of such Product for such indication in the U.S., Janssen Territory and Greater China, including (i) non-clinical development activities and Clinical Studies (which may include IISs and Cooperative Group Studies) designed to generate all data necessary to obtain or maintain Marketing Approval, including post-approval commitments and post-marketing requirements mandated by or undertaken at the request of Governmental Authorities, (ii) a plan for preparing and submitting Drug Approval Applications, and obtaining and maintaining Marketing

-28-

Approvals, in the U.S., Janssen Territory and Greater China (the "**Registration Plan**"), (iii) Early Access Programs, if applicable and (iv) Medical Affairs Studies. The GDP shall allocate responsibility between the Parties for the conduct of each Development activity included in the GDP. The GDP shall also include general study design parameters, specific staffing requirements and the funding budget for each stage of clinical development for each indication in the GDP, and shall be consistent with the terms of this Agreement.

(b) The GDP shall also include a budget for Development Costs to be incurred by the Parties in conducting the Development activities for the Products in the Field for the U.S., Greater China and Janssen Territory in the GDP that are scheduled to be commenced or conducted during the Calendar Year following the time the GDP is to be approved under Section 4.1.3(a) below and the succeeding Calendar Year (the "**Development Budgeted Period**"), [\*\*\*] as determined by the JDC in conjunction with the Finance Working Group (with respect to such Calendar Years, the "**Development Budget**"). Each Development Budget shall also include [\*\*\*] Development Costs for the Calendar Year after the Development Budgeted Period and an annual amount for Medical Affairs Studies designed to generate additional data to support pricing and reimbursement approvals and Commercialization efforts in the U.S., Greater China and Janssen Territory during the Development Budgeted Period, which amounts shall be [\*\*\*] unless otherwise approved by the JSC (without escalation or resolution pursuant to Section 2.8.2 or Section 2.8.3). [\*\*\*]

(c) In addition to the Development Budget, the GDP shall include a high-level forecast of the aggregate amount of the Development Budget for each Calendar Year [\*\*\*] (the "**Development Budget Forecast**").

#### 4.1.2 Initial GDP.

(a) Notwithstanding Section 4.1.1, the initial GDP attached to this Agreement as <u>Exhibit C</u> ("**Initial GDP**") includes all Clinical Studies that, as of the Effective Date, the Parties believe are reasonably necessary to support Marketing Approval of a Product for the indications contemplated by the GDP in the Major Market Countries. For clarity, each Clinical Study described in the Initial GDP is a Clinical Study of the Initial Product for the Field. Promptly following the Effective Date, the JDC will prepare and the JSC shall approve a comprehensive GDP that includes all Development activities that are reasonably necessary to support Marketing Approval and Commercialization of such Product for each indication in the Initial GDP in the U.S., Janssen Territory and Greater China. Unless otherwise agreed by the Parties, such comprehensive GDP shall be consistent with the Initial GDP.

(b) Notwithstanding Section 4.1.1, the Initial GDP includes an initial Development Budget ("**Initial Development Budget**") for Calendar Years [\*\*\*]. Promptly following the Effective Date, the JDC will prepare and the JSC shall approve a comprehensive Development Budget [\*\*\*] in connection with the preparation of the comprehensive GDP pursuant to Section 4.1.2(a). Such comprehensive Development Budget for each such Calendar Year shall be consistent with the Initial Development Budget for the applicable Calendar Year [\*\*\*]. [\*\*\*]

-29-

(c) The initial GDP includes the initial Development Budget Forecast [\*\*\*] (the "**Initial Development Budget Forecast**"). Promptly following the Effective Date, the JDC will prepare and the JSC shall approve a comprehensive Development Budget Forecast [\*\*\*] in connection with the preparation of the comprehensive GDP pursuant to Section 4.1.2(a) and Development Budget pursuant to Section 4.1.2(b). Such Development Budget Forecast shall be consistent with the Initial Development Budget Forecast [\*\*\*].

(d) The initial GDP includes [\*\*\*] of the Initial Product to be conducted in [\*\*\*]. [\*\*\*] as soon as possible after the following criteria have been satisfied:

(i) [\*\*\*] the Initial Product has been [\*\*\*]; and

(ii) the Parties have received guidance from [\*\*\*].

4.1.3 <u>Updates and Amendments to the GDP</u>.

(a) The JDC shall review and update the GDP annually. Concurrently with the annual update of the GDP, the JDC shall prepare an updated Development Budget [\*\*\*] and shall also prepare an updated Development Budget Forecast. The JDC shall submit all such updates to the JSC for review and approval, such that JSC preliminary approval would occur no later than [\*\*\*]. Upon the JSC's preliminary approval, such updates shall be submitted to each Party [\*\*\*], at which time any updates shall be appended to the GDP.

(b) Either Party may submit other proposed updates and amendments to the GDP to the JDC. The JDC shall reasonably consider such proposed updates and amendments, and may also independently develop proposed updates and amendments. Any such proposed updates and amendments that are reviewed or developed by the JDC shall be submitted to the JSC for review and approval; <u>provided</u>, <u>however</u>, that [\*\*\*] shall not be subject to JSC approval. For clarity, [\*\*\*].

(c) If the JSC approves an update or amendment to the GDP (including any corresponding update or amendment to the Development Budget), the GDP (including the Development Budget) shall be deemed to be amended accordingly on the date of such approval. If the JSC does not approve an update or amendment to the GDP within 30 days after such update or amendment is submitted to the JSC for approval, the approval of such update or amendment shall be a Committee Matter subject to resolution in accordance with Section 2.8 and the then-current GDP shall continue to apply (and if such matter is still not resolved by the end of the period covered by the then-current GDP, then during the next succeeding year the non-binding forecast shall be deemed the Development Budget in the GDP) until such Committee Matter is resolved.

# 4.2 Conduct of Development Activities.

4.2.1 <u>Clinical Studies with other Product</u>. Before any Clinical Study of a Product involving another product of a Party (i.e., other than a Product) is conducted under the GDP or as an Independent Development Activity, whether as part of a Combination Regimen or otherwise (i.e. as a comparator or as an induction therapy), the JDC's approval of such Clinical Study is required. For clarity, the Clinical Studies included in the Initial GDP (as such Clinical Studies may be modified or amended in accordance with this Agreement following the Effective Date) are deemed to have been approved by the JDC for purposes of this Section 4.2.1. [\*\*\*] pursuant to this Agreement without [\*\*\*]. Legend acknowledges that [\*\*\*].

-30-

## 4.2.2 Allocation of Development Activities.

(a) The JDC shall allocate responsibility between the Parties for the conduct of Development activities included in the GDP in accordance with this Section 4.2.2, and shall set forth such allocation in the GDP. Unless otherwise agreed by Janssen in accordance with Section 4.2.2(c), and subject to Section 4.2.2(b): (i) Janssen shall conduct all Clinical Studies of the Initial Product under the GDP [\*\*\*].

(b) With respect to any Clinical Study conducted by Janssen under the GDP, Legend shall have a right to [\*\*\*] such Clinical Study as follows: (i) during the [\*\*\*] of such Clinical Study[\*\*\*] and (ii) for [\*\*\*] of such Clinical Study [\*\*\*]. Such individuals shall have appropriate clinical development qualifications [\*\*\*], and such individuals' activities shall be [\*\*\*]. [\*\*\*]. The JDC will have authority over performance issues of such Legend [\*\*\*]. Notwithstanding the foregoing (or clauses (c), (d) or (e) below) the Parties will [\*\*\*] participating in Clinical Studies of the Product being conducted by [\*\*\*] decisions with respect to the conduct of such Clinical Studies (to the extent [\*\*\*] with respect to such Clinical Studies as specified in this Agreement)].

(c) If Janssen agrees, Legend may conduct Clinical Studies for the Initial Product [\*\*\*].

(d) For any other Clinical Studies of the Products [\*\*\*].

(e) In allocating responsibilities between the Parties, the JDC shall take into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities as well as the Parties' intention to provide Legend a reasonable opportunity to build and expand its expertise, capabilities, staffing and available resources in connection with performing Development activities allocated to it.

(f) Notwithstanding the foregoing, (i) responsibility for conducting all regulatory activities in Greater China shall be allocated to Legend (subject to Janssen's rights under Section 4.6.4) and Legend shall be the primary point of contact for interfacing with all Governmental Authorities in Greater China in accordance with Section 4.6, (ii) responsibility for conducting all regulatory activities in the U.S. and Janssen Territory shall be allocated to Janssen (subject to Legend's rights under Section 4.6.4), (iii) responsibility for conducting all Early Access Programs for the Products in the U.S. and the Janssen Territory shall be allocated to Janssen and (iv) the JDC shall determine how to allocate the annual budget for Medical Affairs Studies (i.e., the portion of such budget that will be allocated to conduct of Post-Approval Supplies of Product for IIS or Cooperative Group Studies and the portion of such budget that shall be allocated to each territory based on where data generation would be best accomplished) and shall oversee the conduct of such IIS or Cooperative Group Study that the JDC determines to support.

-31-

4.2.3 <u>Standards of Conduct</u>. Each of Legend and Janssen shall use Diligent Efforts to execute and to perform, or cause to be performed, the Development activities allocated to it in the GDP, and to cooperate with the other in carrying out the GDP, in accordance with the timetables therein. Each Party and its Affiliates shall conduct all Development activities with respect to the Products in good scientific manner and in compliance with applicable Law, including laws regarding environmental, safety and industrial hygiene, and Good Laboratory Practice, Good Clinical Practice, informed consent and Institutional Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.

4.2.4 <u>Clinical Study Protocols</u>. The JDC shall review and approve all initial and amended protocols and master informed consent forms for each Clinical Study in the GDP. The Party conducting a Clinical Study in the GDP shall use only protocols and informed consent forms approved by the JDC in the conduct of such Clinical Study.

4.2.5 <u>Subcontracting</u>. Each Party (or its Affiliate) may subcontract the performance of any activities with respect to the Products undertaken in accordance with this Agreement to one or more Third Parties (each such Third Party, a "**Subcontractor**"), <u>provided</u> that such Third Parties who will perform Development activities with respect to the Products satisfy any subcontractor criteria established by the JDC. All subcontracted activities shall be conducted pursuant to a written agreement between the subcontracting Party and the Subcontractor (a "**Subcontract**"), which shall be consistent with the terms and conditions of this Agreement, shall contain confidentiality provisions no less restrictive than those set forth in ARTICLE IX, and shall contain a certification that such Third Party subcontractor and its officers, employees and agents have not been debarred, and are not subject to debarment, pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, and are not the subject of a conviction described in such section. The subcontracting Party shall oversee the performance of its Subcontractors under the GDP, in each case as is reasonable and customary for the type of activity being conducted. Notwithstanding the foregoing, the subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Subcontractors with the applicable provisions of this Agreement.

4.2.6 <u>Clinical Quality Agreement</u>. Promptly following the Effective Date, the JDC shall form a Quality Working Group and the Parties shall negotiate in good faith and use all reasonable efforts to enter into a clinical quality agreement that documents the standards, expectations, and responsibilities of the Parties with respect to managing clinical quality (including quality assurance (QA), quality control (QC), and quality risk management (QRM)) for the Parties' Development activities with respect to the Products under this Agreement. Such clinical quality agreement shall contain mutually agreed terms and conditions, including with respect to: (i) compliance with applicable Law; and (ii) the communication between the Parties with respect to the management of clinical trial quality and compliance. Among other things, such agreement shall require each Party to maintain complete, current and accurate records of all work conducted by the Parties under this Agreement with respect to the Products and shall grant the other Party the right to review any such records at reasonable times and upon reasonable prior written notice.

-32-

## 4.2.7 Safety Concerns.

(a) Promptly upon request by either Party, the JDC shall establish an independent safety review board (the "**Independent Safety Board**"), comprised of [\*\*\*] independent Third Party safety experts who are neutral, disinterested and impartial, and who have experience relevant to safety matters regarding pharmaceutical products for oncology indications, to consult with the Parties, through the JDC, on safety matters regarding the Development and Commercialization of Products hereunder, with such consultation conducted in manner to minimize impact the timing of the Development activities set forth in the GDP. The JDC will determine whether (and how frequently) it wishes regular review and consultation with the Independent Safety Board, and either Party may contact the Independent Safety Board through the JDC at any time. For clarity, subject to Section 4.2.7(e) the Independent Safety Board shall have no decision-making authority under this Agreement, but shall only make recommendations and be available for consultation with the JDC and the Parties as described in this Section 4.2.7. In the event the JDC does not reach consensus on the appointment of the Third Party safety experts to the Independent Safety Board, [\*\*\*].

(b) Notwithstanding anything to the contrary in this Agreement, a Party shall not be obligated to commence or continue any Development activities with respect to the Products if (i) such Party reasonably and in good faith determines that performance of such Development activity would violate applicable Law or (ii) such Party reasonably and in good faith determines that a Clinical Study would pose an unacceptable bona fide safety or tolerability risk for subjects participating in such Clinical Study.

(c) If a Party who is not sponsoring a Clinical Study of a Product under this Agreement believes in good faith that such a Clinical Study should not commence or termination or suspension of such Clinical Study is warranted, in each case because of safety or tolerability risks to the study subjects, then such Party shall so notify the sponsoring Party and the sponsoring Party shall suspend (or not start) such Clinical Study until the JDC approves a remediation plan under Section 4.2.7(d) to overcome or remedy such concern.

(d) If either Party raises a safety concern under Section 4.2.7(b) or 4.2.7(c), the JDC [\*\*\*] shall promptly meet and attempt to agree upon, in consultation with the Independent Safety Board, a remediation plan to overcome or remedy such safety concern. Each Party shall instruct its JDC representatives to attempt to reach agreement on such a plan in good faith. If the JDC approves a remediation plan, each Party shall use Diligent Efforts to implement such plan.

(e) If (i) all Development activities under the GDP have been terminated or suspended for a [\*\*\*] above, and (ii) the JDC has not approved a remediation plan under Section 4.2.7(d) because of [\*\*\*] may thereafter refer the matter to the [\*\*\*]. If the [\*\*\*]. For clarity, this Section 4.2.7(e) shall not apply (1) if the [\*\*\*] or (2) if any Clinical Studies of the Product are continuing to be conducted under the GDP.

(f) If either Party raises a safety concern under Section 4.2.7(b) or (c), then, while the JDC attempts to agree on a remediation plan under Section 4.2.7(d), each Party shall use Diligent Efforts to overcome or remedy such concern, to the extent such Party has the right to do so under this Agreement without JDC approval or to the extent reasonably acceptable to the other Party.

-33-

(g) If [\*\*\*] and the process set forth in Section 4.2.7(d) does not apply, then [\*\*\*] to overcome or remedy such concern.

4.2.8 <u>Development Reports</u>. At each meeting of the JDC, each Party will report on the Development activities with respect to the Products in the Field that such Party and its Affiliates has performed or caused to be performed since the last meeting of the JDC, evaluate the work performed in relation to the goals of the GDP and provide such other information as may be reasonably requested by the JDC with respect to such Development activities. If a Party fails to adequately provide such report at a meeting of the JDC, the other Party may request, and such Party will provide to such other Party, a written progress report that includes information regarding accrual, site initiation, progress on protocol writing, meeting requests and briefing documents, in the case of clinical or regulatory activities, and in other cases such information as is reasonably necessary to convey a reasonably comprehensive understanding of the status of the applicable Development activity.

4.3 **Independent Development Activities**. If (i) a Party proposes to amend the GDP to add new Development activities in accordance with Section 4.1.3(b) and such amendment is not approved in accordance with Section 4.1.3(c) or 2.8, as applicable and (ii) such new Development activities are for the same version of a Product that is already included in the GDP (i.e., without modification) for any indication in the Field, then the Party that submitted the proposed amendment may, upon written notice to the other Party, conduct the proposed Development (and related CMC Development and Manufacturing in support of such Development) activities (such activities, "**Independent Development Activities**") in accordance with the following provisions of this Section 4.3. For clarity, this Section 4.3 shall not apply to Development activities with respect to Competing BCMA CAR-Ts or any Equivalents of a Product that is being or has been Developed under the GDP, which are the subject of Section 4.10.

4.3.1 <u>Conduct of Independent Development Activities</u>. The provisions of Sections 4.2.1, 4.2.3, 4.2.4 4.2.5, 4.2.6, 4.2.8 and 4.4 shall apply to the conduct of Independent Development Activities; <u>provided</u> that the protocol and informed consent forms for such Independent Development Activities shall not require JDC approval beyond the provisions of Section 4.3.4 below).

4.3.2 <u>Costs of Independent Development Activities</u>. The Party conducting Independent Development Activities shall bear all costs associated with such Independent Development Activities and such costs shall not be treated as Development Costs (or included in the Development Budget) or Allowable Expenses for purposes of this Agreement. Notwithstanding the foregoing, if either Party uses Data generated from such Independent Development Activities (a) to [\*\*\*], (b) to [\*\*\*], or (c) in [\*\*\*], then the non-conducting Party shall reimburse the Party that conducted such Independent Development Activities an amount [\*\*\*] incurred by the conducting Party for such Independent Development Activities, [\*\*\*]. Upon request from time to time, the Party conducting the Independent Development Activities shall [\*\*\*].

4.3.3 <u>Right to Opt-In to Independent Development Activities</u>. The non-conducting Party may opt-in with respect to such Independent Development Activities upon written notice to the conducting Party of the Independent Development Activities for which such Party wishes to opt-in. Following such notice, (i) the GDP shall be deemed to be amended to include such Independent

-34-

Development Activities on the date on which such notice is given to the conducting Party (the "**Opt-In Date**"); (ii) the then-current plan and budget of the conducting Party with respect to such Independent Development Activities shall be deemed to be included within and part of the GDP and Development Budget as of the Opt-In Date, and shall control with respect to such Independent Development Activities unless and until an amendment to the GDP and Development Budget providing for a different or modified plan and budget is approved in accordance with Section 4.1.3; (iii) the Out-of-Pocket Costs and FTE Costs associated with such Independent Development Activities incurred after the Opt-In Date shall be treated as Development Costs and included in the Development Budget; and (iv) the non-conducting Party shall reimburse the conducting Party an amount [\*\*\*], which costs will be determined using the same manner of calculating Development Costs for activities set forth in the GDP.

4.3.4 <u>Right to Object to Independent Development Activities</u>. If, at any time after a Party notifies the other Party that it will conduct Independent Development Activities at its own expense in accordance with this Section 4.3, the other Party determines reasonably and in good faith that (i) any such Independent Development Activities should not be commenced or continued [\*\*\*] or (ii) the commencement or continuation of any such Independent Development Activities [\*\*\*], then (in either case (i) or (ii)) the other Party shall so notify the conducting Party and the conducting Party shall not commence, or shall promptly discontinue (subject to such ethical obligations to continue support of patients already enrolled in Clinical Studies, as the conducting Party may in good faith determine), such Independent Development Activities unless and until the Parties agree that such Independent Development Activities should be permitted.

4.3.5 Exceptions. Neither Party may perform any Development activity as an Independent Development Activity if responsibility for such Development activity is exclusively allocated to the other Party pursuant to Section 4.2.2(f) [\*\*\*]. In the event that Legend conducts an Independent Development Activity that requires a regulatory filing to conduct such activity in the U.S. or Janssen Territory, or completes a Registration Study as an Independent Development Activity and desires to file a Drug Approval Application related to such study in the U.S. or Janssen Territory, Janssen shall make such filing on Legend's behalf at Legend's request and, with respect to any such Drug Approval Application, shall use Diligent Efforts to obtain Commercialization Approval. In the event that Janssen conducts an Independent Development Activity and desires to file a Drug Approval Application related to such study in Greater China, or completes a Registration Study as an Independent Development Activity and desires to file a Drug Approval Application related to such study in Greater China, Legend shall make such filing on Janssen's behalf at Janssen's request and, with respect to any such Drug Approval Application, shall use Diligent Efforts to obtain Commercialization Approval.

4.3.6 Inclusion in GDP at Conducting Party's Request. It is understood that the Party conducting Independent Development Activities may propose that the continuation of such Independent Development Activities be added to the GDP, and if so approved by the JDC, the same shall be added to the GDP. For the sake of clarity, if the JDC does not approve the addition of such Independent Development Activities to the GDP, such matter shall not be subject to escalation to the JSC or the Executive Officers, or resolution by [\*\*\*].

-35-

## 4.3.7 [\*\*\*]

4.4 Clinical Studies of Combination Regimens. Prior to commencing any Clinical Study of a Combination Regimen set forth in the GDP or as an Independent Development Activity, the conducting Party shall notify the JDC if the other product(s) included in such Combination Regimen are in-licensed from a Third Party and, if so, provide the JDC with a summary of the terms of such in-license. Notwithstanding anything to the contrary in this Agreement, the non-conducting Party shall not have any rights to Develop or Commercialize the Combination Regimen, or to own or use any Know-How or Patent Rights conceived, developed or generated during the course of conducting such Clinical Study, except to the extent not prevented under any applicable in-licenses. It is understood this Section 4.4 shall not be deemed to limit the requirements of Section 4.2.1.

4.5 **Companion Diagnostics**. If the JDC determines that it is necessary to Develop a companion diagnostic to support the Development and Commercialization of a Product in the Field, the Parties shall amend this Agreement to include the terms and conditions for the Exploitation of such companion diagnostic. [\*\*\*]

#### 4.6 Regulatory Matters.

## 4.6.1 Regulatory Responsibilities.

(a) Subject to Sections 4.3, 4.6.4 and 4.7, Janssen shall be solely responsible for implementing regulatory matters in the U.S. and Janssen Territory, including preparing and submitting all Regulatory Documentation (including Drug Approval Applications) and to obtaining and maintaining all Regulatory Licenses (including Marketing Approvals and pricing and reimbursement approvals) for Products in the Field in the U.S. and Janssen Territory, and to conduct communications with Regulatory Authorities with respect to the Products in the Field in the U.S. and Janssen Territory. Janssen shall conduct such activities in accordance with the Registration Plan.

(b) Subject to Sections 4.6.4 and 4.7, Legend shall, with Janssen assisting Legend, be responsible for implementing regulatory matters in Greater China, including preparing and submitting all Regulatory Documentation (including Drug Approval Applications) and obtaining and maintaining all Regulatory Licenses (including Marketing Approvals and pricing and reimbursement approvals) for Products in the Field in Greater China. Subject to Sections 4.6.4 and 4.7, Legend shall be the primary point of contact for communications with Regulatory Authorities with respect to the Products in the Field in Greater China. Legend shall conduct such activities in accordance with the Registration Plan.

4.6.2 Transition of Existing Regulatory Documentation and Regulatory License.

(a) [\*\*\*]

(b) Within [\*\*\*] after the Effective Date, [\*\*\*] electronic copies (unless otherwise required by applicable Law) of any Regulatory Documentation relating to the Products in the Field in the [\*\*\*]. Upon the completion of such transfer, [\*\*\*]. In the event that any such IND, Drug Approval Application or Regulatory License [\*\*\*] of such IND, Drug Approval Application or Regulatory License.

-36-

## 4.6.3 Ownership of Regulatory Documentation and Regulatory Licenses; Rights of Reference.

(a) [\*\*\*] shall own all Regulatory Documentation and Regulatory Licenses for the Products in the Field in the U.S. and the Janssen Territory. Subject to the terms and conditions of this Agreement, [\*\*\*] (on behalf of itself and its Affiliates) hereby grants to [\*\*\*] a non-exclusive Right of Reference (including the right to grant further Rights of Reference to any of [\*\*\*] Affiliates, Licensees or Third Party distributors) to any Regulatory Documentation and Regulatory Licenses Controlled by [\*\*\*], to the extent required or reasonably useful to obtain or maintain any Regulatory License of (i) a Product in the Field in Greater China in accordance with this Agreement or (ii) any other product inside or outside Greater China, in each case for the sole purpose of preparing, obtaining and maintaining such Regulatory License and to otherwise Develop, CMC Develop, Manufacture and Commercialize such Product or other product. [\*\*\*] shall notify [\*\*\*] of any additional right of reference granted by [\*\*\*] in accordance with this Section 4.6.3. Notwithstanding the foregoing, clause (ii) of this Section 4.6.3(a) shall not be deemed to grant to [\*\*\*] a license or right to Know-How beyond the licenses and rights granted to [\*\*\*].

(b) [\*\*\*] shall own all Regulatory Documentation and Regulatory Licenses for the Products in the Field in Greater China. Subject to the terms and conditions of this Agreement, [\*\*\*] (on behalf of itself and its Affiliates) hereby grants to [\*\*\*] a non-exclusive Right of Reference (including the right to grant further Rights of Reference to any of [\*\*\*] Affiliates, Licensees or Third Party distributors) to any Regulatory Documentation and Regulatory Licenses Controlled by [\*\*\*], to the extent required or reasonably useful to obtain or maintain any Regulatory License of (i) a Product in the Field in the U.S. or Janssen Territory in accordance with this Agreement or (ii) any other product inside or outside the U.S. or Janssen Territory, in each case for the sole purpose of preparing, obtaining and maintaining such Regulatory License and to otherwise Develop, CMC Develop, Manufacture and Commercialize such Product or other product. [\*\*\*] shall notify [\*\*\*] of any additional right of reference granted by [\*\*\*] in accordance with this Section 4.6.3. Notwithstanding the foregoing, clause (ii) of this Section 4.6.3(b) shall not be deemed to grant to [\*\*\*] a license or right to Know-How beyond the licenses and rights granted to [\*\*\*].

(c) If requested by a Party, the other Party shall provide any signed statement that authorizes any Right of Reference granted to such Party under this Section 4.6.3 that is required by applicable Law or the Regulatory Authority in the applicable country or jurisdiction. In the event that any Affiliate, Licensee, Sublicensee or Third Party distributor of a Party holds any Regulatory Documentation or Regulatory License to which the other Party is granted a Right of Reference under this Section 4.6.3, such Party will cause such Affiliate, Licensee, Sublicensee or Third Party distributor to grant a Right of Reference to the other Party to the same extent that such Party is required to grant such Right of Reference under this Section 4.6.3.

(d) The Rights of Reference granted pursuant to this Section 4.6.3 shall include the right to access all Know-How included or referenced in the applicable Regulatory Documentation or Regulatory License and to use such Know-How in connection with the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such Data and Know-How in its own Regulatory Documentation; [\*\*\*]. Promptly upon the request of a Party, the other Party shall provide to the requesting Party such Data and Know-How (and any other Data or Know-How within the Collaboration Intellectual Property) as is necessary or useful for such purposes (which shall be in electronic form to the extent the same exists in electronic form and otherwise shall be copies for all other materials comprising such Know-How).

-37-

(e) Notwithstanding the foregoing, neither Section 4.6.2 above nor this Section 4.6.3 shall be deemed to assign or require a Party (the "Assigning Party") to assign to the other Party rights to any Data or Know-How contained in any Regulatory Documentation but otherwise owned by the Assigning Party. For clarity, assignment of Regulatory Documentation or a Regulatory License under this Section 4.6 shall be deemed to assign only the legal rights with respect to particular regulatory filings within such Regulatory Documentation or Regulatory Licenses (such as an IND or Marketing Approval) *per se* and not any Data or Know-How contained therein.

#### 4.6.4 Regulatory Cooperation.

(a) Subject to applicable Law, Legend shall have the right to have [\*\*\*] material meetings (including by telephone), conferences and discussions by Janssen or its Affiliate with Regulatory Authorities pertaining to Development, CMC Development, Manufacture or any Regulatory License of a Product in the Field in the U.S. or Janssen Territory, and Janssen shall have the right to have [\*\*\*] material meetings (including by telephone), conferences and discussions by Legend or its Affiliate with Regulatory Authorities pertaining to Development, CMC Development, Manufacture or any Regulatory License of a Product in the Field in Greater China. Each Party shall, to the extent feasible, provide the other Party with [\*\*\*] such meetings and other contact and advance copies of all related documents and other relevant information relating to such meetings or other contact. [\*\*\*].

(b) Janssen shall provide the JDC with advance drafts of any material documents or other material correspondence pertaining to or comprising Regulatory Documentation with respect to Products in the Field, including any proposed labeling, that Janssen plans to submit to any Regulatory Authority in any Key Country [\*\*\*] (the "**Key Regulatory Submissions**"). Legend shall provide the JDC with advance drafts of material documents or other material correspondence pertaining to or comprising Regulatory Documentation with respect to Products in the Field, including any proposed labeling, that Legend plans to submit to any Regulatory Authority in Greater China (the "**Greater China Regulatory Submissions**"). The JDC shall review and approve such Key Regulatory Submissions and Greater China Regulatory Submissions prior to their submission, provided however if the JDC (or, if escalated, the JSC or Executive Officers) does not reach consensus on [\*\*\*] after the Effective Date, [\*\*\*] the JDC all documents or other correspondence pertaining to or comprising Regulatory Documentation with respect to [\*\*\*].

(c) Janssen shall provide Legend with copies of all Key Regulatory Submissions and all material correspondence (including written summaries of material oral correspondence) it receives from, a Regulatory Authority in any Key Country (or, upon request by Legend, any other country in the Janssen Territory) in accordance with this Section 4.6.4. Legend shall provide Janssen with copies of all Greater China Regulatory Submissions and all material correspondence (including written summaries of material oral correspondence) it receives from, a Regulatory Authority in Greater China in accordance with

-38-

this Section 4.6.4. Key Regulatory Submissions and Greater China Regulatory Submissions shall be provided to the JDC a reasonable time in advance in order to allow the JDC a reasonable amount of time to review and approve such Key Regulatory Submissions or Greater China Regulatory Submissions prior to their submission to the applicable Regulatory Authority, [\*\*\*]. Material correspondence and other material documents received from a Regulatory Authority in any Key Country must be provided to Legend as soon as practicable, [\*\*\*]. Material correspondence and other material documents received from a Regulatory Authority in Greater China must be provided to Janssen as soon as practicable, [\*\*\*]. For purposes of this Section 4.6.4, "**Key Country**" means [\*\*\*].

4.7 **Pricing and Reimbursement Approvals**. Janssen shall be responsible for and have the exclusive right to seek and attempt to obtain pricing approvals and reimbursement approvals from Governmental Authorities for the Products in the Field in the U.S. and Janssen Territory [\*\*\*]. Janssen shall keep Legend reasonably informed with regard to any pricing or reimbursement approval proceedings for the Product in the Field in the U.S. or Janssen Territory. Legend shall be responsible for and have the exclusive right to seek and attempt to obtain pricing approvals and reimbursement approvals from Governmental Authorities for the Products in the Field in Greater China [\*\*\*]. Legend shall keep Janssen reasonably informed with regard to any priceedings for the Product in the Field in Greater China.

# 4.8 Pharmacovigilance.

4.8.1 The Parties shall meet to negotiate in good faith and agree on processes and procedures for sharing adverse event and other pharmacovigilance information related to the Products promptly following the Effective Date (and in any event no later than the initiation of clinical or marketing activity with respect to the Products). Such written plan or agreement (the "**Pharmacovigilance Agreement**") shall contain provisions to ensure that adverse event and other pharmacovigilance information is exchanged according to a schedule that will permit each Party to comply with legal and regulatory requirements in its respective territories. Before entering into the Pharmacovigilance Agreement, the Parties shall, as necessary, implement an interim process for the exchange of any and all information concerning adverse events related to the use of the Products regardless of source.

4.8.2 Janssen shall establish and maintain the global safety database of adverse events and relevant pharmacovigilance information, including exposure during pregnancy reports, for the Products that will be used for regulatory reporting, overall drug safety surveillance, and responses to safety queries from Regulatory Authorities by both Parties. If applicable, Legend shall transfer a copy of all safety information for the Product in its possession to the global safety database within an agreed time period, providing Janssen with sufficient time to enter all the data and to obtain validation of the database. Each Party will have the right to use the data in such global safety database and upon Legend's request from time-to-time Janssen shall provide Legend a copy of such global database (so that Legend may maintain a duplicate safety database). Janssen shall provide Legend reasonable electronic access (without the right to add or modify) to such data.

4.9 **Patient Samples**. All patient samples collected and retained in connection with Clinical Studies performed under the GDP, or any Clinical Studies with respect to which either Party provides an opt-in notice pursuant to Section 4.3.3 (together with compilations of Data comprising annotations, or correlating outcomes, with respect to such samples, "**Patient Samples**") shall be a shared

-39-

resource of the Parties. Unless otherwise agreed by the Parties, all Patient Samples shall be maintained and stored at the facilities of a Third Party selected by the JDC, and the fees paid to such Third Party in connection with such maintenance and storage shall be shared as Development Costs during the Term (and after the Term, shared equally by the Parties). Each Party shall access the Patient Samples, and authorize Affiliates and Third Parties to access the Patient Samples, only as determined by the JDC for activities approved by the JDC (or, following termination or expiration of this Agreement, as approved by the Parties) in advance. Without limiting Section 3.5, (i) each Party shall promptly provide the other all Data made, generated or obtained in whole or part through use of the Patient Samples, whether during or after the Term, and (ii) all Know-How made, generated or obtained in whole or part through use of the Patient Samples, whether during or after the Term, and to any inventions within such Know-How, shall be included within the definition of Collaboration Intellectual Property for purposes of Section 3.5.

4.10 [\*\*\*] **Products**. If either Party desires to conduct human clinical Development of [\*\*\*], such Party shall comply with the provisions of this Section 4.10.

4.10.1 If a Party desires to conduct human clinical Development of [\*\*\*], then prior to initiating a Clinical Study for such [\*\*\*], such Party shall submit to the other Party [\*\*\*] Development activities together with a written notice specifically referencing this Section 4.10.1 and proposing to add such [\*\*\*] to the GDP (a "[\*\*\*] **Product Proposal**"), along with [\*\*\*]; provided, however, that a Party may not submit a [\*\*\*] Product Proposal for a [\*\*\*] to the other Party pursuant to this Section 4.10.1 in a Calendar Year if a [\*\*\*] in a prior [\*\*\*] Product Proposal proposed by such Party in such Calendar Year was [\*\*\*] (unless otherwise agreed by the Parties or provided in Section 4.10.3(f)). Within [\*\*\*] after receipt of such [\*\*\*] Product Proposal [\*\*\*], the other Party shall have the right to elect upon written notice to include such [\*\*\*] as a Product under this Agreement. The date of such notice shall be referred to as the "[\*\*\*] **Notice Date**" with respect to such [\*\*\*].

4.10.2 If the other Party elects to include a [\*\*\*] as a Product under this Agreement in accordance with Section 4.10.1 or Section 4.10.3(d), such [\*\*\*] shall become a Product as of the [\*\*\*] Notice Date and is sometimes referred to in this Agreement as a "[\*\*\*] **Product**." On and after the [\*\*\*] Notice Date:

3.6.2 and 3.6.3;

(a) all terms of this Agreement that apply to Products shall apply to such Second Generation Product, including Sections

(b) if, following the Second Generation Notice Date, [\*\*\*];

(c) [\*\*\*] submitted by the proposing Party with respect to such [\*\*\*] Product shall be deemed to be included within and part of the [\*\*\*] as of the [\*\*\*] Notice Date (it being understood that [\*\*\*] by the JDC);

(d) the Out-of-Pocket Costs and FTE Costs associated with the Development of such [\*\*\*] Product incurred after the [\*\*\*] Notice Date in accordance with the GDP [\*\*\*] shall be treated as Development Costs and included in the Development Budget; and

(e) the other Party shall reimburse the proposing Party [\*\*\*] activities with respect to such [\*\*\*] Product conducted before the [\*\*\*] Notice Date, which costs will be determined by the Finance Working Group using the same manner of calculating Development Costs for activities set forth in the GDP.

-40-

4.10.3 If the other Party does not elect to include such [\*\*\*] as a Product in accordance with Section 4.10.1 and [\*\*\*]:

(a) The proposing Party may, at its own expense, conduct clinical and other Development of such [\*\*\*] in accordance with the plan and budget it provided to the other Party;

(b) The proposing Party may modify the plan and budget described in Section 4.10.3(a) above, by so notifying the other Party, provided, however, if the other Party reasonably believes that the modified plan includes a change to [\*\*\*] below, then upon request the JDC shall review the matter and determine whether, as a result of such change, [\*\*\*]. If the JDC determines that [\*\*\*];

(c) The proposing Party shall provide the other Party with all efficacy and safety data generated with respect to [\*\*\*];

(d) At any time prior to the date that is [\*\*\*] days after the conducting Party provides the non-conducting Party with access to all efficacy and safety data from a Clinical Study of the [\*\*\*] in such Clinical Study, including [\*\*\*], (the "**Opt-In Period**") the other Party may elect upon written notice (the "**Opt-In Notice**") to [\*\*\*] under this Agreement (the "**Opt-In Right**"), in which case the provisions of Section 4.10.2 shall apply (other than 4.10.2(e)) (and all references in Section 4.10.2 to the [\*\*\*] Notice Date shall be deemed to refer instead to the date of such Opt-In Notice), and the non-conducting Party shall promptly reimburse the conducting Party [\*\*\*] incurred by the proposing Party for the Development activities with respect to [\*\*\*], which costs will be determined by the Finance Working Group using the same manner of calculating Development Costs for activities set forth in the GDP;

(e) if the other Party does not elect [\*\*\*] under this Agreement by the date set forth in Section 4.10.3(d), then: (i) if the proposing Party [\*\*\*] and (ii) if the proposing Party is [\*\*\*], and in each case paragraphs 4.10.3(b) and (c) above shall no longer apply, and the proposing Party [\*\*\*] this Agreement, [\*\*\*]; and

(f) if the proposing Party conducts clinical Development of [\*\*\*], before the other Party has elected to [\*\*\*] this Agreement, then the [\*\*\*] set forth in Section 4.10.1.

4.10.4 If the other Party does not elect to include [\*\*\*] as a Product [\*\*\*], then the proposing Party shall not conduct any clinical Development activities in the Field with respect to such [\*\*\*].

4.10.5 For purposes of this Section 4.10, [\*\*\*] in the Agreement; and in each case, both (b) the JDC has not reasonably determined that Development of such [\*\*\*]; and (c) the proposing Party has [\*\*\*] on the Effective Date. The JDC shall promptly determine whether a particular [\*\*\*] meets the criteria of (a)-(c) [\*\*\*]. For clarity, if the JDC determines that a [\*\*\*].

-41-

4.10.6 This Section 4.10 shall apply with respect to [\*\*\*], as follows:

(a) The provisions of this Section 4.10 may also be used by a Party to Develop [\*\*\*] that is being or has been Developed under the GDP [\*\*\*]. If a Party desires to Develop such [\*\*\*] using the same mechanism as set forth in this Section 4.10, all of the provisions of this Section 4.10 shall apply to [\*\*\*], except that Section 4.10.3(e) shall not apply with respect to [\*\*\*].

(b) In addition, once a Party (the "**Filing Party**") [\*\*\*], then without the Parties' mutual agreement such [\*\*\*] by (i) the other Party (the "**Non-Filing Party**") or (ii) unless the Filing Party [\*\*\*], by the Filing Party.

4.10.7 Notwithstanding Section 3.4 above, unless the [\*\*\*] described in a [\*\*\*] Product Proposal submitted by a Party is included as a Product hereunder, (a) the other Party shall not have a right or license under Section 3.4 above with respect to any Know-How pertaining to such [\*\*\*] that is disclosed to such Party in connection with such [\*\*\*] Product Proposal or under this Section 4.10; and (b) any Data, Know-How or Patent Rights made, generated or obtained by or on behalf of the conducting Party solely in the course of performing activities with respect to the [\*\*\*] under this Section 4.10 shall not be deemed Collaboration Intellectual Property.

## ARTICLE V COMMERCIALIZATION

## 5.1 Global Commercialization Strategy.

5.1.1 <u>Global Commercialization Strategy Plan</u>. [\*\*\*] shall develop and periodically update, and the JSC shall approve, a written document describing the global product strategy for Commercialization of the Products in the Field in the U.S., Greater China and Janssen Territory (the "**Global Commercialization Strategy Plan**"). The Global Commercialization Strategy Plan will outline strategic commercial efforts that will be undertaken at the global team level that are intended to support pre-launch, launch and life cycle management activities across regions and key functions.

5.1.2 <u>Global Commercialization Strategy Budget</u>. The Global Commercialization Strategy Plan shall include the Global Commercialization Strategy Budget for a given Calendar Year and the succeeding Calendar Year. The "**Global Commercialization Strategy Budget**" means the budget for [\*\*\*]. Each Global Commercialization Strategy Budget shall include [\*\*\*]. The Global Commercialization Strategy Budget is separate from, and would not contain amounts for Allowable Expenses budgeted in, the U.S. Commercialization Budget, Greater China Commercialization Budget and Janssen Commercialization Budget. The Global Commercialization Strategy Budget will cover all Commercialization Budget Benchmark Amounts (i.e., U.S. Commercialization Budget Benchmark Amounts, Greater China Commercialization Budget Benchmark Amounts and Janssen Territory Commercialization Budget Benchmark Amounts) expected to be incurred prior to completion of the first U.S. Commercialization Plan, Greater China Commercialization Plan or Janssen Territory Commercialization Plan, as applicable.

5.1.3 <u>Annual Updates</u>. [\*\*\*] shall develop, and submit to the JSC for review and approval, an annual update to the Global Commercialization Strategy Plan [\*\*\*]. Such update shall be developed and submitted to the JSC in time to permit the JSC's preliminary approval to occur no later than [\*\*\*]. Upon the JSC's preliminary approval, such plan shall be submitted to each Party [\*\*\*]. After final approval by the JSC, such Global Commercialization Strategy Plan shall take effect on the first day of the Calendar Year to which such Global Commercialization Strategy Plan applies.

-42-

5.1.4 <u>Other Updates</u>. Either Party may submit other proposed updates and amendments to the Global Commercialization Strategy Plan to the JSC at any time. The JSC shall reasonably consider such proposed updates and amendments, and may also independently develop proposed updates and amendments. Upon such approval by the JSC, the Global Commercialization Strategy Plan shall be amended accordingly.

## 5.2 Commercialization in the U.S.

5.2.1 <u>General</u>. The Parties shall Commercialize the Products in the Field in the U.S. in accordance with the U.S. Commercialization Plan and the terms of this Section 5.2, subject to the oversight of the USCC as set forth in this Section 5.2.

### 5.2.2 U.S. Commercialization Plan.

(a) [\*\*\*] shall develop and periodically update, and the JSC shall approve, a written plan for Commercialization of the Products in the Field in the U.S. (the "**U.S. Commercialization Plan**") as described in this Section 5.2.2.

(b) The U.S. Commercialization Plan shall set forth the strategy for the Commercialization of the Products in the Field in the U.S., the key Commercialization activities to be performed to implement such strategy and the staffing requirements for each such Commercialization activity. The U.S. Commercialization Plan will be consistent with the Global Commercialization Strategy Plan.

(c) The U.S. Commercialization Plan shall include the U.S. Commercialization Budget, annual Net Trade Sales forecasts for the U.S. for a given Calendar Year and the succeeding Calendar Year (which shall be Confidential Information of each Party), [\*\*\*]. The "**U.S. Commercialization Budget**" means the budget for Allowable Expenses to be incurred by the Parties in conducting Commercialization activities for the Products in the Field in the U.S. pursuant to the U.S. Commercialization Plan [\*\*\*]. Each U.S. Commercialization Budget shall include [\*\*\*].

(d) [\*\*\*] shall develop, and submit to the USCC for review, the initial U.S. Commercialization Plan [\*\*\*]. The USCC shall review, and submit to the JSC for approval, the initial U.S. Commercialization Plan [\*\*\*].

(e) [\*\*\*] shall develop, and submit to the USCC for review, an annual update to the U.S. Commercialization Plan (including an updated U.S. Commercialization Budget). The USCC shall submit each such U.S. Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur no later than [\*\*\*]. Upon the JSC's preliminary approval, such plan shall be submitted to each Party [\*\*\*]. After final approval by the JSC, such U.S. Commercialization Plan shall take effect on the first day of the Calendar Year to which such U.S. Commercialization Plan applies.

-43-

(f) Either Party may submit other proposed updates and amendments to the U.S. Commercialization Plan to the USCC at any time. The USCC shall reasonably consider such proposed updates and amendments, and may also independently develop proposed updates and amendments. Any such proposed updates and amendments that are approved or developed by the USCC shall be submitted to the JSC for review and approval. Upon such approval by the JSC, the U.S. Commercialization Plan shall be amended accordingly.

## 5.2.3 U.S. Co-Commercialization Responsibilities.

(a) Each Party shall use Diligent Efforts to perform the Commercialization activities allocated to such Party in the U.S. Commercialization Plan.

(b) Legend shall have the right to elect to perform [\*\*\*] Commercialization effort in the U.S. (excluding any activities that Janssen has the exclusive right to perform under Section 5.2.3(d)). If Legend elects to exercise such right, Legend shall notify Janssen [\*\*\*] before it will start to perform Commercialization activities in the U.S. and, in the [\*\*\*] of the U.S. Commercialization Plan (or in the initial U.S. Commercialization Plan), the responsibility to develop and execute the U.S. Commercialization Plan shall be [\*\*\*] and the USCC shall allocate Commercialization activities between the Parties [\*\*\*]. Legend shall use Diligent Efforts to ensure that it has sufficient capabilities, staffing and resources in place by the time it is scheduled to commercialization activities to Legend may [\*\*\*] Commercialization effort in the U.S. The Parties acknowledge that, as of the Effective Date, [\*\*\*]. Janssen shall be responsible for conducting all Commercialization activities in the U.S. Commercialization of the Products in the Field in the U.S. to the extent Legend does not exercise its right to be allocated [\*\*\*] of such activities.

(c) Without limiting the foregoing, [\*\*\*] the U.S. Commercialization Plan shall be promptly updated accordingly).

(d) Notwithstanding the foregoing, [\*\*\*].

(e) Each Party shall ensure that its sales representatives perform details of the Products in the U.S. in compliance with applicable Law, all of Janssen's and Legend's reasonable compliance policies and compliance guidance documents relating to the Commercialization of the Products and any corporate integrity agreement between either Party and the HHS Office of Inspector General. Legend shall establish and maintain a compliance program that satisfies the seven elements for an effective compliance program set forth in the HHS Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, including designation of a compliance officer and the conduct of effective training and education. Legend and Janssen shall each be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, contractors and agents pursuant to the requirements of the marketing reporting laws or research expense reporting laws of any Governmental Authority in the United States, including Section 6002 of ACA, commonly referred to as the "Sunshine Act."

<sup>-44-</sup>

5.2.4 <u>U.S. Commercialization Reports</u>. At each meeting of the USCC, each Party will report on any Commercialization activities that such Party and its Affiliates have performed in the U.S. since the last USCC meeting. Each Party will provide an evaluation of the work it and its Affiliates have performed in relation to the goals of the U.S. Commercialization Plan and provide such other information as may be required by the U.S. Commercialization Plan or reasonably requested by a Party's representatives on the USCC with respect to such Commercialization activities.

5.2.5 <u>Booking Sales in U.S.</u> Janssen and its Affiliates shall book all sales of Products in the U.S. and shall be responsible for warehousing and distributing the Products in the U.S., except to the extent that Legend is responsible for performing such activities in connection with its Manufacture of Product in accordance with ARTICLE VI. If Legend receives any orders for a Product in the U.S., it shall refer such orders to Janssen.

5.2.6 <u>U.S. Pricing Matters</u>. [\*\*\*] pricing guidance matters for the Products in the Field in the U.S., [\*\*\*] (the "**U.S. Pricing and Discounting Plan**"). [\*\*\*] with respect to such matter (for clarity, [\*\*\*]. [\*\*\*] authority with respect to the prices charged, any discounts and rebates offered or provided, and any other sale and reimbursement terms and conditions for the Products in the Field in the U.S. consistent with such guidance and the U.S. Pricing and Discounting Plan.

5.2.7 <u>U.S. Recalls</u>. [\*\*\*] shall decide whether to conduct a recall of a Product in the U.S. and the manner in which any such recall shall be conducted, provided that [\*\*\*] with respect to any such recalls, including with respect to whether to conduct a recall and the manner in which a recall is conducted. [\*\*\*] making a recall, and in any case (to the extent safety considerations permit) [\*\*\*] before initiating such a recall.

5.2.8 <u>Product Packaging; Promotional Materials</u>. The U.S. commercial teams shall develop, and submit to the USCC for review and approval, Product packaging and Promotional Materials, in each case for use in the United States, which shall be consistent with the U.S. Commercialization Plan and compliant with each Party's applicable standard operating procedures, the U.S. Commercialization Plan, and applicable Laws and Marketing Approvals. Following approval by the USCC, Product packaging and Promotional Materials shall be subject to approval by Janssen's Promotional Review Committee.

5.2.9 <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Commercialization activities with respect to the Products for which it has or otherwise is assigned responsibility under this Agreement or the U.S. Commercialization Plan and shall keep the other Party reasonably informed as to the progress of such activities, as determined by the USCC.

5.2.10 <u>U.S. Medical Inquiries</u>5.2.11 . Janssen shall handle all medical questions or inquiries from members of the medical profession in the U.S. regarding the Products; provided that Legend shall participate in such activities to the extent provided in the U.S. Commercialization Plan, which shall include, [\*\*\*]. All such Legend medical science liaisons shall have appropriate qualifications (which shall be reasonably evaluated and determined by the Parties using the same criteria and standard Janssen uses for its own personnel on the U.S. Commercialization team) to perform the role of a medical science liaison.

-45-

### 5.3 Commercialization in Janssen Territory.

5.3.1 <u>General</u>. Janssen shall Commercialize the Products in the Field in the Janssen Territory in accordance with the Janssen Territory Commercialization Plan and the terms of this Section 5.3, subject to the oversight of the JSC as set forth in this Section 5.3.

5.3.2 Janssen Territory Commercialization Plan.

(a) [\*\*\*] shall develop and periodically update, and the JSC shall approve, a written plan for Commercialization of the Products in the Field in the Janssen Territory on a regional basis (with such regional basis being consistent with the regional basis Janssen does for commercialization plans and budgets for its other products) (the "Janssen Territory Commercialization Plan") as described in this Section 5.3.2.

(b) The Janssen Territory Commercialization Plan shall set forth an overall marketing and Commercialization strategy for the Products in the Field in the Janssen Territory. The Janssen Territory Commercialization Plan will be consistent with the Global Commercialization Strategy Plan.

(c) The Janssen Territory Commercialization Plan shall include the Janssen Territory Commercialization Budget, annual Net Trade Sales forecasts for the Janssen Territory for [\*\*\*].

(d) [\*\*\*], and submit to the JSC for review and approval, the initial Janssen Territory Commercialization Plan no later

than [\*\*\*].

(e) [\*\*\*], and submit to the JSC for review and approval, an annual update to the Janssen Territory Commercialization Plan (including an updated Janssen Territory Commercialization Budget) with a target for final approval by the JSC no later than [\*\*\*]. After final approval by the JSC, such Janssen Territory Commercialization Plan shall take effect on the first day of the Calendar Year to which such Janssen Territory Commercialization Plan applies.

(f) Either Party may submit other proposed updates and amendments to the Janssen Territory Commercialization Plan to the JSC at any time. The JSC shall reasonably consider such proposed updates and amendments, and may also independently develop proposed updates and amendments. Upon approval of such an update or amendment by the JSC, the U.S. Commercialization Plan shall be amended accordingly.

# 5.3.3 Janssen Territory Commercialization Responsibilities.

(a) Janssen shall be solely responsible for Commercialization of the Products in the Field in the Janssen Territory in accordance with the Janssen Territory Commercialization Plan and the terms of this Agreement. Upon Legend's request, the JSC shall discuss Legend's involvement in [\*\*\*].

-46-

(b) Legend shall have the right to designate [\*\*\*] (the "Legend Representatives") to observe Janssen's (or its Affiliates') strategic planning for and implementation of, Commercialization of Products in [\*\*\*], each of whom shall be an employee of Legend or an Affiliate of Legend. Legend shall [\*\*\*] of the activities of the Legend Representatives under this Section 5.3.3(b). Any such Legend Representatives shall be [\*\*\*], provided that the involvement of such Legend Representatives under this Section 5.3.3(b) shall be [\*\*\*]. Janssen shall [\*\*\*]. Janssen may [\*\*\*]. The Legend Representatives shall have the right to so participate during the [\*\*\*], and for [\*\*\*] prior to such commercial launch covering preparation and ramp-up for launch. Such Legend Representatives shall [\*\*\*]. [\*\*\*] will develop reasonable procedures and policies regarding the Legend Representatives to provide [\*\*\*] by Legend Representatives with respect to Commercialization activities regarding Products in the Field in [\*\*\*] in accordance with this Section 5.3.3(b), while [\*\*\*].

5.3.4 <u>Janssen Territory Commercialization Reports</u>. At each meeting of the JSC, Janssen will report on any Commercialization activities that it and its Affiliates have performed in the Janssen Territory since the last JSC meeting. Janssen will provide an evaluation of the work it and its Affiliates have performed in relation to the goals of the Janssen Territory Commercialization Plan and provide such other information as may be required by the Janssen Territory Commercialization Plan or reasonably requested by Legend or the JSC with respect to such Commercialization activities.

5.3.5 <u>Right to Discuss Janssen Territory Activities</u>. If Legend reasonably believes that Janssen intends to take, or has taken, any action with respect to the Commercialization of the Products in the Field in the Janssen Territory that would reasonably be expected to materially and adversely affect Commercialization of the Products in the Field in the U.S. or Greater China, Legend may so notify the JSC. The JSC shall meet [\*\*\*] after such notice to discuss the concerns raised by Legend and to seek to agree upon a resolution to such concerns. Such concerns may be escalated and resolved as a Committee Matter in accordance with Section 2.8.2.

5.3.6 <u>Booking Sales in Janssen Territory</u>. Janssen and its Affiliates shall book all sales of Products in the Janssen Territory and shall be responsible for warehousing and distributing the Products in the Janssen Territory, except to the extent that Legend is responsible for performing such activities in connection with its Manufacture of Product in accordance with ARTICLE VI or Manufacturing Plans. If Legend receives any orders for a Product in the Janssen Territory, it shall refer such orders to Janssen.

5.3.7 Janssen Territory Pricing Matters. [\*\*\*] for the Products in the Field in the Janssen Territory, including [\*\*\*] (the "Janssen Territory Pricing and Discounting Plan"). In the event [\*\*\*]. Janssen shall otherwise be solely responsible for and have sole authority with respect to the prices charged, any discounts and rebates offered or provided, and other sale and reimbursement terms and conditions for the Products in the Field in the Janssen Territory Pricing and Discounting Plan].

5.3.8 Janssen Territory Recalls. Janssen shall decide whether to conduct a recall of a Product in the Janssen Territory and the manner in which any such recall shall be conducted, provided that Janssen shall consult with the JSC (and keep Legend informed) with respect to any such recalls, including with respect to whether to conduct a recall and the manner in which a recall is conducted. Janssen shall notify the JSC immediately in the event Janssen considers making a recall, and in any case (to the extent safety considerations permit) at least 24 hours before initiating such a recall.

-47-

5.3.9 Janssen Territory Medical Inquiries. Janssen shall handle all medical questions or inquiries from members of the medical profession in the Janssen Territory regarding the Products.

5.3.10 <u>Product Packaging; Promotional Materials</u>. Janssen shall develop Product packaging and Promotional Materials, in each case for use in the Janssen Territory; provided that the same shall be subject to review by the JSC with respect to the Major Market Countries as part of the Janssen Territory Commercialization Plan.

5.3.11 Information. Janssen shall keep Legend reasonably informed as to the progress of the Commercialization activities in the Janssen Territory as reasonably determined by the Joint Steering Committee.

#### 5.4 Commercialization in Greater China.

5.4.1 <u>General</u>. The Parties shall Commercialize the Products in the Field in Greater China in accordance with the Greater China Commercialization Plan and the terms of this Section 5.4, subject to the oversight of the JSC as set forth in this Section 5.4.

# 5.4.2 Greater China Commercialization Plan.

(a) [\*\*\*] shall develop and periodically update, and the JSC shall review, a written plan for Commercialization of the Products in the Field in Greater China (the "Greater China Commercialization Plan") as described in this Section 5.4.2.

(b) The Greater China Commercialization Plan shall set forth the overall marketing strategy and

Commercialization strategy (including pricing strategy and execution components), the key Commercialization activities to be performed to implement such strategy and the staffing requirements for each such Commercialization activity. The Greater China Commercialization Plan will be consistent with the Global Commercialization Strategy Plan.

(c) The Greater China Commercialization Plan shall include the Greater China Commercialization Budget, annual Net Trade Sales forecasts for Greater China for [\*\*\*]. The "**Greater China Commercialization Budget**" means the budget for [\*\*\*] to be incurred by the Parties in conducting Commercialization activities for the Products in the Field in Greater China pursuant to the Greater China Commercialization Plan during [\*\*\*]. Each Greater China Commercialization Budget shall include [\*\*\*] covered by such budget. The Greater China Commercialization Budget shall include budgeted amounts for [\*\*\*], for Commercialization activities in Greater China and [\*\*\*] in conjunction with the Finance Working Group.

(d) [\*\*\*] shall develop, and submit to the GCCC for review the initial Greater China Commercialization Plan as soon as practicable after the Effective Date. The GCCC shall review, and submit to the JSC for approval, the initial Greater China Commercialization Plan as soon as practicable after such Plan has been submitted to the GCCC.

-48-

(e) [\*\*\*] shall develop, and submit to the GCCC for review, an annual update to the Greater China Commercialization Plan (including an updated Greater China Commercialization Budget). The GCCC shall submit each such Greater China Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur no later than [\*\*\*]. Upon the JSC's preliminary approval, such plan shall be submitted to each Party [\*\*\*]. After final approval by the JSC, such Greater China Commercialization Plan shall take effect on the first day of the Calendar Year to which such Greater China Commercialization Plan applies.

(f) Either Party may submit other proposed updates and amendments to the Greater China Commercialization Plan to the GCCC at any time. The GCCC shall reasonably consider such proposed updates and amendments, and may also independently develop proposed updates and amendments. Any such proposed updates and amendments that are approved or developed by the GCCC shall be submitted to the JSC for review and approval. Upon such approval by the JSC, the Greater China Commercialization Plan shall be amended accordingly.

5.4.3 Greater China Commercialization Responsibilities.

(a) Each Party shall use Diligent Efforts to perform the Commercialization activities allocated to such Party in the Greater China Commercialization Plan.

(b) The Commercialization of the Initial Product in Greater China shall initially be conducted under [\*\*\*] in connection with establishing and updating the Greater China Commercialization Plan ("[\*\*\*] **Plan**"). [\*\*\*] establish and implement the [\*\*\*] in accordance with the [\*\*\*] Plan. [\*\*\*] shall conduct the [\*\*\*] with [\*\*\*] making day-to-day decisions with respect to the conduct of the registry and [\*\*\*] interacting with hospitals and key opinion leaders consistent with [\*\*\*] shall be responsible for interacting with Regulatory Authorities in Greater China with respect to the [\*\*\*] in accordance with the [\*\*\*] Plan, and [\*\*\*] shall be responsible for interacting with Regulatory Authorities and to review and approve all documentation submitted to or received from any Regulatory Authorities with respect to the [\*\*\*]. [\*\*\*] the selection of all treatment sites included in the [\*\*\*] Plan and the admission of all patients for treatment under the [\*\*\*]. The [\*\*\*] shall continue in effect until [\*\*\*]; provided, however, in any event the [\*\*\*] shall cease on the receipt of Marketing Approval for [\*\*\*] for a Product in the Field in the U.S., to the extent permitted by applicable Law in Greater China. For clarity, so long as the [\*\*\*] is in effect, neither Party would Commercialize the Initial Product in Greater China except in accordance with the [\*\*\*] Plan; provided that the Parties may Commercialize Product in Greater China other than pursuant to the [\*\*\*] in accordance with this Agreement and applicable Law in Greater China if the [\*\*\*] was to be terminated pursuant to the prior sentence but applicable Law in Greater China did not permit the [\*\*\*] to be terminated.

(c) Except as set forth in this Section 5.4, Legend shall be the lead Party responsible for Commercialization of the Products in the Field in Greater China in accordance with Greater China Commercialization Plan, [\*\*\*]. Except as set forth in this Agreement, Legend shall be responsible for conducting all Commercialization activities in the Greater China Commercialization Plan and shall otherwise be allocated responsibility for Commercialization of the Products in the Field in Greater China [\*\*\*]. Without limiting the foregoing, [\*\*\*].

-49-

(d) Notwithstanding the foregoing, Legend shall always be solely responsible for conducting the following Commercialization activities with respect to the Products in the Field in Greater China: (i) obtaining pricing and reimbursement approvals in accordance with the Pricing and Discounting Plan in the Greater China Commercialization Plan, (ii) price calculations and related reporting to Governmental Authorities and (iii) all aspects of order processing, invoicing, collection of sales proceeds, booking of sales, preparation of sales records and reports, customer relations and services and handling of returns.

5.4.4 <u>Greater China Commercialization Reports</u>. At each meeting of the JSC, each Party will provide a high-level report on any Commercialization activities that such Party and its Affiliates have performed in Greater China since the last JSC meeting. Each Party will provide an evaluation of the work it and its Affiliates has performed in relation to the goals of the Greater China Commercialization Plan and provide such other information as may be required by the Greater China Commercialization Plan or reasonably by a Party's representative on the JSC with respect to such Commercialization activities.

5.4.5 <u>Booking Sales in Greater China</u>. Legend and its Affiliates shall book all sales of Products in Greater China and shall be responsible for warehousing and distributing the Products in Greater China, including for purposes of the [\*\*\*]. If Janssen receives any orders for a Product in Greater China, it shall refer such orders to Legend.

5.4.6 <u>Greater China Pricing Matters</u>. [\*\*\*] shall review, align on and approve pricing guidance matters for the Products in the Field in Greater China, including floor/ceiling list price and net selling price and discounting policies (the "**Greater China Pricing and Discounting Plan**"). In the event [\*\*\*]. [\*\*\*] with respect to the prices charged, any discounts and rebates offered or provided, and any other sale and reimbursement terms and conditions for the Products in the Field in Greater China consistent with such guidance and the Greater China Pricing and Discounting Plan.

5.4.7 <u>Greater China Recalls</u>. [\*\*\*] shall decide, in collaboration with [\*\*\*] whether to conduct a recall of the Initial Product in Greater China and the manner in which any such recall shall be conducted. [\*\*\*] considers making such a recall in Greater China, and in any case (to the extent safety considerations permit) [\*\*\*] before initiating such a recall. Notwithstanding anything to the contrary, in the event [\*\*\*]. [\*\*\*] shall determine whether to conduct a recall of a Product [\*\*\*] in Greater China and the manner in which any such recall shall be conducted.

5.4.8 <u>Product Packaging; Promotional Materials</u>. The GCCC shall develop and approve Product packaging and Promotional Materials, in each case for use in Greater China, which shall be consistent with the Greater China Commercialization Plan and compliant with each Party's applicable standard operating procedures, the Greater China Commercialization Plan, and applicable Laws and Marketing Approvals.

5.4.9 <u>Greater China Medical Inquiries</u>. Legend shall handle all medical questions or inquiries from members of the medical profession in Greater China regarding the Products. Janssen shall participate in such activities to the extent provided in the Greater China Commercialization Plan and, in collaboration with Legend, in connection with the conduct of the [\*\*\*].

-50-

5.4.10 <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Commercialization activities with respect to the Products for which it has or otherwise is assigned responsibility under this Agreement or the Greater China Commercialization Plan and shall keep the other Party reasonably informed as to the progress of such activities, as determined by the GCCC.

## 5.5 General Commercialization Provisions.

5.5.1 <u>Diligence</u>. The U.S. Commercialization Plan, Greater China Commercialization Plan and the Janssen Territory Commercialization Plan (including in each case, the associated Commercialization Budgets) shall [\*\*\*].

5.5.2 <u>Delays in Approving Plans and Budgets</u>. In the event the JSC does not approve an updated Commercialization Plan, including the related Commercialization Budget, prior to the start of the next Calendar Year, either Party may initiate procedures to resolve the issue pursuant to Section 2.8, and the then-current Commercialization Plan, together with the budgeted amounts set forth in the applicable Commercialization Budget, shall continue to apply (and if such matter is still not resolved by the end of the period covered by the then-current Commercialization Budget, [\*\*\*].

5.5.3 <u>Commercialization Subcontracting</u>. Each Party (or its Affiliate) may subcontract the performance of any Commercialization activities with respect to the Products undertaken in accordance with Section 4.2.5, provided that the applicable Subcontractors satisfy any subcontractor criteria established by the USCC, GCCC or JSC, as applicable.

# 5.5.4 Commercialization Compliance Matters.

(a) Legend and Janssen shall each ensure that its and its Affiliates' Sales Representatives promote the Product in accordance with applicable Law and applicable promotion policies of each of Janssen and Legend, and do not make any representation, statement, warranty or guaranty with respect to the Product that is not consistent with the applicable, current package insert of prescribing information or other documentation accompanying or describing a Product, including mutually approved limited warranty and disclaimers, if any, unless otherwise approved by the compliance committees or compliance departments of each Party (e.g., to the extent applicable Law, or changes in applicable Law, permit statements beyond the package insert). Legend and Janssen shall each ensure that its and its Affiliates' Sales Representatives do not make any statements, claims or undertakings to any person with whom they discuss or promote the Products that are not consistent with, nor provide or use any labeling, literature or other materials other than those Promotional Materials currently approved for use for relevant country under this Agreement, unless otherwise approved by the compliance committees or compliance departments of each Party. If at any time the use of specified Promotional Materials is no longer approved under this Agreement for such country, each Party shall immediately take action to remove the Promotional Materials from use by its and its Affiliates' Sales Representatives in such country and destroy such materials.

-51-

(b) Legend and Janssen shall each cause its and its Affiliates' Sales Representatives to comply with applicable Laws and guidelines related to the performance of its obligations hereunder, including Health Care Laws, Drug Regulation Laws, the Federal and State Anti-Kickback Statutes and all applicable regulations thereunder, the AMA and PhRMA Guidelines, and all relevant EMA regulations, authorizations and local laws regarding advertisement, sale and promotion of pharmaceutical products as well as any relevant code of practice. It is understood that in the case of any guidelines or codes of practice that are not legally mandated, the same shall be deemed to apply to a particular country only to the extent generally practiced by pharmaceutical companies in such country unless otherwise required by the compliance committee or compliance department of either Party.

(c) In the event this Agreement requires a Party to comply with the policies or guidelines of the other Party and such Party cannot comply with both such policies or guidelines and applicable Law due to a conflict between the two, the applicable Law shall control and such Party shall not be obligated to so comply with such policy or guidelines to the extent of such conflict.

5.5.5 <u>Parallel Imports</u>. Neither Party nor its Affiliates, Licensees or Sublicensees or Third Party distributors shall knowingly take any action (or enable a Third Party to take any action) to export a Product from Greater China into the U.S. or Janssen Territory (or to solicit or offer incentives to patients in Greater China to obtain treatment with a Product in the U.S. or Janssen Territory), or from the U.S. or Janssen Territory into Greater China (or to solicit or offer incentives to patients in the U.S. or Janssen Territory to obtain treatment with a Product in Greater China).

5.5.6 <u>Sharing of Commercial Information</u>. The Parties and their Affiliates will actively collaborate as set forth in this Agreement in the Commercialization of the Products in the Field. In the event the Committees are disbanded in accordance with Section 2.10, Product-related information and Product-related Know-How supporting such Commercialization shall be exchanged between the Parties to the same extent that such information and Know-How was shared through the USCC, JSC or GCCC, as applicable.

### ARTICLE VI MANUFACTURE AND SUPPLY

### 6.1 Overview.

6.1.1 <u>China</u>. Legend shall be responsible for the manufacture and supply of Product for clinical and commercial use in Greater China under the direction of the JMC and in accordance with a Manufacturing Plan approved by the JSC, all as described further below.

6.1.2 U.S. and Janssen Territories. [\*\*\*] for supply of Product for the initial Phase 1 Clinical Study conducted in the United States under the GDP for the U.S. and Janssen Territory (the "**Initial Phase I Study**"), [\*\*\*]. [\*\*\*] (defined below) will serve as [\*\*\*] for Product for use in the Initial Phase I Study [\*\*\*] for such Initial Phase I Study. [\*\*\*] will be responsible for manufacture of all other clinical supplies of the Product for use under the GDP (a) in the United States through clearance of the pre-approval inspection of [\*\*\*] (defined below) in connection with the first Marketing Approval of the Initial Product in the U.S., and (b) in the Janssen Territory through clearance of the pre-approval inspection of [\*\*\*] (defined below) in connection of [\*\*\*] (defined below) in connection with the first Marketing Approval of the Initial Product for a [\*\*\*] responsibility for manufacture and supply of Product for clinical and commercial use in the U.S. and Janssen Territory, respectively, all as further described below.

-52-

# 6.1.3 Plans and Budgets.

(a) <u>CMC Development Plan</u>. CMC Development activities in connection with the GDP worldwide will be conducted in accordance with a plan and budget for such activities established by the JMC (the "**CMC Development Plan**"). The CMC Development Plan shall outline in reasonable detail the CMC Development activities to be conducted and the allocation of responsibilities between the Parties for such activities, and shall include a budget for the FTE Costs and Out-of-Pocket Costs of such activities (collectively, the "**CMC Development Costs**") [\*\*\*]. Each Party shall use Diligent Efforts to conduct in accordance with the CMC Development Plan all CMC Development activities assigned to it in accordance with such plan. [\*\*\*] CMC Development Costs shall be shared and reconciled in the same manner and at the same time as Development Costs (i.e., in the same manner as provided under Section 7.3 above).

(b) <u>Manufacturing Plan</u>. The establishment of all facilities for the Manufacture of Product [\*\*\*] and the Manufacture of Product in connection with the GDP and for commercial sale worldwide shall be conducted in accordance with a plan and budget established by the JMC (the "**Manufacturing Plan**"). The Manufacturing Plan shall (i) outline in reasonable detail the activities to be so conducted, (ii) reflect and be consistent with the provisions of this ARTICLE VI (and the other applicable terms of this Agreement), (iii) include such other matters as the JMC determines appropriate for the establishment and operation of such facilities and the Manufacture and supply of Product in the United States, the Janssen Territory and Greater China, including the site selection (as determined in accordance with this ARTICLE VI) and design of such facilities and (iv) include a budget for the FTE Costs, Out-of-Pocket Costs and Third Party Expenditures (collectively, the "**Manufacturing Plan Costs**") [\*\*\*]. Each Party shall use Diligent Efforts to conduct in accordance with the then-current Manufacturing Plan all activities assigned to it in accordance with such Plan. The Manufacturing Plan Costs incurred by the Parties; and (b) with respect to Greater China shall be shared as follows: seventy percent (70%) shall be borne by Legend and thirty percent (30%) shall be borne by Janssen. Such Manufacturing Plan Costs shall be shared and reconciled in the same manner and at the same time as Development Costs (i.e., in the same manner as provided under Section 7.3 above).

(c) <u>Initial Plans; Updates and Changes</u>. Promptly following the Effective Date, the JMC shall prepare and provide to the JSC for its review and approval an initial CMC Development Plan and an initial Manufacturing Plan. The initial CMC Development Plan shall be consistent with the CMC Development and Manufacturing roles and responsibilities chart attached hereto as <u>Schedule 6.1.3A</u>. The initial Manufacturing Plan shall be consistent with the CMC Development and Manufacturing roles and responsibilities chart attached hereto as <u>Schedule 6.1.3A</u> and shall include the initial site selection, design plan and budget for the China Manufacturing Facilities attached hereto as <u>Schedule 6.1.3B</u>. Thereafter, the JMC shall provide to the JSC at least annually for its review and approval an updated version

-53-

of the CMC Development Plan and the Manufacturing Plan. The JMC shall submit such annual updates to the JSC for review and approval on a timeline, such that JSC preliminary approval would occur no later than [\*\*\*]. Upon the JSC's preliminary approval, such updates shall be submitted to each Party for [\*\*\*], at which time any updates shall be appended to the CMC Development Plan and the Manufacturing Plan, as applicable. [\*\*\*] In addition to such annual updates to the CMC Development Plan and the Manufacturing Plan, the JMC shall consider from time to time such other modifications or amendments thereto as either Party may request, with any disagreements regarding any such proposed modification or amendments similarly being deemed a Committee Matter to be resolved in accordance with Section 2.8 above.

(d) <u>Supply Costs</u>. [\*\*\*] As further described below in Section 6.2 and 6.3, the Clinical Supply Costs incurred in accordance with the GDP for clinical supplies of Product used in activities under the GDP shall be included in Development Costs, and the Commercial Supply Costs (as defined below) incurred in accordance with the applicable Commercialization Plan (and the applicable Supply Agreement) for commercial supplies of Product for distribution in the U.S., Janssen Territory and Greater China shall be included in Allowable Expenses.

(e) Certain Definitions. For purposes of this Agreement:

# (i) "Clinical Supply Costs" means [\*\*\*].

(ii) "Third Party Expenditures" means [\*\*\*].

6.1.4 <u>Global Product Specifications and CQAs</u>. The JMC shall develop and approve global Product specifications (the "**Global Product Specifications**") and global critical quality attributes (the "**Global CQAs**") for each Product [\*\*\*] as further described on <u>Schedule 6.1.4</u>. The Global Product Specifications and Global CQAs shall apply to all Product Manufactured for human use in the U.S., Janssen Territory and/or Greater China. For clarity, the Global Product Specifications and Global CQAs shall be directed to characteristics of the Product, and not the process by which the Product is made (and, for clarity, will not require the use of automated processes). [\*\*\*].

# 6.2 Supply for U.S. and Janssen Territories.

### 6.2.1 Phase 1 Supply.

(a) [\*\*\*]. [\*\*\*] have primary responsibility for supply of Product for the Initial Phase I Study through [\*\*\*]; provided that, following the Effective Date, [\*\*\*] shall use Diligent Efforts promptly to amend [\*\*\*], and in any case to enter into a related Quality Agreement with [\*\*\*], in each case so that [\*\*\*] may obtain its requirements of Product (or material for use in Manufacturing the Initial Product) for the Initial Phase 1 Study directly from [\*\*\*]. In connection with such amendment of the [\*\*\*] shall enter into a separate agreement containing reasonable provisions to preserve [\*\*\*] outside of the Initial Product and to otherwise coordinate [\*\*\*] with respect to the Initial Product. [\*\*\*] shall be responsible for the final release of Product Manufactured by [\*\*\*] testing of such Product (i.e., [\*\*\*] shall review such test results and approve such Product for release based on such results). The Clinical Supply Costs incurred by [\*\*\*] in connection with the acquisition of clinical supplies of the Initial Product for the Initial Phase I Study from [\*\*\*] as Development Costs in accordance with the GDP.

-54-

(b) [\*\*\*]. [\*\*\*] for Product for use in the Initial Phase I Study [\*\*\*] for the Initial Phase I Study. [\*\*\*] shall be responsible for supplying the Product for such purposes on an "as needed" basis from [\*\*\*] to Manufacture the Product at [\*\*\*]. The costs associated with the [\*\*\*] shall be borne by [\*\*\*] to Manufacture clinical supplies of the Initial Product for use in the Initial Phase I Study shall be [\*\*\*] as Development Costs in accordance with the GDP.

(c) <u>Cell Collection</u>. [\*\*\*] shall be responsible for collecting cells from patients at the clinical site(s) for the Initial Phase I Study, storing them and shipping them to [\*\*\*] Clinical Supply Cost incurred in the collection, testing and shipping of the unprocessed cells from a patient to [\*\*\*] as Development Costs in accordance with the GDP.

6.2.2 Other Clinical Supply prior to [\*\*\*].

(a) <u>General</u>. [\*\*\*] will be responsible for supply of Product for all Development activities under the GDP in the United States and the Janssen Territory beyond the Initial Phase I Study (including the Registration Study for the Initial Product) [\*\*\*].

(b) Establishment of Manufacturing Facilities in [\*\*\*].

(i) [\*\*\*] shall establish in accordance with the Manufacturing Plan [\*\*\*] for Products in the U.S. and the Janssen Territory, [\*\*\*].

(ii) The [\*\*\*] will be a facility that [\*\*\*] unless the Parties mutually agree that using a [\*\*\*] would reasonably be expected to delay the projected launch of the Initial Product in the U.S. (which as of the Effective Date is expected to be in the [\*\*\*] shall initially be [\*\*\*]. In such event, [\*\*\*] the Manufacturing Plan. If the Parties use [\*\*\*] the Parties will use Diligent Efforts to [\*\*\*].

(iii) [\*\*\*] shall be established in [\*\*\*] which may be a site [\*\*\*].

(iv) The JMC shall review and approve [\*\*\*] of the Initial Product.

(v) The Manufacturing Plan shall provide for [\*\*\*] the Products. The FTE Costs, Out-of-Pocket Costs and Third Party Expenditures of [\*\*\*] incurred in accordance with the Manufacturing Plan shall be Manufacturing Plan Costs for the U.S. or Janssen Territory, respectively, and [\*\*\*] as described above in Section 6.1.3(c). [\*\*\*].

(vi) [\*\*\*] in accordance with the Manufacturing Plan; however following commencement of operations at each such Facility, [\*\*\*] at such Facility, with the [\*\*\*], and a reasonable schedule for [\*\*\*] specified in the Manufacturing Plan. [\*\*\*] responsibility for management of the Facility (under the oversight of the JMC and in accordance with the Manufacturing Plan), but [\*\*\*] in the Manufacture of the Product and the operation and management of such Facility.

-55-

(vii) [\*\*\*] will be operated pursuant to an agreement as follows:

(1) If the Facility is [\*\*\*] after the Effective Date, the Parties shall negotiate and enter into an agreement with respect to [\*\*\*], as described further below, to commence on the [\*\*\*] (as defined in Section 6.2.3(a)) for the [\*\*\*], to commence on the [\*\*\*] (as defined in Section 6.2.3(a)) for the [\*\*\*], to commence on the [\*\*\*] (as defined in Section 6.2.3(a)) for the [\*\*\*]. Each such agreement is referred to herein as a "Facilities Use Agreement". The Facilities Use Agreement for the [\*\*\*] shall (i) contain the key terms set forth in <u>Schedule 6.2.2B</u> and such other terms and conditions as are reasonable or customary under the circumstances and (ii) [\*\*\*], depending on which type of agreement is most appropriate in light of the terms of the agreement described in clause (i) and the arrangement between the Parties as contemplated under this ARTICLE VI. The Facilities Use Agreement for the [\*\*\*] shall (i) contain terms similar to the key terms set forth in <u>Schedule 6.2.2B</u>, if such [\*\*\*], and such other terms and conditions as are reasonable or customary under the circumstances. and (ii) [\*\*\*], depending on which type of agreement is most appropriate in light of the terms of the agreement described under this ARTICLE VI. As with [\*\*\*] of each Facility, each Facilities Use Agreement shall provide for [\*\*\*] to Manufacture the Products. In the event the Parties are unable to reach agreement regarding any material terms of a Facilities Use Agreement, such matter shall be [\*\*\*], except to the extent otherwise provided in the Facilities Use Agreement.

(2) If the Facility is [\*\*\*]. In such event, the Parties shall determine each Party's responsibilities with respect to [\*\*\*] of the Agreement.

(c) <u>Key Terms of Manufacturing Operations</u>. The Manufacturing Plan will include operational aspects of Manufacturing the Product in the [\*\*\*] and shall include the following key operating parameters (together with such other parameters as the JMC determines) with respect to the clinical supplies of Products Manufactured by [\*\*\*]:

(i) [\*\*\*] shall be responsible for all required cell collection from patients;

(ii) [\*\*\*] for all Registration Trials (and, as further described in Section 6.2.3 below, for all commercial supply of Product for the U.S. and Janssen Territory);

(iii) The chain-of-identity of the entire process from [\*\*\*];

(iv) All Products produced in such Facilities shall comply with the Global Product Specifications and Global Critical Quality Attributes;

-56-

(v) All [\*\*\*] facilities and manufacturing operations will comply with [\*\*\*];

(vi) If [\*\*\*] fails or is not able to consistently deliver GMP supplies, then [\*\*\*] shall have the right to direct remediation, including site correction plans or other manufacturing facilities, and [\*\*\*] shall use Diligent Efforts to implement such remedial measures as [\*\*\*].

(d) <u>Supply Costs prior to [\*\*\*</u>]. For clarity, it is understood that the Clinical Supply Costs incurred by Janssen in connection with the Manufacture of clinical supplies of Product for use in activities under the GDP for the U.S. and Janssen Territory shall be shared as Development Costs.

6.2.3 <u>Commercial Supply and Clinical Supply after [\*\*\*]. [\*\*\*]</u> shall be responsible for the Manufacture and supply of Product for commercial use in the U.S. and Janssen Territory (and for use in all further Development in the U.S. and Janssen Territory following [\*\*\*] in accordance with Section 6.2.3(b) below), with such Manufacturing being carried out at the applicable Facility, as further described in this Section 6.2.3.

(a) <u>Timing of [\*\*\*]</u> <u>Manufacturing Facilities</u>. Following [\*\*\*] of the Initial Product in the U.S., [\*\*\*]. Similarly, upon [\*\*\*] of the Initial Product in [\*\*\*]. The date that [\*\*\*] in accordance with this Section 6.2.3(a) shall be the "[\*\*\*]" with respect to such Facility.

(b) <u>Manufacturing Responsibilities following [\*\*\*</u>]. Following the [\*\*\*] shall be responsible for the Manufacture and supply of [\*\*\*] to be supplied from the applicable Facility (and for use in all further Development in such territory), all as further described below and in accordance with the Manufacturing Plan (or GDP) and the Product Supply Agreement. [\*\*\*] shall be responsible for the Manufacture and supply of [\*\*\*] to be supplied from the applicable Facility (and for use in all further Development in such territory). [\*\*\*] shall also be responsible for [\*\*\*] to be supplied from the applicable Facility (and for use in all further Development in such territory). [\*\*\*] will invoice [\*\*\*] for the FTE Costs of any personnel supporting the applicable Facility in accordance with Section 6.2.3(b) and the Manufacturing Plan following the [\*\*\*], and such FTE Costs, together with the FTE Costs of any [\*\*\*] the applicable Facility shall be included in the Commercial Supply Costs (or Clinical Supply Costs, as applicable), and otherwise shared as Allowable Expenses or Development Costs.

(c) <u>Product Supply Agreements for [\*\*\*].</u> [\*\*\*] contract manufacturing organization ("**CMO**") with respect to Manufacture and supply of Product for clinical and commercial use in the territory to be supplied from each Facility, in accordance with a supply agreement and related quality agreement (respectively, the "**Product Supply Agreement**" and "**Product Quality Agreement**") for such Facility to be negotiated in good faith and entered into [\*\*\*] such Facility. In the event that [\*\*\*] execute a Product Supply Agreement and related Product Quality Agreement for such Facility by such date, then the terms of such Agreement(s) shall be [\*\*\*]. Unless [\*\*\*] the Product Supply Agreement for each Facility will include customary terms and conditions for the supply of cell therapy products, including ordering and forecasting provisions, as well as the following terms set forth below in this Section 6.2.3(d), to the extent consistent with this ARTICLE VI. If determined necessary [\*\*\*] will execute a separate Product Supply Agreement and Product Quality Agreement for clinical supplies of Products.

-57-

# (i) Terms Applicable to Personnel at the Facility.

(1) As of the [\*\*\*], the personnel working at the Facility will be [\*\*\*] as further described in Section 6.2.2(b)(iv). Following the [\*\*\*] shall have the right to [\*\*\*], provided that (x) [\*\*\*] shall not have the right to [\*\*\*] at the Facility and (y) the [\*\*\*] at the Facility (which, unless otherwise mutually agreed, shall be as soon as reasonably practicable).

(2) [\*\*\*].

(3) The Product Supply Agreement shall include [\*\*\*] at the Facility.

(4) Unless otherwise [\*\*\*] shall be employees or contractors of [\*\*\*] or an Affiliate of [\*\*\*] shall be employees or contractors of [\*\*\*] or an Affiliate of [\*\*\*].

(ii) Terms Applicable to Supply of Product.

(1) [\*\*\*] will Manufacture at the Facility, and supply to [\*\*\*] of Products for commercial and clinical use in the territory to be supplied from the Facility. [\*\*\*] will purchase such commercial supplies of Product at a supply price [\*\*\*] (the "**Commercial Supply Costs**"), and [\*\*\*] will purchase such clinical supplies of Product at a supply price [\*\*\*] Clinical Supply Costs.

(2) In its Manufacture of the Products for the US and Janssen Territory, [\*\*\*].

(3) [\*\*\*] will be responsible for manufacturing release of Product from [\*\*\*].

(4) All Product Manufactured and supplied to [\*\*\*] shall comply with the Global Product Specifications and Global CQAs.

(5) [\*\*\*] shall store all Product at the applicable Facility. The Product will be delivered to the [\*\*\*].

(6) If [\*\*\*] fails or is not able to consistently deliver GMP supplies, then [\*\*\*] shall have the right to direct remediation, including but not limited to site correction plans or other manufacturing facilities, and [\*\*\*] shall use Diligent Efforts to implement such remedial measures as [\*\*\*].

-58-

(iii) Terms Applicable to Facility and Manufacturing Process.

(1) The chain-of-identity of the entire Product Manufacturing process, [\*\*\*], shall be GMP/GTP controlled to ensure the Product's identity and product traceability.

(2) The Facility and all Manufacturing operations in the Facility will comply with [\*\*\*]. For clarity, as used herein, references to [\*\*\*].

(iv) *Terms Applicable to Other Products*. In addition to production of Products for supply to [\*\*\*], the Facility shall be available for production of other [\*\*\*] products [\*\*\*] that are being Developed or Commercialized by a Party in accordance with Section 4.10], subject to the following, all as determined by [\*\*\*]:

(1) there is available capacity to manufacture such products in addition to [\*\*\*] of Products for clinical and commercial use;

(2) such other products can be manufactured within the Facility using (A) [\*\*\*] and (B) [\*\*\*] other products supplies at [\*\*\*] and can be added or deployed without (i) impairing the ability of the Facility to supply all requirements of the Products, (ii) if such Facility is [\*\*\*] or (iii) [\*\*\*] the Facility;

(3) the manufacture of such other products in the Facility does not (and is not reasonably expected to) negatively impact [\*\*\*] of Products or create a [\*\*\*] of the Products or any other products that are being made on the same premises as the Facility [\*\*\*];

(4) [\*\*\*] whose other product is being made in the Facility bears the applicable Commercial Supply Costs or Clinical Supply Costs of such other product (*mutatis mutandis*, and where references in these definitions to Products will be read to refer to such other product) and a [\*\*\*] to such other products;

(5) [\*\*\*] may Manufacture at the Facility, or [\*\*\*] the Facility to Manufacture, any products [\*\*\*]; provided that, for clarity, the Manufacture of a product that (A) was Developed in whole or in part by a Party and (B) is being Manufactured for supply to [\*\*\*].

(6) [\*\*\*] of other appropriate terms and conditions for the manufacture and supply of such other [\*\*\*] product.

(d) <u>Unprocessed Cells Supply Agreements for [\*\*\*]. [\*\*\*]</u> will collect cells from patients who will be administered Product and deliver such cells to [\*\*\*] to be used in the Manufacture of Product for clinical and commercial use in the territory to be supplied from each Facility, in accordance with an Unprocessed Cells Supply Agreement and related

-59-

Unprocessed Cells Quality Agreement to be [\*\*\*] such Facility. In the event that the Parties do not execute an Unprocessed Cells Supply Agreement and related Unprocessed Cells Quality Agreement for such Facility by such date, then the terms of such Agreement(s) shall be [\*\*\*]. Unless the Parties agree otherwise, the Unprocessed Cells Supply Agreement for each Facility will include customary terms and conditions for the collection and delivery of patient cells, as well as the following terms:

(i) [\*\*\*] will collect, ship and deliver to the Facility, and [\*\*\*] incurred in accordance with the Manufacturing Plan in the collection, testing and shipping of the unprocessed cells from a patient to the Facility [\*\*\*] (the "**Unprocessed Cells Supply Price**"), patient cells necessary to Manufacture [\*\*\*] of Products for clinical and commercial use in the territory to be supplied from the Facility; and

(ii) the chain-of-identity of the entire Product Manufacturing process, [\*\*\*], shall be GMP/GTP controlled to ensure the Product's identity and product traceability.

(e) [\*\*\*] Supply Agreements for [\*\*\*]. [\*\*\*] will be responsible for the Manufacture and supply, either internally or through an Affiliate or Third Party in accordance with the Manufacturing Plan, [\*\*\*] of Product for clinical and commercial use in the territory to be supplied from each Facility, in accordance with a [\*\*\*] of such Facility. In the event that the Parties do not execute a [\*\*\*] for such Facility by such date, then the terms of such Agreement(s) shall be determined by [\*\*\*]. Unless otherwise agreed by the Parties, the [\*\*\*] Facility will include will include customary terms and conditions, including ordering and forecasting provisions. Under the [\*\*\*] will be responsible for the Manufacture and supply, either internally or through an Affiliate or Third Party, of [\*\*\*] of Products for clinical and commercial use in the territory to be supplied from the Facility.

(f) <u>Supply Costs after [\*\*\*</u>]. The Commercial Supply Costs or Clinical Supply Costs of Product Manufactured and supplied [\*\*\*] under the Product Supply Agreement shall be [\*\*\*], as the case may be. The Finance Working Group will, in good faith, make any changes to this calculation on an as needed basis to ensure that any mark-up on the supply of Products or materials included in the Commercial Supply Costs or Clinical Supply Costs of Product Manufactured and supplied [\*\*\*] under the Product Supply Agreement shall be [\*\*\*], such changes to be made in connection with the reconciliation of Development Costs and Pre-Tax Profit or Loss as further described in Sections 7.3 (with respect to Development Costs) and 7.4.1, 7.4.3 and 7.4.5 (with respect to Pre-Tax Profit or Loss) below. Any [\*\*\*] under a Facilities Use Agreement shall [\*\*\*] under the Product Supply Agreement or such payments are [\*\*\*].

(g) If the [\*\*\*] of the applicable Facilities Use Agreement, [\*\*\*] of such applicable Facilities Use Agreement. If [\*\*\*] of such applicable Facilities Use Agreement, such matter shall be subject to [\*\*\*]; <u>provided</u>, <u>however</u>, that the [\*\*\*] of the Facilities Use Agreement without [\*\*\*] consent. If [\*\*\*], then the applicable Facilities Use Agreement shall be amended to reflect [\*\*\*]. If [\*\*\*] the Manufacture of the Products to [\*\*\*] of the applicable Facilities Use Agreement.

-60-

6.2.4 <u>Rights on Termination of this Agreement</u>. In the event of a termination of this Agreement by [\*\*\*] or a termination of this Agreement by [\*\*\*], then the following terms of this Section 6.2.4 shall apply.

(a) <u>Term of Facilities Use Agreement</u>. Upon request by [\*\*\*], if the term of the Facilities Use Agreement has not yet commenced on or before the effective date of termination, then it shall commence as of the effective date of such termination. The term of the Facilities Use Agreement shall be automatically modified to expire, unless earlier terminated by [\*\*\*] in accordance with the terms of the Facilities Use Agreement, on [\*\*\*] of the effective date of termination of this Agreement unless extended in accordance with Section 6.2.4(b)(i) (the "**Modified Facility Expiration Date**"). Notwithstanding the foregoing, if [\*\*\*] not to extend the term of the Facilities Use Agreement under Section 6.2.3(g), then the Modified Facility Expiration Date shall [\*\*\*] of the applicable Facilities Lease Agreement, unless extended in accordance with Section 6.2.4(b)(i) below.

(b) Technology Transfer to Alternate Facility.

(i) If [\*\*\*], then following the effective date of termination of this Agreement, [\*\*\*] shall use Diligent Efforts to undertake a technology transfer of the Manufacture of the Initial Product (and any other Products) from each Facility to an alternate facility, including selecting an alternate facility for each Facility, establishing a Product Manufacturing process at such alternate facility and obtaining all Regulatory Approvals necessary to manufacture such Products at such alternate facility, in accordance with this Section 6.2.4(b). [\*\*\*] shall commence such undertaking as soon as reasonably practicable after the effective date of termination of this Agreement. [\*\*\*] shall use Diligent Efforts to complete a Successful Technology Transfer of the Manufacture of the Initial Product [\*\*\*] to an alternate facility within [\*\*\*] from the effective date of termination of this Agreement, to the extent such Successful Technology Transfer can reasonably be completed without causing [\*\*\*]. The Modified Facility Expiration Date shall be [\*\*\*] of the effective date of termination of this Agreement in the event that either: (x) notwithstanding [\*\*\*] of Diligent Efforts to complete a technology transfer of the Manufacture of such Products to an alternate facility, a Successful Technology Transfer is not completed by the end of the then-current term or (y) a Successful Technology Transfer could not completed by the end of the transfer (to the extent provided above). For clarity, the Modified Facility Expiration Date shall [\*\*\*] has continued to use Diligent Efforts to effect the transfer (to the extent provided above). For clarity, the Modified Facility Expiration Date shall [\*\*\*] of the effective date of termination of this Agreement. For purposes of this Agreement, a "Successful Technology Transfer" means that [\*\*\*] to manufacture the Initial Product [\*\*\*] alternate facility.

(ii) Upon [\*\*\*] shall provide consultation and use Diligent Efforts to provide assistance to [\*\*\*] in connection with the technology transfer until the completion of a Successful Technology Transfer in accordance with the transition plan established by [\*\*\*].

-61-

(c) <u>Allocation of Designated Equipment</u>. Following the effective date of termination of this Agreement, [\*\*\*] Designated Equipment utilized for the applicable Facility and to [\*\*\*]. For clarity the Designated Equipment to be [\*\*\*] at such Facility. In the event that [\*\*\*] of the Designated Equipment, then [\*\*\*] Designated Equipment and, if [\*\*\*] of the Designated Equipment, [\*\*\*] such Designated Equipment that is [\*\*\*] of the Designated Equipment for an amount [\*\*\*] of such Designated Equipment [\*\*\*] as of the effective date of termination of this Agreement). If any Designated Equipment [\*\*\*] under this Section 6.2.4(c), [\*\*\*] Designated Equipment to [\*\*\*], in which case, (i) if [\*\*\*] of the Designated Equipment, then the [\*\*\*], (ii) if [\*\*\*] of the Designated Equipment, then [\*\*\*] of the Designated Equipment. In the event that Designated Equipment was treated as [\*\*\*], the Finance Working Group will determine [\*\*\*].

(d) <u>Reimbursement of [\*\*\*]</u>. In the event this Agreement is terminated [\*\*\*]:

(i) if [\*\*\*] of the FTE Costs, Out-of-Pocket Costs and Third Party Expenditures [\*\*\*] incurred by the Parties with respect to the [\*\*\*] of such Facility (provided, however, that if there is any Excess Amount under Section 7.3.5 that has not yet been recouped by [\*\*\*] such Excess Amount);

[\*\*\*].

(ii) if [\*\*\*] Manufacturing Products at such Facility following termination of the Agreement, then [\*\*\*] of such Facility

(e) <u>Operation of Facility after Termination</u>. Following the effective date of termination of this Agreement with respect to the territory in which a Facility is located, [\*\*\*] shall have the right to [\*\*\*] such Facility and to [\*\*\*] at such Facility as promptly as practicable, in accordance with a transition plan established by the JMC. Notwithstanding the foregoing, if any [\*\*\*] such Facility as of the effective date of termination of this Agreement, [\*\*\*] shall continue to have the right to continue to [\*\*\*] in the Facility [\*\*\*] in accordance with such transition plan until the Modified Facility Termination Date; provided that [\*\*\*] shall continue to be responsible for the costs associated with the Manufacture of [\*\*\*] in the Facility to the extent provided in Section 6.2.3(c)(iv)(4).

(f) <u>Costs Incurred after Termination</u>. Following the effective date of termination of this Agreement, [\*\*\*] for all FTE Costs and Out-of-Pocket Costs incurred by [\*\*\*]; provided, however, that [\*\*\*] any such FTE Costs incurred in providing technology transfer assistance pursuant to Section 6.2.4(b)(ii) during period [\*\*\*].

(g) <u>Termination Prior to [\*\*\*]</u>. If the effective date of termination of this Agreement occurs prior to the [\*\*\*] with respect to a Facility, then in addition to the terms set forth above in Sections 6.2.4(a) through 6.2.4(e), the following shall apply:

(i) [\*\*\*] the Facility according to the then-current Manufacturing Plan in effect on the date of notice of termination (as the same may be modified thereafter by [\*\*\*] the Manufacturing Plan Costs associated with [\*\*\*] for such Facility;

(ii) [\*\*\*] shall be responsible for [\*\*\*] for such Facility following the effective date of termination of this Agreement (and, for clarity, [\*\*\*]); and

-62-

(iii) If [\*\*\*] are being Manufactured in the Facility as of the effective date of termination of this Agreement, [\*\*\*], to the same extent provided in Section 6.2.3(c)(i).

(h) <u>Termination for Cause</u>. In the event of a termination of this Agreement under Section 12.2 of this Agreement, [\*\*\*].

(i) <u>Transition</u>. In the event of any termination of this Agreement, the Parties shall cooperate fully to effect a smooth and orderly transition of the applicable Facility consistent with the foregoing provisions of this Section 6.2.4.

(j) <u>Supply Agreements</u>. The terms of the Product Supply Agreement[\*\*\*] shall be consistent with the foregoing terms of this

# Section 6.2.4.

#### 6.3 Greater China

6.3.1 Establishment of Manufacturing Facilities in Greater China.

(a) <u>China Manufacturing Facilities</u>. [\*\*\*] the manufacturing facilities to be used for supply of Products for Development and Commercialization in Greater China, including the clinical manufacturing facility that [\*\*\*] as of the Effective Date (the "**China Manufacturing Facilities**") in accordance with the Manufacturing Plan, and subject to [\*\*\*] in accordance with Section 6.3.4 below, [\*\*\*], as further described below. Following the Effective Date, [\*\*\*] shall have the right to conduct a reasonable and customary audit of the clinical manufacturing facility that [\*\*\*] as of the Effective Date. The Parties acknowledge that the design of the China Manufacturing Facilities may [\*\*\*], provided that the Products Manufactured by Legend in the China Manufacturing Facilities for human use shall comply with the applicable Global Product Specifications and Global CQAs, except to the extent that such compliance would require automation of the Product Manufacturing process for Greater China.

(b) <u>Construction</u>. The construction and equipping of each China Manufacturing Facility shall be carried out in accordance with a plan and budget [\*\*\*] in the Manufacturing Plan. [\*\*\*] construction plans for the China Manufacturing Facilities, [\*\*\*] of the construction of such facilities and shall [\*\*\*] such facilities when ready for clinical and commercial Manufacturing of Products.

(c) <u>Costs</u>. The FTE Costs, Out-of-Pocket Costs and Third Party Expenditures incurred by [\*\*\*] the Effective Date in the construction and equipping the China Manufacturing Facilities shall, to the extent incurred in accordance with the Manufacturing Plan and to the extent related to the Manufacture of the Products, be Manufacturing Plan Costs for Greater China and [\*\*\*] as described above in Section 6.1.3(c). Each such item of equipment for which [\*\*\*] ("**Designated China Equipment**") shall be [\*\*\*] the equipment for the [\*\*\*] and subject to the applicable terms of this Agreement, provided that [\*\*\*] of the Designated China Equipment.

6.3.2 Supply of Product from China Manufacturing Facilities.

-63-

(a) <u>General</u>. [\*\*\*] will be responsible for supply of Product for all Greater-China Specific Development Activities in the GDP, and for supply of Product for commercial distribution in Greater China.

(b) <u>Key Terms of Manufacturing Operations</u>. The Manufacturing Plan will include operational aspects of Manufacturing the Product in the China Manufacturing Facilities, and [\*\*\*] will operate the China Manufacturing Facilities in accordance with the Manufacturing Plan and the following key operating parameters (together with such other parameters as the JMC determines) with respect to the clinical and commercial supplies of Products Manufactured by [\*\*\*]:

(i) [\*\*\*] shall be responsible for all required cell collection from patients;

(ii) [\*\*\*] for use in the Manufacture of clinical and commercial supplies of Product for Greater China;

(iii) the China Manufacturing Facilities and Manufacturing operations in Greater China shall comply with [\*\*\*] for Greater China, and all Product Manufactured by [\*\*\*] in such China Manufacturing Facilities for human use shall comply with the Global Product Specifications and Global CQAs, and shall comply with [\*\*\*] for Greater China;

(iv) [\*\*\*] shall have the right to monitor the operation of the China Manufacturing Facilities with respect to the Products, by means of customary audits, person-in-the-plant provisions and other customary oversight provisions, which will be set forth in detail in the China Product Quality Agreement;

(v) the chain-of-identity of the entire Manufacturing process of Products for human use, [\*\*\*], shall be GMP/GTP controlled to ensure the Product's identity and traceability, to the extent required under [\*\*\*];

(vi) [\*\*\*] Products from collection of patient samples through Manufacturing to administration to patients as part of the China Product Quality Agreement; and

(vii) if [\*\*\*] fails or is not able to consistently deliver GMP supplies of Products, then [\*\*\*] shall have the right to direct remediation, including site correction plans or other manufacturing facilities.

(c) <u>Product Release</u>. With respect to Initial Product (i) to be supplied to [\*\*\*] for use in Clinical Studies in Greater China for which [\*\*\*] is the conducting Party, (ii) to be used in the [\*\*\*] or (ii) to be supplied to [\*\*\*] (as described in Section 6.3.3 below), [\*\*\*] shall be responsible for the final release of such Product based on [\*\*\*] of the Product (i.e., [\*\*\*] shall review such test results and approve the Initial Product for release based on such results). In all other cases [\*\*\*] shall be responsible for the release of Product produced in the China Manufacturing Facilities.

-64-

6.3.3 <u>Supply for [\*\*\*]</u>. The Parties recognize that there may be advantages to [\*\*\*] China Manufacturing Facilities. Accordingly, if [\*\*\*] China Manufacturing Facilities would be advantageous in [\*\*\*] involvement in the logistics of distribution and supply of Product in [\*\*\*]. In the event that the Parties reach agreement regarding the supply of Product for commercialization in [\*\*\*], such agreement shall be memorialized in a supply agreement and supplemental quality agreement.

6.3.4 <u>China Product Supply Agreement</u>. Within [\*\*\*] following the Effective Date, [\*\*\*] shall negotiate in good faith and enter into a supply agreement and related quality agreement governing [\*\*\*] the China Manufacturing Facilities for [\*\*\*] in Greater China in accordance with the GDP (respectively, the "**China Product Supply Agreement**" and "**China Product Quality Agreement**"). In the event that the [\*\*\*] a China Product Supply Agreement and related China Product Quality Agreement within [\*\*\*] after the Effective Date, then the terms of such Agreement(s) shall be [\*\*\*]. Unless the Parties agree otherwise, the China Product Supply Agreement will include customary terms and conditions for the supply of cell therapy products, including ordering and forecasting provisions, as well as the terms set forth in Section 6.3.2 and the following terms set forth below in this Section 6.3.4. Pursuant to the China Product Supply Agreement, [\*\*\*] will Manufacture at the China Manufacturing Facilities, and supply to [\*\*\*] in conducting Clinical Studies of the Products in Greater China in accordance with the GDP.

6.3.5 <u>Costs of China Product Supplies</u>. The Commercial Supply Costs or Clinical Supply Costs of Product Manufactured and supplied [\*\*\*] under the China Product Supply Agreement shall be [\*\*\*], as the case may be.

6.3.6 <u>Other Products</u>. In addition to production of Products for supply [\*\*\*], the China Manufacturing Facilities shall be available for production of other [\*\*\*] products [\*\*\*], subject to the following, all as determined by [\*\*\*]:

(a) there is available capacity to manufacture such products in addition to [\*\*\*] of Products for clinical and commercial use;

(b) such other products can be manufactured within the China Manufacturing Facilities using (A) the existing equipment, capacity, space and personnel dedicated to the Products and (B) [\*\*\*];

(c) the manufacture of such other products in the China Manufacturing Facilities [\*\*\*] of Products or create a [\*\*\*] the Products or any other products that are being made on the same premises as the China Manufacturing Facilities [\*\*\*];

(d) [\*\*\*] Commercial Supply Costs or Clinical Supply Costs of such other product (*mutatis mutandis*, and where references in these definitions to Products will be read to refer to such other product) and [\*\*\*] such other products;

(e) [\*\*\*] may not Manufacture at the China Manufacturing Facilities [\*\*\*]; and

(f) [\*\*\*] of other appropriate terms and conditions for the manufacture and supply of such other [\*\*\*] product.

-65-

6.3.7 <u>Rights upon Termination of this Agreement</u>. Following the effective date of termination of this Agreement, [\*\*\*] shall have the right to retain [\*\*\*] any or all Designated Equipment utilized for the China Manufacturing Facility and [\*\*\*] to the China Manufacturing Facility.

6.4 **No Liability for Failure to Supply.** Without limiting the remedies available under Section 6.2.2(c)(iv), 6.2.3(c)(ii)(6) and 6.3.2(b)(vii) or the applicable Supply Agreement, so long as the Party responsible for supply of Product or other materials pursuant to this ARTICLE VI uses Diligent Efforts to effect such supply, such Party shall not be liable to the other Party for monetary damages as a result of a shortage of supply such Product or materials in accordance with this ARTICLE VI; provided that the limitation in this Section 6.4 shall not apply with respect to a shortage caused by the gross negligence, intentional misconduct or violation of Law by the responsible Party.

6.5 **JMC Authority.** The Parties agree that the foregoing does not set forth all of the terms and conditions as may be necessary or appropriate to govern the manufacturing and supply arrangements outlined in this ARTICLE VI. Accordingly, the JMC shall have the authority to determine additional terms or conditions as are reasonably necessary or appropriate with respect to such arrangements, including the establishment and operation of the US Facility and the European Facility, and the orderly transition thereof upon termination or expiration of this Agreement.

# ARTICLE VII FINANCIAL PROVISIONS

7.1 Upfront Payments . In partial consideration of the rights granted to Janssen under this Agreement, Janssen shall make a non-refundable, non-creditable payment of [\*\*\*] to Legend U.S. within [\*\*\*] after the Effective Date [\*\*\*] with respect to the United States (the "U.S. Upfront Payment") and a non-refundable, non-creditable payment of [\*\*\*] to Legend Ireland within [\*\*\*] after the Effective Date [\*\*\*] with respect to the Janssen Territory and Greater China (the "Ireland Upfront Payment"), and together the "Upfront Payment").

#### 7.2 Milestone Payments.

7.2.1 <u>Milestone Events</u>. Janssen shall make the non-refundable, non-creditable payments (each, a "**Milestone Payment**") to Legend set forth in the table below not later than [\*\*\*] after Legend delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below (each, a "**Milestone Event**"), subject to Sections 7.2.2 through 7.2.8 below. Janssen shall provide notice to Legend within [\*\*\*] after Janssen's or its Affiliates' achievement of any of the Milestone Events.

Milestone Event		Milestone Payment			
	Initial Milestone Events				
1.	[***] Milestone Event	[***]			
2.	[***] Milestone Event	[***]			
3.	3. Dosing of the fifth (5th) patient in a Phase 1 Clinical Study in the United States with United States				
	subjects (the "Phase I Milestone")	US\$25 million			

-66-

4.							
5.							
6.			US\$25 million				
7.	Receipt of response data readout from 20 patients in the first Phase 1 Clinical Study in the United States with United States subjects showing a least 50% ORR (the " <b>Initial ORR Milestone</b> ")	ıt					
	Additional Develo	opment Events					
		First Original GDP	Second Original GDP	[+++]	[+++]	[++++]	
8.	Dosing of the fifth (5th) patient in a Registration Study of a Product in th	Indication	Indication	[***]	[***]	[***]	
0.	United States, EU or Japan	US\$30 million	US\$30 million	[***]	[***]	[***	
	Regulatory Fil						
		[***]	[***]	[***]	[***]	[***	
9.	[***]	[***]	[***]	[***]	[***]	[***	
10.	[***]	[***]	[***]	[***]	[***]	[***	
11.	[***]	[***]	[***]	[***]	[***]	[***	
	Commercialization .	Approval Events					
		[***]	[***]	[***]	[***]	[***	
	[***]	[***]	[***]	[***]	[***]	[***	
12.		[+++]	[***]	[***]	[***]	[***	
	[***]	[***]	ĹĴ				
13.	[***]	[***]	[***]	[***]	[***]	[***	
12. 13. 14. 15.	[***] Additional Mile	[***]	ĹĴ		[***]	[***	

7.2.2 <u>Definitions</u>. For purposes of Section 7.2.1:

(a) "[\*\*\*] **Milestone Event**" means the date on which it is demonstrated that [\*\*\*].

(b) "[\*\*\*] **Milestone Event**" means the date on which it is demonstrated that [\*\*\*].

-67-

(c) "Additional Development Events" means Milestone Event 5 set forth in the table in Section 7.2.1.

(d) "Additional Milestone Events" means Milestone Events 12 and 13 set forth in the table in Section 7.2.1.

(e) "Commercialization Approval Events" means Milestone Events 9, 10 and 11set forth in the table in Section 7.2.1.

(f) "**Cost of Goods Sold**" or "**COGS**" means a Party's reasonable and necessary internal and third party costs incurred in manufacturing or acquisition of product, determined in accordance with Party's standard cost accounting policies that are in accordance with U.S. generally accepted accounting principles and consistently applied across Party's manufacturing network to other products that the Party manufactures. "COGS" are comprised of [\*\*\*], where:

(i) [\*\*\*];

(ii) [\*\*\*]; and

(iii) [\*\*\*].

For the avoidance of doubt, COGS for purposes of Section 7.2.1 shall [\*\*\*].

(g) [\*\*\*]

(h) [\*\*\*]

(i) [\*\*\*]

(j) "Initial Milestone Events" means Milestone Events 1, 2, 3 and 4 set forth in the table in Section 7.2.1.

(k) "Original GDP Indication" means, subject to Section 7.2.7 each of the following indications:[\*\*\*]

(l) "Regulatory Filing Events" means Milestone Events 6, 7 and 8set forth in the table in Section 7.2.1.

7.2.3 Each Milestone Payment Paid Only Once. Each Milestone Payment shall be payable only one-time upon the first occurrence of the relevant Milestone Event by the first Product for which the Milestone Event occurred, even if the Milestone Event occurs with respect to more than one Product or multiple times with respect to the same Product.

7.2.4 <u>Milestone Payments for Additional Development Events</u>. Subject to Section 7.2.7, with respect to each Additional Development Event, such Milestone Event shall be deemed to occur:

-68-

(a) for the First Original GDP Indication when the fifth (5th) patient is dosed in the first Registration Study of a Product in the United States, EU or Japan for [\*\*\*];

(b) for the Second Original GDP Indication when the fifth (5th) patient is dosed in the first Registration Study of a Product in the United States, EU or Japan for [\*\*\*] other than the First Original GDP Indication with respect to which the Additional Development Event previously occurred;

(c) [\*\*\*];
(d) [\*\*\*]; and
(e) [\*\*\*].

For clarity, the Milestone Payments for Milestone Event 5 shall be payable with respect to only [\*\*\*] that achieve the Additional Development Event, even if the Additional Development Event is achieved by a [\*\*\*] that achieves the Additional Development Event, even if the Additional Development Event is achieved by a [\*\*\*].

7.2.5 <u>Milestone Payments for Regulatory Filing Events</u>. Subject to Section 7.2.7, with respect to each Regulatory Filing Event for a particular jurisdiction [\*\*\*], such Regulatory Filing Event shall be deemed to occur:

(a) [\*\*\*]

For clarity, the Milestone Payments for each Milestone Events 6, 7 and 8 set forth in the table in Section 7.2.1 for a particular jurisdiction [\*\*\*] shall be payable with respect to only the [\*\*\*] that achieve the Regulatory Filing Event, even if the applicable Milestone Event is achieved by [\*\*\*] that achieves the applicable Milestone Event, even if such Milestone Event is achieved by [\*\*\*].

7.2.6 <u>Milestone Payments for Commercialization Approval Events</u>. Subject to Section 7.2.7, with respect to each Commercialization Approval Event for a particular jurisdiction [\*\*\*] such Commercialization Approval Event shall be deemed to occur:

(a) [\*\*\*]

For clarity, the Milestone Payments for Milestone Events 9, 10 and 11 for a particular jurisdiction [\*\*\*] shall be payable with respect to only the [\*\*\*] that achieve the Commercialization Approval Event, even if the Commercialization Approval Event is achieved by [\*\*\*] that achieves the Commercialization Approval Event, even if the Commercialization Approval Event is achieved by [\*\*\*].

7.2.7 <u>Skipped Milestones</u>. The following provisions would apply with respect to certain circumstances that could result in one or more of the Milestone Events not being achievable or achieved.[\*\*\*]

-69-

7.2.8 <u>Independent Development Activities</u>. If any Milestone Events are achieved through the performance of Independent Development Activities by a Party in accordance with Section 4.3, the corresponding Milestone Payment shall [\*\*\*]

7.2.9 <u>Allocation of Certain Milestone Payments</u>. Milestone Payments for Milestone Events 1, 2, 5, 12 and 13 will be allocated [\*\*\*] and payable to [\*\*\*]. Milestone Payments for Milestone Events 3, 4, 6 and 9 shall be payable to [\*\*\*] Milestone Payments for Milestone Events 7, 8, 10 and 11 shall be payable to [\*\*\*].

#### 7.3 Shared Costs.

7.3.1 <u>Cost Sharing</u>. Subject to Sections 7.3.5 and 14.2.3 below, Development Costs incurred during the Term by the Parties and their Affiliates shall be borne: (a) 50% by Janssen and 50% by Legend with respect to Development Costs other than Greater China-Specific Development Costs and (b) 30% by Janssen and 70% by Legend with respect to Greater China-Specific Development Costs. Development Costs will not be included in Allowable Expenses for purposes of calculating Pre-Tax Profit or Loss in accordance with the Financial Exhibit, and any amounts included in Allowable Expenses will not be included in Development Costs (and in any case no item of expense shall be counted more than once in Development Costs or Allowable Expenses).

7.3.2 <u>Clinical Studies Involving Other Products of a Party</u>. If any Clinical Studies or other Development activities are conducted under the GDP that involve the use of a product of a Party or its Affiliate, other than a Product, as part of a Combination Regimen or otherwise (i.e. as a comparator or as an induction therapy), the Party whose other product is involved shall supply such other product for purposes of such study or activity [\*\*\*]. In addition, if the other product involved in such Clinical Study would benefit separately from the results, [\*\*\*] shall be included as Development Costs (or Allowable Expenses, as applicable) hereunder; provided, however, that [\*\*\*] shall be included as Development Costs. It is understood this Section 7.3.2 shall not be deemed to limit the requirements of Section 4.2.1.

7.3.3 <u>Costs Reports</u>. Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 7.3.4 and subject to Section 7.3.5. Each Party shall calculate and maintain records of Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the Finance Working Group in coordination with the JDC. The procedures for quarterly reporting of actual results, quarterly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs will be determined by the Finance Working Group (the "**Development Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party. The Development Reconciliation Procedures shall provide that, within [\*\*\*], each Party shall submit to the Finance Working Group and the JDC a report, in such reasonable detail and format established by the Finance Working Group, of all Development Costs incurred by such Party and its Affiliates during [\*\*\*] (each, a "**Cost Report**"). [\*\*\*] following the receipt of each Cost Report, each Party shall reasonably cooperate to provide additional information related to the other Party's and its Affiliates' Development Costs during [\*\*\*] in order to confirm that such other Party's spending is in conformance with the approved Development Budget. The Finance Working Group shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes.

-70-

### 7.3.4 Reimbursement of Shared Costs.

(a) Subject to Sections 7.3.5 and 14.2.3 below, the Party (with its Affiliates) that incurs more than its share of the total actual Development Costs with respect to [\*\*\*] shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual Development Costs in such Calendar Quarter pursuant to Section 7.3.1. Notwithstanding the foregoing, on a [\*\*\*], the Parties shall not share any Development Costs in excess of the amounts allocated for such [\*\*\*] period in the Development Budget, except as follows:

(i) Development Costs in excess of the Development Budget shall be included in the calculation of Development Costs to be shared by the Parties to the extent such excess Development Costs [\*\*\*] Development Costs allocated to be incurred by such Party and its Affiliates in the applicable [\*\*\*] in accordance with the applicable Development Budget for such [\*\*\*];

(ii) the Parties shall share any and all Development Costs in excess of the Development Budget, as applicable, to the extent attributable to: [\*\*\*]. The Party incurring such excess Development Costs will notify [\*\*\*] of such event giving rise to (or reasonably expected to give rise to) any such excess Development Costs.

If any excess Development Costs are [\*\*\*] period pursuant to the foregoing sentence, such excess Development Costs shall be [\*\*\*] and, to the extent the total Development Costs incurred by such Party and its Affiliates for the [\*\*\*] to such Party under the Development Budget for such [\*\*\*] period, such [\*\*\*] shall be included in Development Costs to be shared by the Parties for such [\*\*\*]

(b) The Development Reconciliation Procedures shall require the Finance Working Group to develop a written report setting forth in reasonable detail the calculation of any net amount owed by Legend to Janssen or by Janssen to Legend, as the case may be, as necessary to accomplish the sharing of Development Costs set forth in Section 7.3.1 and this Section 7.3.4, as well as any reimbursement payments that become due from one Party to the other during such Calendar Quarter pursuant to Section 4.3, andnexispute is resolved by the Finance Working Group. In establishing the Development Reconciliation Procedures, the Finance Working Group shall work to coordinate and harmonize all Reconciliation Procedures to permit for reconciliation, and associated payments, with respect to Development Costs as well as Pre-Tax Profit or Loss within [\*\*\*].

7.3.5 [\*\*\*] in the event that [\*\*\*] as reasonably determined by the Finance Working Group [\*\*\*], then the [\*\*\*] shall be borne by [\*\*\*] on the following terms set forth in this Section 7.3.5, and the reimbursement calculations set forth in Section 7.3.4 and the reconciliation of Pre-Tax Profit or Loss pursuant to the Financial Exhibit shall be [\*\*\*]. By way of example, see the sample calculations set forth on <u>Schedule 7.3.5</u>.

-71-

(a) Definitions.[\*\*\*]

(b) Annual Cap. The [\*\*\*].

(c) *Annual Reconciliation*. The Reconciliation Procedures shall include procedures to reconcile the [\*\*\*] at the end of each Calendar Year to take into account [\*\*\*].

(d) *Independent Development Activities Amounts*. If amounts become due from Legend to Janssen pursuant to Section 4.3.2 or 4.3.3 with respect to Independent Development Activities conducted by Janssen, and milestone payments under Section 7.2 are then due, or concurrently become due, as provided in Section 7.2.8 with respect to such Independent Development Activities, Janssen may offset against such milestone payments all or part of that portion of amounts that are due from Legend pursuant to Section 4.3.2, or that are due pursuant to clause (iv) of Section 4.3.3, in each case with respect to the applicable Independent Development Activities, that would otherwise be [\*\*\*].

- (e) [\*\*\*] (f) [\*\*\*] (g) [\*\*\*]
- (h) [\*\*\*]

# 7.4 Pre-Tax Profit or Loss.

7.4.1 <u>United States Pre-Tax Profit or Loss</u>. The Parties shall share in Pre-Tax Profit or Loss in the United States as follows: Legend U.S. shall bear (and be entitled to) 50%, and Janssen shall bear (and be entitled to) 50%. Each Party's share of the Pre-Tax Profit or Loss in the United States shall be adjusted on a Calendar Quarter basis to ensure that profits and losses from commercial manufacturing activities and other collaboration activities in the U.S. under this Agreement result in an overall profit and loss 50%/50% split for Janssen and Legend as follows:

With respect to a Party, such Party's adjusted share of Pre-Tax Profit or Loss for the U.S. equals [\*\*\*] for the U.S.; and

[\*\*\*] equals [\*\*\*] (in accordance with the definitions of such terms).

For clarity, [\*\*\*] be taken into account when determining Pre-Tax Profit or Loss as described in Section 6.2.3(f).

Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit, will be established by the Finance Working Group (the "**U.S. Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.

-72-

7.4.2 <u>Greater China Pre-Tax Profit or Loss</u>. The Parties shall share in Pre-Tax Profit or Loss in Greater China as follows: Legend Ireland shall bear (and be entitled to) 70%, and Janssen shall bear (and be entitled to) 30%. Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit, will be established by the Finance Working Group (the "**Greater China Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.

7.4.3 Janssen Territory Pre-Tax Profit or Loss. The Parties shall share in Pre-Tax Profit or Loss in the Janssen Territory as follows: Legend Ireland shall bear (and be entitled to) 50%, and Janssen shall bear (and be entitled to) 50%. Each Party's share of the Pre-Tax Profit or Loss in the Janssen Territory shall be adjusted on a Calendar Quarter basis to ensure that profits and losses from commercial manufacturing activities and other collaboration activities in the Janssen Territory under this Agreement result in an overall profit and loss 50%/50% split for Janssen and Legend as follows:

With respect to a Party, such Party's adjusted share of Pre-Tax Profit or Loss for the Janssen Territory equals [\*\*\*] for the Janssen Territory.

For clarity, [\*\*\*] be taken into account when determining Pre-Tax Profit or Loss as described in Section 6.2.3(f).

Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit, will be established by the Finance Working Group (the "Janssen Territory Reconciliation Procedures" and, together with the U.S. Reconciliation Procedures, Greater China Reconciliation Procedures and the Development Reconciliation Procedures, the "Reconciliation Procedures"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.

7.4.4 Quarterly Reconciliation and Payments. The Reconciliation Procedures shall provide that [\*\*\*] after the end of each Calendar Quarter, each Party shall submit to the Finance Working Group a report, in such reasonable detail and format as is established by the Finance Working Group, of all Net Trade Sales and Allowable Expenses and other amounts necessary to calculate Pre-Tax Profit or Loss for the United States, Greater China and for the Janssen Territory. [\*\*\*] following the receipt of such report, each Party shall cooperate to provide additional information necessary to permit calculation and reconciliation of Pre-Tax Profit or Loss for the United States, Greater China and for the Janssen Territory for the applicable Calendar Quarter, and to confirm that Allowable Expenses are in conformance with the approved Commercialization Budgets. The Reconciliation Procedures shall provide for the Finance Working Group to develop a written report setting forth in reasonable detail the calculation of Pre-Tax Profit or Loss in the United States, Greater China and in the Janssen Territory for the applicable Calendar Quarter, amounts owed by Legend to Janssen or by Janssen to Legend, as the case may be, as necessary to accomplish the sharing of Pre-Tax Profit or Loss in the United States, Greater China and in the Janssen Territory for the applicable Calendar Quarter, and to prepare such report promptly following delivery of the reports from the Parties as described above in this Section 7.4.4 and in a reasonable time (to be defined in the Reconciliation Procedures) in advance of applicable payments to accomplish the sharing of Pre-Tax Profit or Loss in the United States, Greater China and in the Janssen Territory for the applicable Calendar Quarter. Payments to reconcile Pre-Tax Profit or Loss in the United States, Greater China and the Janssen Territory for the applicable Calendar Quarter. Payments to reconcile Pre-Tax Profit or Loss in the United States, Greater China and the Janssen Territory, and Development Costs,

-73-

7.4.5 <u>Pre-Tax Profit or Loss Adjustment Example</u>. By way of example only, see the sample Pre-Tax Profit or Loss adjustment calculations set forth on Schedule 7.4.5.

7.5 **Third Party Intellectual Property**. If after the Effective Date, a Party proposes to either: (a) use with or incorporate into a Product Patent Rights or Know-How from a Third Party or (b) to license or acquire rights from a Third Party Patent Rights or Know-How to be used or practiced solely in connection with Exploitation of a Product hereunder, in each case where such use or incorporation would require the payment of amounts to a Third Party or would impose other obligations or conditions with respect to such Exploitation (other than in connection with a settlement of an Infringement Claim pursuant to Section 8.5 (Claimed Infringement) (such licensed or acquired Patent Rights or Know-How referred to in (a) and (b), **"Third Party Intellectual Property**"), then the following shall apply:

7.5.1 Before using the Third Party Intellectual Property in connection with the Exploitation of a Product (or, in the case of clause (b) above, before licensing or acquiring such Third Party Intellectual Property), the Party proposing to use, incorporate, license or acquire such Third Party Intellectual Property ("**Proposing Party**") shall notify the JSC in writing of the Third Party Intellectual Property and provide to the JSC a copy of the contract pursuant to which the Proposing Party licensed or acquired rights to such Third Party Intellectual Property (or, in the case of clause (b) above, any and all financial and other terms proposed by the potential Third Party that would apply if the Third Party Intellectual Property were licensed or acquired and applied to the applicable Product(s)) (such notice, the "**Proposing Party Notice**"); and

7.5.2 The JSC shall meet to discuss and determine, and shall notify the Proposing Party [\*\*\*] after receipt of the Proposing Party Notice, whether it approves the use or incorporation of the Third Party Intellectual Property in the Exploitation of the applicable Product(s) in the Field under this Agreement. If the JSC approves the use of such Third Party Intellectual Property, the Parties shall be jointly responsible for all obligations under the contract pursuant to which such Third Party Intellectual Property was licensed or acquired that would accrue based on the practice of such Third Party Intellectual Property for purposes of the Exploitation of Products under this Agreement, provided that to the extent that any payments made by the Proposing Party under the applicable agreement to license or acquire Third Party Intellectual Property are not attributable to Exploiting Products under this Agreement in the U.S., Greater China or Janssen Territory (which determination shall be made by the Finance Working Group), but are attributable to the general licensing or acquisition of rights to such Third Party Intellectual Property, a reasonable portion of such amounts as determined by the Finance Working Group shall be allocated to the Exploitation of Products in the U.S., Greater China and Janssen Territory and taken into account in determining Pre-Tax Profit or Loss (for clarity, the Finance Working Group shall also allocate such amounts between the U.S. and Janssen Territory on the one hand, and Greater China on the other hand, to the extent such amounts are not specific to U.S. or Janssen Territory on the one hand, or Greater China on the other hand). Additionally, with respect to Third Party Intellectual Property, the rights to which have not yet been licensed or acquired, the JSC may designate a Party to use Diligent Efforts to obtain such rights under such Third Party Intellectual Property, with the terms of such license or other agreement (economic or otherwise) to be subject to JSC approval.

7.5.3 Any amounts paid to any Third Party to license or acquire any Third Party Intellectual Property which the JSC has approved for use in the Exploitation of the Products under this Agreement pursuant to this Section 7.5 to the extent attributable to Exploiting Products in the Field in the U.S., Greater China or Janssen Territory (or otherwise allocated thereto by the Finance Working Group pursuant to Section 7.5.2) ("**Third Party IP Costs**") shall be taken into account in determining Pre-Tax Profit or Loss as provided in the Financial Exhibit.

-74-

### 7.6 Audits

7.6.1 Each Party shall keep, and cause its Affiliates to keep, complete and accurate records of the items underlying Development Costs, CMC Development Costs, Manufacturing Plan Costs, Allowable Expenses, Other Income, Net Trade Sales, Third Party IP Costs and the other elements required to prepare the reports or calculate payments required by ARTICLE VI, Sections 7.2, 7.3 and 7.4 and the Reconciliation Procedures, and any other payments under this Agreement. Each Party will have the right annually at its own expense to have an independent, certified public accountant, selected by such Party and reasonably acceptable to the other Party, review any such records of the other Party and its Affiliates in the location(s) where such records are maintained by the other Party or its Affiliates upon [\*\*\*] prior written notice and during normal business hours and under obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under ARTICLE VI, Sections 7.2, 7.3 and 7.4 and the Reconciliation Procedures, and any other payments due under this Agreement, within the prior [\*\*\*]. An audit of the records relating to a particular Calendar Year may be conducted not more than once. For clarity, however, if a discrepancy is identified by the accountant during the course of an audit and the Parties do not agree upon a resolution of such discrepancy, then the auditing Party's accountant may re-inspect the books and records to the extent reasonably relevant to resolving such discrepancy.

7.6.2 The report of the independent certified public accountant shall be shared with the audited Party prior to distribution to the auditing Party solely for the audited Party to review the report and provide written feedback to the independent certified public accountant. The audited Party shall provide to the auditing Party any such feedback and such report shall be distributed to the auditing Party at the time the audited Party provides such feedback, and in any case [\*\*\*] after sharing the report with the audited Party. The audited Party shall not otherwise correspond with the independent certified public accountant about such report prior to such report being provided to the auditing Party. The final audit report shall specify whether the amounts paid to the auditing Party during the audited period were correct or, if incorrect, the amount of any underpayment or overpayment. The audit report shall only contain the information relevant to support the statement as to whether the amounts due under this Agreement were calculated and paid accurately and shall not include any confidential or additional information that is ordinarily not included in the reports to the auditing Party disclosed to the auditor during the course of the audit and not necessary to convey information relevant to support the statement as to whether the amounts due under this Agreement were calculated and paid accurately.

7.6.3 If the review of such records reveals that the other Party has failed to accurately report information pursuant to Section 7.3 and 7.4, or the Reconciliation Procedures, or make any payment (or portion thereof) required under this Agreement, then the other Party shall pay, [\*\*\*] after receipt of the final audit report by the audited Party, to the auditing Party any underpaid amounts due under Sections 7.2, 7.3 and 7.4, or the Reconciliation Procedures, or otherwise due under this Agreement, together with interest calculated in the manner provided in Section 7.10. If any such discrepancies are an underpayment of amounts due under this Agreement [\*\*\*] of the amounts actually due for any Calendar Year, the other Party shall pay all reasonable costs incurred in conducting such review. If the audited Party disagrees with the findings of the audit report, the Parties will first seek to resolve the matter between themselves, and in the event they fail to reach agreement, the dispute resolution provisions set forth in ARTICLE XIII shall apply.

-75-

## 7.7 Tax Matters.

7.7.1 Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

7.7.1 Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the "**Payor**") on behalf of the Party receiving the payment (the "**Payee**") to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax. Any such Tax, to the extent withheld and paid to the appropriate Governmental Authority, shall be treated for all purposes of this Agreement as having been paid to the Payee. Any such Tax required to be withheld will be an expense of and borne by Payee.

7.7.2 The Parties will cooperate with respect to all documentation required by any taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. If the withholding tax rate is reduced according to the provisions of an applicable double tax treaty or regulations applicable thereto, no deduction or withholding shall be made (or a reduced amount shall be deducted or withheld), in each case as applicable, only if the Payor is timely furnished with necessary documents or certification by the Payee issued by the tax authority certifying that the payment is exempt from tax or subject to a reduced tax rate or the Payee otherwise satisfies the requirements to obtain the treaty benefit in question.

7.7.3 If Payor had a duty to withhold Taxes in connection with any payment it made to Payee under this Agreement but Payor failed to withhold, and such Taxes were assessed against and paid by Payor, then Payee will indemnify and hold harmless Payor from and against such Taxes, except to the extent such Taxes resulted from Payor's negligent failure to withhold; provided, however, that Payor shall only be responsible for such Taxes to the extent such Taxes do not exceed the amount of Tax that Payor Would have withheld if it had received from Payee the documentation necessary to secure any available reduction in the rate of applicable Taxes. If Payor makes a claim under this Section 7.7.3, it will comply with the obligations imposed by Section 7.7.1 as if Payor had withheld Taxes from a payment to Payee.

7.7.4 The Parties acknowledge that Legend has provided to Janssen an IRS Form W-9 with respect to Legend US and agree that no Tax will be withheld from the US Upfront Payment. [\*\*\*].

7.7.5 **"Tax"** or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, withholdings, assessments or fees of any nature (including penalties and additions to tax and interest thereon). "**Tax Return**" shall mean any return, report, declaration or similar document filed or required to be filed with any Governmental Authority relating to Taxes.

-76-

### 7.8 Tax Returns.

7.8.1 To the extent attributable to any activities in the U.S., the Parties hereby agree to treat the activities giving rise to Pre-Tax Profit or Loss in the U.S. as a partnership (the "**U.S. Territory Partnership**") for U.S. federal and state income tax purposes between Janssen and Legend U.S. upon first receipt of Marketing Approval of any Product in the United States. Janssen shall act as the Tax Representative for the U.S. Territory Partnership. The designation of Tax Representative for such partnership will be effective only for activities conducted by the Parties pursuant to this Section 7.8.1. In performing its responsibilities, the Tax Representative shall consider the interests and requests of both Parties, shall consult with Legend U.S. with respect to any material Tax matters with respect to the U.S. Territory Partnership, and except as noted in Section 7.8.3 below, the Tax Representative will not make any tax elections or take any other material actions affecting tax matters of the U.S. Territory Partnership without obtaining the prior written concurrence of Legend U.S., with any disagreements over tax matters resolved by the JSC.

7.8.2 To the extent attributable to any activities in the Janssen Territory and Greater China, the Parties hereby agree to treat the activities giving rise to Pre-Tax Profit or Loss in the Janssen Territory and Greater China as required under the applicable Law of the relevant jurisdiction (the "**Ex-U.S. Territory Activities**"). The Parties agree that each Party shall be responsible for the filing of such Party's own Tax Returns and the paying of such Party's own Taxes with respect to the Ex-U.S. Territory Activities, and shall have no liability whatsoever to the other Party with respect to the filing of any such Tax Returns (including, for the avoidance of doubt, the positions taken on such Tax Returns) and the paying of any such Taxes (except as otherwise required by applicable Law. For each jurisdiction, Legend Ireland and Janssen shall designate either itself or an Affiliate as the relevant party with respect to the Ex-U.S. Territory Activities. For the avoidance of doubt, the Ex-U.S. Territory Activities shall be separate and distinct from the U.S. Territory Partnership, and each Party shall use commercially reasonable efforts in undertaking the activities pursuant to this Agreement in a manner consistent with the foregoing. In the event Janssen assigns, licenses, or sublicenses all or a part of its rights under this Agreement as described in Section 7.8.5 below, each Party shall keep a separate set of books and records with respect to the U.S. Territory Partnership and the Ex-U.S. Territory Activities, as applicable.

7.8.3 The Parties hereby agree that 100% of any deductions for tax purposes, other than deductions that are taken into account for purposes of calculating Pre-Tax Profit or Loss, attributable to amounts paid or incurred by a Party pursuant to this Agreement shall be deductible or amortizable solely by such Party. All Tax Returns reflecting any such amounts shall be filed in a manner consistent with the foregoing.

7.8.4 For every other purpose besides the preparation and reporting of U.S. partnership income tax returns, the Parties understand and agree that their legal relationship to each other under applicable Law with respect to all activities is as set forth in Section 14.8 of this Agreement.

7.8.5 In the event Janssen assigns, licenses, or sublicenses all or a part of its rights under this Agreement with respect to the Ex-U.S. Territory Activities to an Affiliate, the Parties agree to make conforming changes to this Agreement to reflect the proper separation of activities attributable to the U.S. Territory Partnership and the Ex-U.S. Territory Activities.

7.8.6 For purposes of this Agreement:

(a) **"Partnership Audit Procedures**" means the amendments to the Code that were enacted as section 1101 of the Bipartisan Budget Act of 2015, P.L. 114-74.

-77-

(b) "**Tax Representative**" means the "partnership representative," as such term is defined in section 6223 of the Code (as amended by the Partnership Audit Procedures).

# 7.9 Currency Exchange.

7.9.1 <u>Currency of Payments</u>. All payments under this Agreement shall be paid in U.S. Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

7.9.2 <u>Currency Conversion(a)</u>. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are received or paid in a currency other than U.S. Dollars, then such amounts shall be converted to their U.S. Dollar equivalent as follows:[\*\*\*]

7.10 **Late Payments**. If either Janssen or Legend shall fail to make a timely payment pursuant to Section 7.2, 7.3, 7.4 or any other provision of this Agreement, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest at a rate [\*\*\*] or the maximum rate allowable by applicable Law, whichever is lower, calculated on the number of days such payment is overdue.

# ARTICLE VIII

# INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

## 8.1 Ownership of Inventions.

8.1.1 <u>Sole Inventions</u>. As between the Parties, each Party (or its Affiliate) shall exclusively own all inventions conceived solely by such Party and its Affiliates, and their employees, agents and consultants in the course of such Party's and its Affiliates' performance of Development, CMC Development, Manufacturing or Commercialization activities under this Agreement ("**Sole Inventions**"). Sole Inventions conceived solely by Janssen or its Affiliates or any of their employees, agents and consultants are referred to herein as "**Janssen Sole Inventions**". Sole Inventions conceived solely by Legend or its Affiliates or any of their employees, agents and consultants are referred to herein as "**Legend Sole Inventions**".

8.1.2 Joint Inventions. The Parties or their Affiliates shall jointly own all inventions conceived jointly by employees, agents and consultants of Janssen and its Affiliates, on the one hand, and employees, agents and consultants of Legend and its Affiliates, on the other hand, in the course of performing Development, CMC Development, Manufacturing or Commercialization activities under this Agreement, on the basis of each Party having an undivided interest in the whole ("**Joint Inventions**").

8.1.3 <u>Inventorship</u>. For purposes of determining under this Agreement only whether an invention is a Janssen Sole Invention, a Legend Sole Invention or a Joint Invention, questions of inventorship worldwide shall be resolved in accordance with United States patent laws.

-78-

### 8.2 Prosecution and Maintenance of Patent Rights Globally.

8.2.1 Legend Patent Rights and Joint Patent Rights Prosecution. Legend or its Affiliate shall have the first right, using outside legal counsel selected by Legend and reasonably approved by Janssen (with outside counsel used by Legend as of the Effective Date being deemed approved by Janssen), to prepare, file, prosecute, validate, maintain and extend the Legend Patent Rights and Joint Patent Rights on a global basis. Within thirty (30) days after the Effective Date, Legend shall provide Janssen with copies of the prosecution histories of the Legend Patent Rights, and shall thereafter promptly provide Janssen with copies of all correspondence to or from the USPTO, EPO and equivalent patent offices in foreign jurisdictions, relating to the Legend Patent Rights and Joint Patent Rights directed to the composition, manufacture, or use of Licensed CARs or Products. Legend or its Affiliate shall take into account and consider in good faith Janssen and its Affiliates' interests (regarding Licensed CARs or Products) and requests regarding the filing, prosecution and maintenance of Patent Rights or Joint Patent Rights, elects not to file, prosecute or maintain such patent applications or ensuing patents within the (i) Legend Patent Rights to the extent the same pertain to Licensed CARs or Products or Joint Patent Rights, Legend shall give Janssen notice thereof within a reasonable period prior to allowing such patent applications or patents to lapse or become abandoned or unenforceable, and Janssen or its Affiliate shall thereafter have the right, but not the obligation, to prepare, file, prosecute and maintein patent applications and patents concerning all such inventions and discoveries, to such extent. In the event that Janssen or its Affiliate assumes responsibility for such Legend Patent Rights or Joint Patent Rights pursuant to this Section 8.2.1, Legend and its Affiliates shall reasonably cooperate with Janssen in maintaining and prosecuting such Patent Rights.

8.2.2 Janssen Patent Rights Prosecution. Janssen or its Affiliate shall have the first right, using in-house or outside legal counsel selected by Janssen and mutually acceptable to each Party, to prepare, file, prosecute, validate, maintain and extend the Janssen Patent Rights on a global basis and a second such right as to Joint Patent Rights as described in Section 8.2.1. Janssen shall promptly provide Legend with copies of all correspondence to or from the USPTO, EPO and equivalent patent offices in foreign jurisdictions, relating to all Janssen Patent Rights, if any, directed to the composition, manufacture, or use of Licensed CARs or Products. Janssen shall take into account and consider in good faith Legend and its Affiliates' interests (regarding Licensed CARs or Products) and requests regarding the filing, prosecution and maintenance of Patent Rights under this Section 8.2.2. If Janssen or its Affiliate, prior or subsequent to filing patent applications that would constitute any Janssen Patent Rights, elects not to file, prosecute or maintain such patent applications or ensuing patents within the Janssen Patent Rights, to the extent the same pertain to Licensed CARs or Products, Janssen shall give Legend notice thereof within a reasonable period prior to allowing such patent applications or patents to lapse or become abandoned or unenforceable, and Legend or its Affiliate shall thereafter have the right, but not the obligation, to prepare, file, prosecute and maintain patent applications and patents concerning all such inventions and discoveries, to such extent. In the event that Legend or its Affiliate assumes responsibility for such Janssen Patent Rights pursuant to this Section 8.2.2, Janssen and its Affiliates shall reasonably cooperate with Legend in maintaining and prosecuting such Patent Rights.

8.2.3 <u>Maintenance and Prosecution Costs</u>. All reasonable Patent Costs incurred by the Parties and their respective Affiliates with respect to Legend Patent Rights, Janssen Patent Rights and Joint Patent Rights that Cover the Products shall be [\*\*\*] with respect to Joint Patent Rights, Legend Patent Rights or Janssen Patent Rights for which it would otherwise be [\*\*\*] under this Section 8.2.3 by giving the other Party [\*\*\*] prior written notice of such election identifying the specific Joint Patent Rights, Legend Patent Rights or Janssen Patent Rights to which such election pertains, in which event: (a)

-79-

if [\*\*\*] provides such notice with respect to any [\*\*\*] shall no longer be included within any license granted to [\*\*\*] under this Agreement, (b) if [\*\*\*] provides such notice with respect to any [\*\*\*] shall no longer be included within any license granted to [\*\*\*] under this Agreement and (c) if [\*\*\*] provides such notice with respect to any [\*\*\*] shall no longer be included within the license grant to [\*\*\*].

8.2.4 <u>Cooperation</u>. Each Party agrees to reasonably cooperate, and to cause its Affiliates to cooperate, with the other with respect to the preparation, filing, prosecution, validation, extension (pursuant to Section 8.6) and maintenance of Patent Rights pursuant to this Section 8.2. The Party responsible for preparing, filing, prosecuting or maintaining Patent Rights in accordance with Section 8.2.1 or 8.2.2 shall provide the other Party with advance copies (which may be in draft form) of all material filings as well as copies of all material correspondence from the relevant patent office, in each case relating to such Patent Rights, and shall consider in good faith all comments from such other Party relating to such filings and correspondence. Legend shall also provide Janssen with reasonable prior notice and opportunity to review and comment and shall consider in good faith all reasonable comments from Janssen on any proposed prosecution of Legend Patent Rights or any other Patent Rights that claim priority to or common priority with any of the Legend Patent Rights, including any continuations, continuations-in-part, divisions, or substitute applications, any patents issued or granted from any such patents, and any confirmation patents or registration patents or patents of addition based on any such patents, and all foreign counterparts or equivalents of any of the foregoing. At the request of the other Party, the Party responsible for preparing, filing, prosecuting, validating, maintaining and extending a Patent Right shall make reasonable efforts to separately prosecute subject matter solely related to the Licensed CARs or Products separate from other subject matter which may be disclosed or claimed in any Patent Right hereunder, to the extent it may reasonably do so without jeopardizing or impairing any such Patent Rights.

8.3 **Third Party Infringement**. Each Party shall promptly notify the other of any apparent, threatened or actual infringement by a Third Party of any Legend Patent Rights, Janssen Patent Rights or Joint Patent Rights of which it becomes aware, to the extent such infringement is by a Licensed CAR or Product or pertains to a CAR T-Cell Therapy within the Field utilizing a CAR directed to BCMA (an "**Infringement**").

8.3.1 Enforcement in the United States and Janssen Territory.

(a) If an Infringement in the United States or Janssen Territory is with respect to any [\*\*\*] that (i) also Cover subject matter [\*\*\*], and (ii) do not Cover the [\*\*\*] may institute or undertake an Infringement Action (as defined below) with respect to such [\*\*\*] with respect to such Infringement and if so, [\*\*\*] shall have the right to do so and other matters pertaining to such an Infringement Action. Unless otherwise [\*\*\*], paragraphs (b) through (c) below shall apply to such Infringement Action with respect to such [\*\*\*] (*mutatis mutandis*, in the event the [\*\*\*] will initiate and undertake such Infringement Action).

(b) [\*\*\*] shall have the first right to institute infringement suits or take other action under the [\*\*\*], in each case to the extent the same is directed to an Infringement, including defense of a declaratory judgment action with respect to a potential Infringement [\*\*\*] (each, an "**Infringement Action**"), in each case in the [\*\*\*] shall have the right to institute such suit or other appropriate action in the name of [\*\*\*].

-80-

(c) In the event that [\*\*\*] institutes or undertakes an Infringement Action in accordance with Section 8.3.1(b) [\*\*\*] shall, and shall cause its Affiliates to, cooperate fully with [\*\*\*] in its efforts to protect such [\*\*\*], in each case with respect to such Infringement Action. Further, [\*\*\*] shall have a right, in [\*\*\*], to join or otherwise participate in such Infringement Action with legal counsel selected by [\*\*\*] apprised in writing of such Infringement Action and shall consider and take into account [\*\*\*] reasonable interests and requests regarding such Action.

(d) In the event that [\*\*\*] does not institute or undertake an Infringement Action in [\*\*\*] such Infringement Action may be brought, [\*\*\*] may institute or undertake and thereafter control such Infringement Action. In such event, [\*\*\*] shall have the right, but not the obligation, to institute or undertake such suit or other appropriate Infringement Action in the name of [\*\*\*].

8.3.2 <u>Conduct of Patent Litigation Under the Biologics Price Competition and Innovation Act</u>. If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the PHSA or equivalent in any other jurisdiction pertaining to and naming a Product as a reference product (a "**Biosimilar Application**") or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(1)(9)(C) of the PHSA), such Party shall, within [\*\*\*], notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(1)(1)(B)(iii) of the PHSA or equivalent in any other jurisdiction. If either Party receives any equivalent or similar certification or notice in any other jurisdiction, such Party shall, within [\*\*\*], notify and provide the other Party with copies of such communication. Regardless of the Party that is the "reference product sponsor" for purposes of such Biosimilar Application, (a) with respect to [\*\*\*] an Infringement Action against the filer of the Biosimilar Application in [\*\*\*] and (b) with respect to [\*\*\*] an Infringement Action against the filer of not to utilize, in whole or in part, the procedures provided in Section 351 of the PHSA in [\*\*\*]. If such Party institutes any such Infringement Action, then [\*\*\*]. Notwithstanding the foregoing, prior to [\*\*\*] initiating such an Infringement Action with respect to a [\*\*\*] shall determine whether such an Infringement Action with respect to a [\*\*\*] shall be initiated, and if so, which Party shall have the right to initiate and undertake such Action and other matters pertaining to such Action.

## 8.3.3 Enforcement in China.

(a) As between the Parties, [\*\*\*] Infringement Actions under the [\*\*\*], in each case to the extent the same is directed to an Infringement in Greater China. [\*\*\*] such suit or other appropriate action in the name of [\*\*\*].

(b) In the event that [\*\*\*] Infringement Action in accordance with Section 8.3.3(a), [\*\*\*] in any such Action, if required. Further, [\*\*\*] in such Infringement Action with legal counsel selected by [\*\*\*] of such Action and shall [\*\*\*] regarding such Infringement Action.

-81-

(c) In the event that [\*\*\*] an Infringement Action in Greater China for [\*\*\*] such Infringement Action, provided that prior to doing so, [\*\*\*]. In such event, [\*\*\*] Infringement Action in the name of [\*\*\*].

8.3.4 <u>Cooperation</u>. In any Infringement Action brought under the Legend Patent Rights, Janssen Patent Rights or Joint Patent Rights in any jurisdiction, each Party shall, and shall cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the Legend Patent Rights, Janssen Patent Rights and Joint Patent Rights and shall agree to be a party to such Infringement Action, if necessary. Notwithstanding the above, [\*\*\*]. Furthermore, Legend shall provide Janssen with reasonable prior notice and opportunity to review and comment and shall consider in good faith all reasonable comments from Janssen on any proposed arguments asserted or to be asserted in any enforcement action in the United States or Janssen Territory of any Legend Patent Rights other than an Infringement Action.

8.3.5 <u>Conduct of Certain Actions; Costs</u>. The Party initiating or undertaking an Infringement Action under this Section 8.3 shall have the sole and exclusive right to select counsel, mutually acceptable to the Parties (approval of such counsel not to be unreasonably withheld, conditioned or delayed), for any suit initiated by it pursuant to this Section 8.3. If required under applicable Law in order for the initiating Party to initiate or maintain such Infringement Action, the other Party or its Affiliate shall join as a party to the Action. Such other Party shall offer reasonable assistance to the initiating Party in connection therewith at no charge to the initiating Party except for reimbursement of reasonable Out-of-Pocket Costs that are incurred in rendering such assistance. The Out-of-Pocket Costs that are reasonably incurred by either the initiating Party or the other Party in connection with any Infringement Action pursuant to Section 8.3, including the reasonable fees and expenses of the counsel selected by the initiating Party, and the reasonable Out-of-Pocket Costs that are incurred by the other Party or its Affiliate in connection with such Action shall be included in the Shared Patent Costs. The other Party shall have the right to participate and be represented in any such suit by its own counsel.

8.3.6 <u>Recoveries(a)</u>. With respect to any Infringement Action initiated pursuant to this Section 8.3, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:[\*\*\*].

#### 8.4 Patent Invalidity Claims.

8.4.1 <u>Right to Respond</u>. If during the Term a Third Party initiates a patent opposition, reexamination, or other proceeding in the US Patent Office, European Patent Office or foreign equivalent, asserting that Legend Patent Rights, Janssen Patent Rights or Joint Patent Rights Covering Licensed CAR or the Product are invalid or otherwise unenforceable (an "**Invalidity Claim**"), the Parties shall mutually agree upon which Party shall control the response to such Invalidity Claim. If the Parties do not mutually agree upon which Party shall control the response, [\*\*\*]. For the avoidance of doubt, any response to a Third Party declaratory judgment action with respect to the Legend Patent Rights, Janssen Patent Rights or Joint Patent Rights or a counterclaim of invalidity or unenforceability made in the context of an Infringement Action, to the extent the same pertains to a potential Infringement, shall be deemed an Infringement Action and shall be governed by Section 8.3.

-82-

8.4.2 <u>Conduct of Certain Actions; Costs</u>. The non-controlling Party shall cooperate with the controlling Party in the preparation and formulation of a response to an Invalidity Claim, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. The controlling Party shall have the sole and exclusive right to select counsel for the response to such Invalidity Claim. The Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Invalidity Claim shall be included in Shared Patent Costs. The non-controlling Party shall also have the right to participate and be represented relative to such proceeding by its own counsel at its own expense. The controlling Party shall not settle or compromise any Invalidity Claim [\*\*\*]. To the extent any amounts are paid in settlement of such Invalidity Claim, the same shall be shared by the Parties as part of Pre-Tax Profit or Loss.

8.5 **Claimed Infringement**. Each of the Parties shall promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Janssen or Legend or any of their respective Affiliates with respect to the Development, Manufacture, Commercialization or use of any LCAR-B38M Equivalent or Product (any such suit or other action referred to herein as an "**Infringement Claim**"). In the event of any Infringement Claim, the Parties shall promptly, and within [\*\*\*] of written notice from either Party to the other thereof, discuss which Party shall control the response to such Infringement Claim, and if the Parties do not mutually agree upon which Party shall control, then [\*\*\*]. Upon the request of the Party controlling the response to the Infringement Claim. The other Party shall reasonably cooperate with the controlling Party at the controlling Party's expense in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation at its own expense. The damages or recovery obtained by the Third Party asserting such Infringement Claim shall be included as Allowable Expense and the Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Infringement Claim shall be included in Shared Patent Costs; provided that any amounts paid in settlement of an Infringement Claim shall not be included in Allowable Expenses unless such settlement was approved by the JSC.

8.6 **Patent Term Extensions**. Janssen shall have the sole discretion, after consultation with the JSC, to determine which Legend Patent Rights, Janssen Patent Rights or Joint Patent Rights, if any, are extended pursuant to U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country in the Janssen Territory. Legend and Janssen shall each cooperate and use reasonable efforts to gain such patent term extension. All filings for such extensions shall be made by the Party responsible for the prosecution of such Patent Rights. Notwithstanding the above, Janssen shall not extend, or enable a Third Party to extend, any Legend Patent Rights or Joint Patent Rights for a Product other than the Initial Product without the prior written consent of Legend.

## 8.7 Trademarks.

8.7.1 Selection of Product Trademarks. The JSC shall select and approve trademark(s) and service mark(s) to be used in connection with the Commercialization of the Products in the U.S., Janssen Territory and Greater China ("**Product Trademarks**"). The Parties expect to use the same Product Trademarks in the U.S., Janssen Territory and Greater China. If the JSC does not approve a global Product Trademark, Section 2.8.2(b) shall not apply and, instead, Janssen shall select a Product Trademark for the U.S. and Janssen Territory, and Legend shall select a Product Trademark for Greater China.

-83-

8.7.2 <u>Ownership of Product Trademarks</u>. Janssen shall own and retain all rights to Product Trademark(s) in the U.S. and Janssen Territory, and all goodwill associated therewith throughout the U.S. and Janssen Territory, and Legend shall own and retain all rights to Product Trademark(s) in Greater China, and all goodwill associated therewith throughout Greater China. Each Party shall own rights to any Internet domain names incorporating the Product Trademark(s) owned by such Party or any variation or part of such Product Trademark(s) as its URL address or any part of such address.

8.7.3 <u>Trademark License</u>. Janssen hereby grants, and shall cause its Affiliates to grant, to Legend a royalty-free, fully paid up, co-exclusive license to use the Product Trademark(s) and Internet domain names described in Section 8.7.2 solely for the purpose of Commercializing the Product in the U.S. and the Janssen Territory in the Field in accordance with this Agreement.

8.7.4 <u>Product Trademarks and Co-Branding</u>. Unless otherwise agreed by the Parties, all packaging materials, labels and Promotional Materials relating to Products in the Field shall display the Product Trademark(s) and no other product-specific trademarks or branding. In addition, all such materials used in the U.S. and Janssen Territory shall display the trade names of both Janssen and Legend in equal size and prominence, to the extent permitted by applicable Law, as determined by the JSC. The trade dress, style of packaging and the like with respect to each Product in the Field within the U.S. shall be approved by the USCC. The trade dress, style of packaging and the like with respect to each Product in the Field within the Janssen Territory shall be approved by the JSC.

8.7.5 <u>Enforcement</u>. In the event either Party becomes aware of any infringement of any Product Trademark by a Third Party, such Party shall promptly notify the other Party. Janssen shall be responsible in its sole discretion for all such enforcement efforts, including the cost thereof, for infringements in the U.S. and Janssen Territory, and Legend shall be responsible in its sole discretion for all such enforcement efforts, including the cost thereof, for infringements in Greater China, and each Party shall keep the other reasonably informed of such efforts. Upon either Party's request, the other shall reasonably cooperate with the requesting Party in such enforcement efforts.

## ARTICLE IX CONFIDENTIALITY AND PUBLICITY

9.1 Non-Disclosure and Non-Use. During the Term and for a [\*\*\*], the Party (the "Receiving Party") receiving or holding Confidential Information of the other Party (the "Disclosing Party") shall, and shall cause its Affiliates to: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 9.3 and 9.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement, including those expressly permitted in Sections 9.3 and 9.4, or to exercise its rights or perform its obligations under this Agreement (it being understood that this ARTICLE IX shall not create or imply any rights or licenses not expressly granted under this Agreement). As used herein, "Confidential Information" shall mean all non-public or proprietary information disclosed orally, visually, in writing or other form by or on behalf of a Party (or an Affiliate or representative of such Party) to the other Party (or to an Affiliate or representative of such Party) pursuant to or in connection with this Agreement, whether prior to, on or after the Effective Date. The Parties agree that all Data and Know-How within the Collaboration Intellectual Property shall also be deemed the Confidential Information of both Parties, regardless of whether such Data or Know-How is disclosed by one Party to the other Party.

-84-

9.2 **Exceptions**. The obligations in Section 9.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent written evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this

(b) is known to the Receiving Party or any of its Affiliates (to the extent the use and disclosure thereof is not restricted by any obligation to the Disclosing Party or a Third Party), prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party that, to the Receiving Party's knowledge after due inquiry, is not bound by a duty of confidentiality to the Disclosing Party or restriction on its use, to the extent the Receiving Party has the right to use and disclose such information;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement, generally known or available to the public, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates, in each case without the use of or reference to the Confidential Information of the Disclosing Party.

9.3 **Authorized Disclosure**. The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement:

(a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by and in accordance with this

Agreement;

Agreement;

(b) as reasonably required in generating Regulatory Documentation and filing for and obtaining Regulatory Licenses for the Product as permitted by this Agreement;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) complying with applicable Law (including regulations promulgated by securities exchanges, but subject to Section 9.4) or court or administrative orders;

(e) complying with any obligation under this Agreement;

-85-

(f) in communications with existing or bona fide prospective acquirers, merger partners, financing sources, investment bankers, lenders or investors, and consultants and advisors of the Receiving Party in connection with transactions or bona fide prospective transactions with the foregoing or in other similar corporate or financing transactions, in each case on a need-to-know basis and under appropriate confidentiality provisions substantially equivalent to those of this Agreement; provided, however, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Third Party receiving such Confidential Information; and provided, further, however, that if the Third Party recipient is pharmaceutical or biotechnology company, the Receiving Party shall not disclose any Confidential Information that is [\*\*\*]; or

(g) to its Affiliates and existing or prospective (sub)licensees, subcontractors, consultants, agents, advisors and others, in each case to the extent reasonably necessary or useful for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound under a written agreement containing confidentiality and non-use provisions that are consistent with those set forth in this Agreement, <u>provided</u> that the Receiving Party shall remain responsible for any violation of the confidentiality and non-use provisions in this Agreement by any Person who receives Confidential Information pursuant to this Section 9.3(g) (as if such Person was directly bound by such provisions).

If and whenever any Confidential Information is disclosed in accordance with this Section 9.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 9.3(c) or Section 9.3(d) (other than to comply with Securities Disclosure Obligations, which disclosures are covered by Section 9.4.2), it will, except where impracticable or not legally permitted, give [\*\*\*] days' advance notice (or, if [\*\*\*] days' notice is not possible under the circumstances, reasonable advance notice) to the other Party of such disclosure, give the Disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information from disclosure (but no less than reasonable efforts). In addition, the Parties and their respective Affiliates (and each employee, representative, or other agent of the Parties) may disclose to any and all persons, without limitation of any kind, the United States federal tax treatment and tax structure of the transactions set forth in this Agreement and all materials of any kind (including opinions or other tax analyses) that are provided to the Parties or their respective Affiliates relating to such tax treatment and tax structure.

#### 9.4 Confidential Terms.

9.4.1 This Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 9.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement, including information relating to the Products: (a) to certain Third Parties in accordance with Section 9.3(f); (b) to the extent required, in the reasonable opinion

-86-

of such Party's counsel, to comply with the rules, requirements and regulations (the "**Securities Disclosure Obligations**") promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market, Hong Kong Stock Exchange or similar security Governmental Authorities or stock market in other countries ("**Securities Authority**").

9.4.2 If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with clause (b) of Section 9.4.1, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information. The Parties will use reasonable efforts in connection with such disclosure to seek the confidential treatment of any such provision or information. The Parties shall cooperate, each at its own expense, in such disclosure, including without limitation such confidential treatment request. The Parties will reasonably cooperate in responding promptly to any comments received from the Securities Authority with respect to such disclosure in an effort to achieve confidential treatment of redacted provisions or information; provided, however, that a Party shall be relieved of such obligation to seek confidential treatment for a provision or information requested by the other Party if such treatment is not achieved after the second round of responses to comments from the Securities Authority.

## 9.5 Publicity.

9.5.1 <u>Initial Press Releases</u>. Each Party may, but is not obligated to, make a public announcement of the execution of this Agreement in the forms attached as <u>Schedule 9.5.1A</u> and <u>Schedule 9.5.1B</u> to this Agreement, which shall be issued in a mutually agreed way, after the Effective Date, while adhering to both Parties' obligations under the respective local stock market and other legal regulations.

9.5.2 <u>Further Publicity</u>. Except as required to comply with applicable Law or as permitted by Section 9.3, 9.4 or 9.5.1, (i) if either Party intends to issue any press release or make other public statement disclosing any results or developments regarding the Products in the Field or other activities in connection with this Agreement, it shall give the other Party a reasonable opportunity to review and comment [\*\*\*] and shall consider any such comments in good faith and in the case of press releases, (ii) shall not issue such press release without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. If a Party intends to issue such a press release or other public statement as required to comply with applicable Law, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure. Notwithstanding the foregoing, once information relating this Agreement has been publicly disclosed as permitted under this Agreement, neither Party shall be required to obtain the other Party's consent or provide notice of its further public disclosure, provided that such information remains accurate and not misleading in all material respects at the time of such further public disclosure. The Parties shall not proactively or reactively make any statements to the media on [\*\*\*] unless both Parties agree. If both Parties intend to issue press releases or make other public statements with respect to the same event or matter, then the Parties shall cooperate in good faith with respect to the timing of such releases or statements.

9.6 **Prior Non-Disclosure Agreement**. As of the Effective Date, the terms of this ARTICLE IX shall supersede the Mutual Confidentiality Agreement by and between Janssen Research & Development, LLC and Legend Biotech Co. Ltd. dated as of June 6, 2017 and the confidentiality terms of that certain letter agreement between the same entities dated on or about August 28, 2017. Any information disclosed pursuant to either of such agreements by a Party or its Affiliates that was deemed "Confidential Information" under either of such agreements shall be deemed Confidential Information of such Party under this Agreement.

-87-

9.7 **Equitable Relief**. Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this ARTICLE IX. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE IX.

#### 9.8 Publications.

9.8.1 <u>Global Publication Strategy</u>. The JDC shall develop, and the JSC shall approve, a global publication strategy for the Development, CMC Development and Commercialization activities related to the Products in the Field (the "**Global Publication Strategy**") that is consistent with the GDP, CMC Development Plans and the Commercialization Plans. The Parties agree that the Global Publication Strategy shall permit the Parties to publish the results of the Clinical Studies for the Product in the Field in scientific journals and to provide public notice consistent with industry practices including at least as much notice as stated in the Johnson & Johnson Policy of the Registration and Reporting of Results of Johnson & Johnson Pharmaceutical Company Sponsored Clinical Studies. The publication and presentation of the results of Development and CMC Development carried out on the Products in the Field shall be governed by the Global Publication Strategy, and the Parties shall conduct such publication activities in accordance with the Global Publication Strategy. The Parties acknowledge that Legend has entered into agreements with Third Party clinical investigators prior to the Effective Date which permit such Third Parties to make publications regarding Products, and agree that the Global Publication Strategy shall reasonably accommodate the ability of Third Party clinical investigators, academic institutions and other similar entities to make such publications. Notwithstanding the foregoing (or Section 9.8.2 below), the Global Publication Strategy shall not be construed to limit a Party's rights to make disclosures pursuant to Section 9.5 above.

9.8.2 <u>Approval of Publications</u>. Prior to publishing or presenting the results of any Clinical Studies involving the Products, each Party (the "**Publishing Party**") shall provide to the other Party (the "**Reviewing Party**") a copy of any proposed abstracts, manuscripts or summaries of presentations that such Publishing Party intends to publish or present ("**Proposed Publications**"). Each Party shall designate a Person or Persons who shall be responsible for reviewing (or having reviewed) all Proposed Publications submitted by the other Party. [\*\*\*] a Reviewing Party's designated Person shall notify the Publishing Party in writing whether the Reviewing Party has an objection to the Proposed Publications because the Reviewing Party reasonably believes it needs to seek patent protection. If a Reviewing Party notifies a Publishing Party that it has such an objection, the Publishing Party shall reasonably cooperate with the Reviewing Party to address such concern and, upon the Reviewing Party's request, shall delay publication in order to enable the preparation and filing of a patent application on any patentable subject matter described in the manuscript for [\*\*\*]; provided, however, that such delay shall not prejudice a Party's timely prosecution and maintenance of its intellectual property rights hereunder. The Publishing Party shall reasonably consider any other suggestions of the Reviewing Party that are provided in a timely manner and, after doing so and after [\*\*\*] requested for filing of a patent application, may proceed with the Proposed Publication. With respect to any proposed abstracts, manuscripts or summaries of presentations that investigators or other Third Parties propose to publish or present, such materials shall be subject to review under this Section 9.8.2, to the extent that Legend or Janssen, as the case may be, has the right to do so.

-88-

#### ARTICLE X REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

10.1 **Representations of Authority**. Legend and Janssen each represents and warrants to the other Party that, as of the Effective Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement.

10.2 **Consents**. Legend and Janssen each represents and warrants to the other Party that, except for any Regulatory Licenses, pricing or reimbursement approvals, manufacturing approvals or similar approvals necessary for the Exploitation of the Products, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement (as contemplated as of the Effective Date) have been obtained by the Effective Date, except for those that would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the Exploitation of the Products.

10.3 **No Conflict**. Legend and Janssen each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate in any material respect any requirement of Laws existing as of the Effective Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date, except, in each case, for those conflicts, violations, breaches or defaults that would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the Exploitation of the Products.

10.4 **Enforceability**. Legend and Janssen each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, except as such enforcement may be limited by bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other laws affecting the rights of creditors generally and general equitable principles (whether considered in a proceeding in equity or at law).

10.5 Additional Representations and Warranties of Legend. Legend represents and warrants to Janssen that, as of the Effective Date:

10.5.1 Neither Legend nor any of its Affiliates is party to any license agreement with a Third Party in effect on the Effective Date pursuant to which Legend (or their respective Affiliates) is obligated to pay any amount to such Third Party for the practice of any intellectual property rights with respect to Legend's (or their respective Affiliates') Development, Manufacture or Commercialization of the Initial Product in the Field pursuant to the Agreement.

-89-

10.5.2 Legend or one of its Affiliates is the sole and exclusive owner of, or otherwise Controls, the Legend Intellectual Property. Legend has all rights necessary to grant the licenses under the Legend Intellectual Property that it grants to Janssen in this Agreement.

10.5.3 Legend has not previously (i) licensed, assigned, transferred, or otherwise conveyed any right, title or interest in, to or under the Legend Patent Rights, or (ii) otherwise granted any rights, in each case to any Third Party in any way that would legally conflict with the licenses and rights granted to Janssen under this Agreement.

10.5.4 The Legend Patent Rights are free and clear of any liens, charges and encumbrances that would conflict with the license grants to Janssen hereunder.

10.5.5 To the best of Legend's knowledge, neither Legend nor any of its Affiliates or their respective current or former employees has misappropriated any of (i) the Know-How necessary or used by Legend for the Exploitations of the Licensed CARs and Products by Legend as of the Effective Date, or (ii) the Legend Know-How, in each case from any Third Party, and Legend is not aware of any claim by a Third Party that such misappropriation has occurred.

10.5.6 Legend has not received any written notice of any existing or threatened actions, suits or other proceedings pending against it with respect to the Legend Intellectual Property (other than patent office actions or the actions of any Regulatory Authority) that have not already been disclosed to Janssen.

10.5.7 Except as already disclosed, Legend has not received written notice from a Third Party claiming that a patent owned by such Third Party would be infringed by the manufacture, use, sale, offer for sale or import of Initial Product in the U.S. or Janssen Territory, and no Third Party has threatened in writing to make any such claim.

10.5.8 The Legend Patent Rights listed in <u>Schedule 1.77</u> represent all Patent Rights that Legend or any of its Affiliates owns or Controls that Cover or disclose any invention necessary or used by Legend for the Exploitation of the Initial Product and the Licensed CAR utilized therein as of the Effective Date. The Legend Patent Rights that are existing as of the Effective Date are listed in <u>Schedule 1.77</u>. Legend: (i) is not aware of any claim made against it asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of listed Legend Patent Rights other than patent office actions or the actions of any Regulatory Authority and, (ii) is not aware of any claim made against it challenging Legend's Control of listed Legend Patent Rights or making any adverse claim of ownership of the rights of Legend to listed Legend Patent Rights. Legend believes that each of the patent applications listed in <u>Schedule 1.77</u> as of the Effective Date (or alternatively a related Patent Right of such patent application) will issue as a Patent Right in the U.S., EPO, Japan and China (as applicable) with generic or specific claims Covering the composition of matter of Initial Product and, if issued, that such claims would not be unenforceable as to such Initial Product.

10.5.9 Legend has (i) prepared, maintained and retained all Regulatory Documentation and Regulatory Licenses for the Initial Product pursuant to and in accordance in all material respects with all applicable law, including, as applicable, GLP and Legend has not, to its knowledge, made any false and misleading statements regarding such Regulatory Documentation and Regulatory Licenses; (ii) conducted, and has used reasonable efforts to cause its contractors and

-90-

consultants to conduct, all studies, tests and pre-clinical trials of the Products conducted prior to, or being conducted on, the Effective Date in accordance with the applicable experimental protocols, procedures and controls pursuant to accepted professional scientific standards, accepted ethical standards and applicable law, including, as applicable, GLP in all material respects; (iii) except as disclosed or provided access to in writing by Legend to Janssen prior to the Effective Date, no adverse event involving human subjects reported to Legend has occurred in connection with any study, test or pre-clinical trial of the Products; and (iv) to the best of Legend's knowledge, Legend has made available to Janssen true, correct and complete copies or originals of all material information relating to the Development, Manufacture and Commercialization of the Products as conducted by or on behalf of Legend to date, including complete and correct copies of the following (to the extent there are any): adverse event reports; clinical study reports and material study data; and Regulatory Authority inspection reports, notices of adverse findings, warning letters, Drug Approval Applications filings and letters and other material correspondence with Regulatory Authorities.

10.5.10 Legend has been and all activities related to the Initial Product have been conducted in compliance with applicable Law in all material respects. Legend has all Governmental Approvals necessary for its activities related to the Products conducted prior to the Effective Date.

10.5.11 There is no claim, action, suit, arbitration, inquiry, audit or investigation by or before any Governmental Authority pending, or to Legend's knowledge pending, against Legend or involving any of the Products. There is no award, stay, writ, judgement, injunction, decree or similar order of any Governmental Authority outstanding, or to Legend's knowledge pending, involving Legend or any of the Products.

10.5.12 All interactions by Legend with hospitals, doctors, health care providers and key opinion leaders have been conducted in compliance with applicable Law, and the terms and conditions of any contractual or other business relationships, including the provision of compensation or other consideration, between Legend and such entities, groups and individuals are in compliance with applicable Law in all material respects.

10.5.13 All biological material and personal data collected, processed or disclosed from clinical trial subjects for the Initial Product have been and are being collected, processed or disclosed in compliance with applicable Laws. Legend has secured all required patient consents for the collection, processing and disclosure of such data or biological materials.

10.5.14 Legend, together with its Affiliates, has access to sufficient cash or lines of credit or other sources of funds, including the amounts available to Legend under Section 7.3.5, to satisfy its financial obligations under this Agreement.

10.5.15 All of the interests, assets and rights of Legend and its Affiliates related to the Licensed CARs and Products are owned by Legend or Legend Biotech Corporation (Cayman), or by a subsidiary corporation all of the equity securities of which are owned by Legend or Legend Biotech Corporation (Cayman).

-91-

10.6 **No Warranties**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE LICENSED CARS AND PRODUCTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE EXPLOITATION OF THE LICENSED CARS AND PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE PRODUCTS WILL BE ACHIEVED.

10.7 **No Debarment or Exclusion**. Each Party represents and warrants that, as of the Effective Date, neither it nor any of its Affiliates, nor any of their officers, employees or agents has been debarred or is subject to debarment as authorized by Section 306 of the United States Federal Food, Drug, and Cosmetic Act or has been excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7, and neither Party nor any of its Affiliates will use in any capacity, in connection with the Exploitation of the Products in the Field, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, who is the subject of a conviction described in such section, who has been excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7 or who has been convicted of any crime or engaged in any conduct for which such Person could be excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7. Each Party agrees to inform the other Party in writing immediately if it, any of its officers, employees or agents, or any Person who is performing services hereunder is debarred, is the subject of a conviction described in Section 306 of the United States Federal Food, Drug, and Cosmetic Act, is excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7 or is convicted of any crime for which such Person could be excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment, exclusion or conviction of such Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Exploitation of the Products.

## 10.8 Compliance with Anti-Corruption Laws.

10.8.1 Notwithstanding anything to the contrary in the Agreement, each Party hereby agrees that:

(a) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the U.S. Foreign Corrupt Practices Act, collectively "Anti-Corruption Laws") that may be applicable to such Party in such country; and

(b) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party related to the transaction with the purpose of influencing decisions related to either Party and/or its business in a manner that would violate Anti-Corruption Laws;

-92-

(c) Legend shall designate an individual within its organization to receive training from Janssen on Anti-Corruption Laws as well as applicable rules on interactions with health care professionals, as mutually agreed to by the Parties. Such designated individual shall then provide such training on Anti-Corruption Laws, using applicable training materials to be provided by Janssen, on at least an annual basis to all persons employed by Legend who perform any activities under this Agreement and interact with government officials or health care professionals in the normal course of their responsibilities. Upon the Parties' mutual agreement, such training may also be provided directly by Janssen to such employees of Legend. Legend and Janssen shall each use reasonable efforts to provide such training or training materials to any contractors or subcontractors of such Party engaged to perform activities under this Agreement where such contracted or subcontracted activities include responsibility for, directly or indirectly, interacting with Public Officials. Legend may fulfill its obligation under the preceding sentence by requesting appropriate materials from Janssen and forwarding such materials, if any, received from Janssen to the applicable contractor or subcontractor. In the event that Legend is not able to obtain a contractor or subcontractor and not object to reasonable efforts of Janssen to provide such training or materials to the applicable contractor or subcontractor. Any training and materials provided by Janssen does not relieve Legend of any obligations it has independent of the Agreement and Legend shall not rely on Janssen's training and materials for any such obligations;

(d) it shall, on an annual basis upon request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or will provide details of any exception to the foregoing; and

(e) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 10.8, and upon request of the other Party, up to once per year and upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 10.8. Acceptance of a proposed Third Party auditor may not be unreasonably withheld by either Party. It is expressly agreed that the costs related to the Third Party auditor will be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

10.8.2 Each Party hereby represents and warrants to the other Party that, to its knowledge as of the Effective Date, neither such Party nor any of its Subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of such Party or any of its subsidiaries or any of their Affiliates:

(a) has taken any action in violation of any applicable anti-corruption law, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78 dd-1 et seq.), to the extent applicable; or

-93-

(b) has corruptly, offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 10.8.4 below), for the purposes of:

(i) influencing any act or decision of any Public Official in his official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever;

in each case in a manner that violates applicable Anti-Corruption Laws.

10.8.3 Each Party hereby represents and warrants to the other Party that, as of the Effective Date, none of the officers, directors, employees of Legend or of any of its Subsidiaries or agents acting on behalf of Legend or any of its Subsidiaries, in each case that are employed or reside outside the United States, are themselves Public Officials.

10.8.4 For purposes of this Section 10.8, "Public Official" means:

(a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division;

(b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility;

(c) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and

(d) any person acting in an official capacity for any government or government entity, enterprise or organization identified

above.

10.9 **Insurance**. Beginning at the time any Product is being distributed, sold or Commercialized, each Party will secure and maintain in full force and effect adequate insurance coverage against its liabilities under this Agreement including commercial general liability and product liability insurance in an amount not less than [\*\*\*]. Such insurance shall be maintained beyond the expiration or termination of this Agreement for [\*\*\*]. Prior to the initiation of any Clinical Study, the Party responsible for the applicable Clinical Study shall secure and maintain in full force and effect clinical trial insurance in compliance with applicable Law in those territories where Clinical Studies are conducted. Upon written request, each Party shall provide the other with a certificate of insurance evidencing the required coverage.

-94-

### ARTICLE XI INDEMNIFICATION

11.1 General Indemnification by Legend. Legend shall indemnify and hold harmless Janssen, its Affiliates and their respective directors, officers, employees and agents (collectively, the "Janssen Indemnified Parties"), from, against and in respect of any and all Actions, damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, Government Orders, taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts fees and expenses), resulting from a claim or Action of a Third Party or Governmental Authority (collectively, "Losses"), incurred or suffered by the Janssen Indemnified Parties or any of them as a result of, arising out of or relating to: (i) any breach of, or inaccuracy in, any representation or warranty made by Legend in this Agreement, or any breach or violation of any covenant or agreement of Legend in or pursuant to this Agreement; (ii) the gross negligence, intentional misconduct or violation of Law by Legend, its Affiliates and their respective directors, officers, employees and agents or any of them; or (iii) Legend's and its Affiliates' Exploitation of the Initial Product before the Effective Date (provided that such Losses shall be deemed not to include Losses arising after the Effective Date and resulting from, arising out of or relating to Exploitation of the Initial Product on or after the Effective Date which are a result of, arise out of or relate to the design of the Initial Product (e.g., design defect and intellectual property infringement claims)) except, in each case, to the extent caused by and attributable to the gross negligence, willful misconduct or violation of Law of or by Janssen or any of the other Janssen Indemnified Parties, or any breach or violation of any covenant or agreement in or pursuant to this Agreement by Janssen or any of the other Janssen Indemnified Parties. For clarity, Losses shall not include any losses or damages sustained by any Janssen Indemnified Party as a result of the actions described in clauses (i) or (ii) of the immediately preceding sentence, except to the extent that such losses or damages are paid by a Janssen Indemnified Party to a Third Party or Governmental Authority as a result of a claim or Action of a Third Party or Governmental Authority.

11.2 **General Indemnification by Janssen**. Janssen shall indemnify and hold harmless Legend, its Affiliates and their respective directors, officers, employees and agents (collectively, the "**Legend Indemnified Parties**"), from, against and in respect of any and all Losses incurred or suffered by the Legend Indemnified Parties or any of them as a result of, arising out of or relating to: (i) any breach of, or inaccuracy in, any representation or warranty made by Janssen in this Agreement, or any breach or violation of any covenant or agreement of Janssen in or pursuant to this Agreement; or (ii) the gross negligence, intentional misconduct or violation of Law by Janssen, its Affiliates and their respective directors, officers, employees and agents or any of them, except, in each case, to the extent caused by and attributable to the gross negligence, willful misconduct or violation of Law of or by Legend or any of the other Legend Indemnified Parties, or any breach or violation of any covenant or agreement in or pursuant to this Agreement by Legend or any of the other Legend Indemnified Parties. For clarity, Losses shall not include any losses or damages sustained by any Legend Indemnified Party to a Third Party or Governmental Authority as a result of a claim or Action of a Third Party or Governmental Authority.

11.3 **Product Liability Costs**. Except with respect to such portion (if any) of Product Liability Costs that are Losses entitled to indemnification under Section 11.1 or Section 11.2, all Product Liability Costs (the "**Shared Product Liability Costs**") prior to expiration or termination of the Term shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in the Financial Exhibit.

-95-

#### 11.4 Claims for General Indemnification.

11.4.1 <u>Notice</u>. A person entitled to indemnification under Sections 11.1, 11.2 and 11.3 (an "**Indemnified Party**") shall give prompt written notification to the person from whom indemnification is sought (the "**Indemnifying Party**") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought (each, a "**Claim**") or, if earlier, upon the assertion of any such Claim by a Third Party; <u>provided</u>, <u>however</u>, failure by an Indemnified Party to give notice of a Claim as provided in this Section 11.4.1 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice. Each claim notice shall describe in reasonable detail the basis for such claim (the "**Claim Basis**"), and specify the amount or the estimated amount of Losses actually incurred or paid by the Indemnified Party as a result of the Claim Basis, to the extent then ascertainable (the "**Claim Amount**").

11.4.2 <u>Defense</u>. Within [\*\*\*] days after delivery of a notice of any Claim in accordance with Section 11.4.1, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of, and have sole power to direct, the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense.

11.4.3 <u>Cooperation</u>. The Party controlling the defense of any Claim shall keep the other Party advised of the status of such Claim and the defense thereof and shall reasonably consider recommendations made by the other Party with respect thereto. The other Party shall cooperate fully with the Party controlling such defense and its Affiliates and agents in defense of the Claim, at the Indemnifying Party's expense.

11.4.4 <u>Settlement</u>. The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than obligations to pay amounts for which the Indemnifying Party indemnifies the Indemnified Party) hereunder without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld.

## 11.5 Conduct of Product Liability Claims.

11.5.1 Each of the Parties shall promptly notify the other in the event that any Third Party asserts or files any products liability claim or other Action relating to alleged defects in the Product (whether design defects, manufacturing defects or defects in sales or marketing) ("**Third Party Products Liability Action**") against such Party. In the event of a Third Party Products Liability Action against such a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to join or

-96-

otherwise participate in such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party. The Party named in such Third Party Products Liability Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. In the event of a Third Party Products Liability Action against both Parties, the Parties shall mutually agree upon which Party shall control the response to such Third Party Products Liability Action. In the event the Parties do not agree, both Parties may appear in the action, each represented by its own counsel and shall reasonably cooperate in the defense thereof.

11.5.2 The non-controlling Party of a Third Party Products Liability Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Products Liability Action, and in taking other steps reasonably necessary to respond to such Third Party Products Liability Action. The controlling Party shall have the sole and exclusive right to select its counsel for the defense to such Third Party Products Liability Action. If required under applicable Law in order for the controlling Party to maintain a suit in response to such Third Party Products Liability Action, the non-controlling Party shall join as a party to the suit. Each Party shall pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings related to such Third Party Products Liability Action, including the fees and expenses of the counsel selected by it. The non-controlling Party shall also have the right to participate and be represented in any such suit by its own counsel at its own expense. All Out-of-Pocket Costs and FTE Costs incurred in connection with any litigation or proceeding related to such Third Party Products Liability Action in determining Party shall be Product Liability Costs and shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in the Financial Exhibit, subject to Section 11.3. The controlling Party shall not settle or compromise any Third Party Products Liability Action without the consent of the other Party, which consent shall not be unreasonably withheld.

## ARTICLE XII TERM AND TERMINATION

12.1 **Term**. Unless terminated earlier in accordance with this ARTICLE XII, this Agreement shall remain in force for the period commencing on the Effective Date and ending upon the expiration (whether by the terms of this Agreement or by operation of Law) of all payment obligations under Section 7.4 of this Agreement (which for clarity shall survive as long as any Product is being sold) (the "**Term**").

12.2 **Termination for Material Breach**. Upon any material breach of this Agreement by a Party (the "**Breaching Party**"), the other Party (the "**Non-Breaching Party**") may terminate this Agreement by providing 90 days' written notice to the Breaching Party, which notice shall, in each case (i) expressly reference this Section 12.2, (ii) reasonably describe the alleged breach which is the basis of such termination and (iii) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period, <u>provided</u> that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to the Product. Notwithstanding the foregoing, if such breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses Diligent Efforts to cure such breach in accordance with such written plan, <u>provided</u> that no such extension shall exceed 90 days without the consent of the Non-Breaching Party.

-97-

### 12.3 Termination by Janssen Unilaterally.

12.3.1 Janssen may terminate this Agreement in its entirety or with respect to any Region without cause, upon one hundred eighty (180) days' prior written notice to Legend, which notice expressly references this Section 12.3.1. For such purposes, a "**Region**" shall mean [\*\*\*]

12.3.2 Janssen may terminate this Agreement in its entirety if an unforeseen material safety event (whether as to the type of event or magnitude or severity of the safety issue) occurs, upon sixty (60) days' prior written notice to Legend, which notice expressly references this Section 12.3.2.

#### 12.3.3 [\*\*\*]

12.3.4 In the event of termination pursuant to this Section 12.3, during the period from the date of Janssen's notice of termination until the effective date of termination: (i) all licenses and rights of Janssen under this Agreement shall be non-exclusive, (ii) the provisions of Section 12.4.1(g) shall apply, (iii) in accordance with Section 3.6.5, the Exclusivity Period (if then in effect) shall terminate on the date of Janssen's notice of termination and (iv) this Agreement shall otherwise remain in full force and effect until the effective date of such termination.

# 12.4 Effects of Termination or Expiration.

12.4.1 <u>Termination for Any Reason</u>. In the event of expiration or any termination of this Agreement, the provisions of this Section 12.4.1 shall apply.

(a) <u>Accrued Obligations</u>. Expiration or termination of this Agreement for any reason shall not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination. The Parties acknowledge and agree that any outstanding Excess Amounts are not liabilities or obligations that have accrued on behalf of Legend and are only reimbursable to Janssen as set forth in Section 7.3.5 (or as required under Section 14.2.1, if applicable) prior to such expiration or termination, and Legend shall have no obligation to reimburse or repay Janssen for any unrecouped Excess Amounts outstanding on the effective date of termination of this Agreement after the final reconciliation of Pre-Tax Profit or Loss under Section 7.4 in accordance with Reconciliation Procedures and the Financial Exhibit.

(b) <u>Non-Exclusive Remedy</u>. Notwithstanding anything herein to the contrary, expiration or termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

-98-

(c) Survival. In the event of any expiration or termination of this Agreement, the provisions set forth in:

(i) Articles I, IX (other than Section 9.8), and XI (provided that Section 11.5 shall apply only for Third Party Products Liability Actions pertaining to activities during the Term);

(ii) Sections 2.6.2 (together with Sections 2.7, 2.8.1, 2.8.2, 2.8.4, 2.8.5 and 2.9, in each case solely to the extent necessary to reconcile Development Costs, Manufacturing Plan Costs, CMC Development Costs and Pre-Tax Profit or Loss incurred or earned during the Term), 3.4, 3.5, 3.8, 3.9, 3.10, 4.6.3(a) (other than the first sentence), 4.6.3(b) (other than the first sentence and only with respect to the Right of Reference granted under clause (ii) and only with respect to Regulatory Documents and Regulatory Licenses arising during the Term), 4.6.3(c), (d) and (e) (in each case to the extent that Sections 4.6.3(a) and 4.6.3(b) survive), 4.9, 4.10.7, 6.2.4 (and any other provisions of ARTICLE VI that survive termination thereunder or that are necessary to give effect to the provisions of Section 6.2.4), 6.3.7, 7.3.3-7.3.4 (in each case to the extent necessary to reimburse Development Costs, Manufacturing Plan Costs and CMC Development Costs incurred during the Term), 7.3.5(h)(v), 7.4.3-7.4.4 (in each case to the extent necessary to reconcile Pre-Tax Profit or Loss based on Allowable Expenses incurred, Supply Mark-up or lease payments paid or received or Other Income or Net Trade Sales earned, during the Term), 7.6 (for the period set forth therein), 7.7, 7.8 (with respect to tax matters relating to the Term), 7.9, 7.10, 8.1, 10.6, 10.9 (for the time period set forth therein), 12.4, 13.1, 13.3, 14.1, 14.3, 14.4, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12, 14.13 and 14.14 and the Financial Exhibit (in each case to the extent necessary to reconcile Pre-Tax Profit or Loss based on Allowable Expenses incurred, Supply Mark-up or lease payments paid or received on Allowable Expenses incurred, Supply Mark-up or lease payments paid or received or Allowable Expenses incurred, Supply Mark-up or lease payments paid or received or Other Income or Net Trade Sales earned, during the Term); and

(iii) Solely for purposes of Committee Matters to be decided by the JMC after termination to the extent provided in this Agreement or the Facility Use Agreements: Sections 2.1, 2.5, 2.7, 2.8.1, 2.8.2 [\*\*\*], 2.8.6 and 2.9;

as well as any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, shall survive. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement shall survive to the extent required. Except as otherwise provided in this ARTICLE XII, all rights and obligations of the Parties under this Agreement, including any licenses and sublicenses granted hereunder, shall terminate upon expiration or termination of this Agreement for any reason.

(d) <u>Regulatory Documentation and Data</u>. Janssen shall promptly assign and transfer to Legend all Regulatory Documentation and Regulatory Licenses for Reverted Products (as defined below) that are held or controlled by or under authority of Janssen or its Affiliates as of the effective date of termination, and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Documentation and Regulatory Licenses to Legend. Janssen shall also promptly transfer control of and responsibility for maintaining the global safety database for Products to Legend, and Legend shall accept such transfer and responsibility. If applicable Law prevents or delays the transfer of ownership of any such Regulatory Documentation or Regulatory Licenses to Legend, Janssen shall grant, and does hereby grant, to Legend an exclusive and irrevocable right of access and reference to such Regulatory

-99-

Documentation and Regulatory Licenses for the Reverted Products, and shall cooperate fully to make the benefits of such Regulatory Documentation and Regulatory Licenses available to Legend or its designee(s). [\*\*\*] Janssen shall provide to Legend copies of: (i) all such Regulatory Documentation and Regulatory Licenses; and (ii) of all Data and other Know-How in its or its Affiliate's possession and Control pertaining to any Reverted Product, or the manufacture or use thereof, to the extent actually used in connection with a Reverted Product during the Term (such Know-How, the "**Reverted Know-How**"). For clarity, Legend shall be free to disclose such Regulatory Documentation, Regulatory Licenses and Data and Know-How in connection with the manufacture, development and commercialization of Reverted Products anywhere in the world.

(e) Licenses. Janssen hereby grants, and shall cause its Affiliates to grant, to Legend, effective upon, as applicable, the notice of termination by Janssen under Section 12.2 or 12.3, or the effective date of termination by Legend under Section 12.2, a worldwide, irrevocable, fully paid-up, exclusive license, with the right to grant and authorize sublicenses, under the Janssen Intellectual Property and Janssen's interest in the Collaboration Intellectual Property to make, have made, use, sell, offer for sale import and otherwise Exploit Reverted Products; provided, however, that if any such Patent Rights or Know-How was in-licensed or acquired from a Third Party, and is subject to payment or other obligations to such Third Party, Janssen shall promptly disclose such obligations to Legend in writing and such Patent Rights and Know-How shall be subject to the license granted in this Section 12.4.1(e) only to the extent Legend agrees in writing to be bound by such obligations and reimburse all amounts owed to such Third Party as a result of Legend's exercise of such license with respect to such Patent Rights or Know-How, as applicable. For purposes of this Agreement, "**Reverted Product**" means any Product and Licensed CAR.

(f) <u>Marks and Domains</u>. Effective upon the effective date of termination, Janssen hereby assigns and shall cause to be assigned to Legend all worldwide rights in and to (i) any Product Trademarks and Promotional Materials specific to one or more Products that Janssen or any of its Affiliates used in connection with Product(s), and (ii) all Internet domain names incorporating the applicable Product Trademark(s) or any variation or part of such Product Trademark(s) as its URL address or any part of such address. It is understood that such assignment shall not include the name of Janssen or any of its Affiliates, nor the corporate logo, service mark, trade dress or trademark that is not specific to the Products, which was created or acquired and used by Janssen or any of its Affiliates independently of this Agreement for purposes other than the Products.

(g) <u>Governance During Wind-Down</u>. Beginning on the date of notice of termination, Sections 2.8.3 through 2.8.6 shall no longer apply with respect to any decisions of the JSC, JDC, JMC, GCCC or USCC (other than with respect to decisions to be made by the JMC on or after the date of notice of termination pursuant to Section 6.2.4), and Legend shall have final decision-making authority with respect to any matter to be decided by such Committees, which final decision-making authority shall be deemed the decision of such Committee; provided, however, that Legend may not use such final decision-making authority (a) to impose additional responsibilities on Janssen under the GDP, CMC Development Plan, Manufacturing Plan, any Commercialization Plans of a materially different nature or magnitude than Janssen's responsibilities thereunder prior to termination, or to modify Janssen's post-termination obligations under ARTICLE VI; (b) to increase the budget included within a Development Budget, the budget included in the CMC Development Plan, the budget included in the Manufacturing Plan or the Commercialization Budgets, as last approved by the JSC; or (c) with respect to any matter to be decided by the Finance Working Group. [\*\*\*]

-100-

(h) <u>Return of Materials</u>. [\*\*\*] each Party shall destroy, and cause its Affiliates to use Diligent Efforts to destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or control, and provide written certification of such destruction, or prepare such tangible items of Confidential Information for shipment to the other Party, at the first Party's expense, <u>provided</u> that such Party may retain one copy of such Confidential Information of the other Party for its legal archives. Notwithstanding the foregoing, (i) each Party shall be permitted to retain, use and (subject to the surviving provisions of ARTICLE IX) disclose tangible items and materials containing Confidential Information of the other Party or its Affiliate that are Collaboration Intellectual Property and are necessary or useful to practice the license under Section 3.5, and (ii) Legend shall be permitted to retain, use and (subject to the surviving provisions of ARTICLE IX) disclose tangible items and materials containing Confidential Information of Janssen or its Affiliate that are necessary or useful to practice any Janssen Intellectual Property that is licensed to Legend pursuant to Section 12.4.1(e)

(i) <u>Post-Termination Shared Product Liability Costs</u>. In the event a Party or any of its Affiliates incurs any Shared Product Liability Costs described in Section 11.3 after the Term and after the final reconciliation of Pre-Tax Profit or Loss under Section 7.4 in accordance with Reconciliation Procedures and the Financial Exhibit, which Shared Product Liability Costs are attributable to sales or other activities under this Agreement prior to expiration or termination of the Term, [\*\*\*] Shared Product Liability Costs (but only to the extent attributable to sales or other activities under this Agreement prior to expiration or termination of the Term). Each Party will promptly pay the other Party its share of any such Shared Product Liability Costs after receipt of detailed supporting documentation evidencing such Shared Product Liability Costs.

12.4.2 Janssen Termination Unilaterally; Legend Termination for Cause. In the event that Janssen terminates this Agreement pursuant to Section 12.3.1 or 12.3.2, or Legend terminates this Agreement pursuant to Section 12.2, the provisions of this Section 12.4.2 shall apply in addition to the provisions of Section 12.4.1.

(a) <u>On-Going Trials</u>. In the event that any Clinical Study with respect to Products has been initiated (first patient dosed) and is on-going as of the effective date of any termination of this Agreement (each, an "**On-Going Clinical Study**"):

(i) if [\*\*\*] terminates this Agreement pursuant to [\*\*\*] with respect to such On-Going Clinical Study for [\*\*\*] after the effective date of termination. In addition, if there are any On-Going Clinical Studies being conducted by or under authority of [\*\*\*] or its Affiliate at the time of notice of termination, [\*\*\*] may request, to (A) promptly transition to [\*\*\*] or its designee some or all of such On-Going Clinical Studies and the activities related to or supporting such trials, (B) continue to conduct such On-Going Clinical Studies for a period requested by [\*\*\*] after the effective date of such termination, or (C) terminate such On-Going Clinical Studies in a manner consistent with applicable Laws

-101-

(ii) if [\*\*\*] terminates this Agreement pursuant to [\*\*\*] such On-Going Clinical Study and (ii) [\*\*\*] shall be responsible for conducting and funding [\*\*\*] such On-Going Clinical Study in a manner consistent with applicable Laws.

[\*\*\*] shall have no obligation to commence any new Development activities following the date of notice of termination, and shall have no obligation to share the Development Costs for any Development activities commenced by [\*\*\*] following the effective date of termination.

(b) <u>Commercialization Wind-Down</u>. In the event that Janssen terminates this Agreement pursuant to Section 12.3.1, or Legend terminates this Agreement pursuant to Section 12.2, if requested by Legend, Janssen and its Affiliates shall continue to distribute and sell Products already commercially launched as of the effective date of termination (the "**Launched Products**") in each country within the U.S. and Janssen Territory (and continue to conduct any Commercialization activities allocated to it in Greater China under the Greater China Commercialization Plan) for which Marketing Approval has been obtained, in accordance with the terms and conditions of this Agreement, for a period [\*\*\*] the "**Agreement Wind-Down Period**"), <u>provided</u> that [\*\*\*]. If [\*\*\*] Legend shall grant, and hereby grants, to Janssen for the duration of the Agreement Wind-Down Period [\*\*\*], a non-exclusive license under the Legend Intellectual Property to use, sell, offer to sell, have sold, import and otherwise Commercialize, and have Commercialized the Launched Products in the Field, solely to perform such distribution and sale (or other Commercialization activities) with respect to Launched Products [\*\*\*]. For the avoidance of doubt, during the Agreement Wind-Down Period, Janssen's, and its Affiliates', rights with respect to Products (including the licenses granted under Section 3.1) shall be non-exclusive, the Parties' obligations under Section 3.6 shall not apply, and Legend shall have the right to engage one or more other partner(s) or distributor(s) of Products in all or part of the U.S., Greater China and Janssen Territory during the Agreement Wind-Down Period. Any Products sold or disposed by Janssen or its Affiliates during the Agreement Wind-Down Period shall be subject to the applicable payments under the Financial Exhibit. After the Agreement Wind-Down Period, Janssen and its Affiliates shall no longer have a right to sell Products hereunder.

(c) <u>Transition; Manufacturing; Inventory</u>. Janssen agrees, and agrees on behalf of its Affiliates, to reasonably cooperate with Legend and its designee(s) to facilitate a smooth, orderly and prompt transition of the program and activities with respect to Reverted Products, including any ongoing Development, CMC Development, Manufacturing and Commercialization of Reverted Products to Legend or its designee(s), during the Agreement Wind-Down Period, in accordance with this Section 12.4.2 and the applicable provisions of ARTICLE VI. If Janssen or its Affiliate Manufactured any Product, or component thereof or other material used for the Manufacture of Product, at the time of termination, then Janssen (or its Affiliate) shall continue to provide for manufacturing of such Product, component or other material, for Legend, at the Supply Costs therefor, from the date of notice of such termination until such time as Legend is able, using Diligent Efforts to do so, to secure an acceptable alternative commercial manufacturing source from which sufficient quantities of such Product, component or other material, may be procured and legally sold throughout the United States,

-102-

Greater China and Janssen Territory, but in any event no longer than [\*\*\*] after the effective date of termination. If a Manufacturing Subcontractor Manufactures a Product, or component thereof or other material used for the Manufacture of Product, on Janssen's or its Affiliate's behalf at the time of termination, upon request of Legend, Janssen shall use Diligent Efforts to transfer the applicable Manufacturing Subcontract to Legend on or promptly after the effective date of termination. Prior to expiration of the Agreement Wind-Down Period, (i) Legend shall have the right to purchase from Janssen, and Janssen shall sell to Legend if requested by Legend, all of Janssen's and its Affiliate's existing inventory of Reverted Products, or components thereof or other material used for the Manufacture of Reverted Products, at Janssen's Supply Cost for such Products, components or other materials (taking into account the portion, if any, of such Supply Costs for such inventory previously shared by Legend under this Agreement) and (ii) Janssen shall transfer to Legend, or its designee, all applicable cell banks used for the Manufacture of Reverted Products.

12.4.3 Janssen Termination for Cause. In the event that Janssen terminates this Agreement pursuant to Section 12.2 or Section 12.3.3, the provisions of this Section 12.4.3 shall apply in addition to the provisions of Section 12.4.1.

(a) <u>On-Going Trials</u>. If there are any On-Going Clinical Studies being conducted by or under authority of Janssen or its Affiliate at the time of notice of termination, Janssen agrees, as Legend may request, to (i) promptly transition to Legend or its designee some or all of such On-Going Clinical Studies and the activities related to or supporting such trials or (ii) terminate such On-Going Clinical Studies in a manner consistent with applicable Laws.

(b) <u>Transition; Manufacturing; Inventory</u>. Janssen agrees, and agrees on behalf of its Affiliates, to reasonably cooperate with Legend and its designee(s) to facilitate a smooth, orderly and prompt transition of the program and activities with respect to Reverted Products, including any ongoing Development, CMC Development, Manufacturing and Commercialization of Reverted Products to Legend or its designee(s), during the Agreement Wind-Down Period, in accordance with this Section 12.4.3 and the applicable provisions of ARTICLE VI; provided, however that Janssen and its Affiliates shall not be obligated to continue any On-Going Clinical Studies (except as necessary to transfer or wind down pursuant to Section 12.4.3(a)) or to continue promotion of any Products after the effective date of termination. If Janssen or its Affiliate Manufactured any Product, or component thereof or other material used for the Manufacture of Product, at the time of termination, then Janssen (or its Affiliate) shall continue to provide for manufacturing of such Product, component or other material, for Legend, at the Supply Costs therefor, from the date of notice of such termination until such time as Legend is able, using Diligent Efforts to do so, to secure an acceptable alternative commercial manufacturing source from which sufficient quantities of such Product, component or other material, may be procured and legally sold throughout the United States, Greater China and Janssen Territory, but in any event no longer than [\*\*\*] after the effective date of termination. If a Manufacturing Subcontractor Manufactures a Product, or component thereof or the Manufacture of Product, on Janssen's or its Affiliate's behalf at the time of termination, upon request of Legend, Janssen shall use Diligent Efforts to transfer the applicable Manufacturing Subcontract to Legend on or promptly after the effective date of termination. Prior to expiration of the Agreement Wind-Down Period, (i) Legend shall have the right to

-103-

purchase from Janssen, and Janssen shall sell to Legend if requested by Legend, all of Janssen's and its Affiliate's existing inventory of Reverted Products, or components thereof or other material used for the Manufacture of Reverted Products, at Janssen's Supply Cost for such Products, components or other materials (taking into account the portion, if any, of such Supply Costs for such inventory previously shared by Legend under this Agreement) and (ii) Janssen shall transfer to Legend, or its designee, all applicable cell banks used for the Manufacture of Reverted Products.

(c) Within [\*\*\*] after the effective date of termination of this Agreement, Legend shall reimburse Janssen for all outstanding Excess Amounts under Section 7.3.5 that have not previously been recouped by Janssen or reimbursed as set forth therein, together with interest thereon as set forth in Section 7.3.5.

### ARTICLE XIII DISPUTE RESOLUTION

13.1 **Exclusive Dispute Resolution Mechanism**. The Parties agree that the procedures set forth in this ARTICLE XIII shall be the exclusive mechanism for resolving (i) any dispute that arises out of or in relation to or in connection with this Agreement, excluding any Committee Matter (which shall be subject to resolution under Section 2.8); and (ii) any issue relating to the interpretation, application, enforcement, termination or validity of this Agreement (any dispute or issue described in clause (i) and (ii), a "**Dispute**"). For clarity, a dispute regarding any of the following shall constitute a Dispute: (a) whether a matter is a Committee Matter; or (b) whether an exercise of final decision-making authority is made in accordance with Sections 2.8.3 and 2.8.5. Any Dispute shall be resolved in accordance with this ARTICLE XIII.

13.2 **Resolution by Executive Officers**. Except as otherwise provided in this ARTICLE XIII, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on such basis, either Party may, by written notice to the other Party, refer the Dispute to the Executive Officers for attempted resolution by good faith negotiation within [\*\*\*] after such notice is received (unless otherwise agreed by the Parties). Each Party may, in its discretion, seek resolution of any and all Disputes that are not resolved under this Section 13.2 in accordance with Section 13.3.

#### 13.3 Arbitration.

13.3.1 <u>Arbitration</u>. Any Dispute that has been referred to the Executive Officers for resolution in accordance with Section 13.2 and has not been resolved within the time specified in Section 13.2, will be submitted for final, binding resolution to arbitration pursuant to the Non-Administered Arbitration Rules then in effect for the International Institute for Conflict Prevention and Resolution ("**CPR**") (available at http://www.cpradr.org), or successor, except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in [\*\*\*].

13.3.2 <u>Pane</u>l. The panel shall consist of three arbitrators chosen from the CPR Panels of Distinguished Neutrals (unless the Parties agree on the selection of the arbitrators) each of whom shall be [\*\*\*]. In the event the aggregate damages sought by the claimant are stated to be [\*\*\*], then a single arbitrator shall be chosen, having the same qualifications and experience specified above. Each arbitrator shall be impartial and independent of the Parties and shall abide by the *Code of Ethics for Arbitrators in Commercial Disputes* (available at <u>http://www.adr.org/EthicsAndStandards</u>).

-104-

13.3.3 <u>Procedures if Arbitrator(s) Not Agreed</u>. In the event the Parties cannot agree upon selection of the arbitrator(s), CPR will select arbitrator(s) as follows: CPR shall provide the Parties with a list of no less than [\*\*\*] proposed arbitrators ([\*\*\*] if a single arbitrator is to be selected) having the credentials referenced above. Within 25 days of receiving such list, the Parties shall rank at least [\*\*\*] of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The Parties may then jointly interview the [\*\*\*] candidates ([\*\*\*] if a single arbitrator is to be selected) with the highest combined rankings for no more than [\*\*\*] each and, following the interviews, may exercise one peremptory challenge each. The panel will consist of the remaining three candidates (or one, if one arbitrator is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR shall select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side challenges for cause and one peremptory challenge each.

13.3.4 <u>Timing</u>. The Parties agree to cooperate (i) to attempt to select the arbitrator(s) by agreement within [\*\*\*] of initiation of the arbitration, including jointly interviewing the final candidates; (ii) to meet with the arbitrator(s) within [\*\*\*] of selection; and (iii) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than [\*\*\*] after selection of the arbitrator(s) and in the award being rendered within [\*\*\*] of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within [\*\*\*] after the conclusion of the hearings. In any event, the Parties shall endeavor in good faith to complete any arbitration under this Section 13.3 within [\*\*\*] months following the initiation of such arbitration.

13.3.5 <u>Discovery</u>. In the event the Parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in Section 13.3.4, then the arbitrator(s) shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accordance with the Section 13.3.4 schedule as closely as practical. The arbitrator(s) shall provide for discovery according to those time limits, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery will be limited so that the schedule set forth in Section 13.3.4 may be met without undue burden. The arbitrator(s) shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery, <u>provided</u> that the arbitrator(s) shall permit such discovery as the arbitrator(s) deem necessary to permit an equitable resolution of the dispute, which may in the arbitrator(s)' discretion include requests for admission or interrogatories. The arbitrator(s) shall not order or require discovery against either Party of a type or scope that is not permitted against the other Party. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of any ruling on evidence. A transcript of the testimony adduced at the hearing shall be made and shall, upon request, be made available to either Party.

13.3.6 <u>Motions; Independent Expert</u>. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing, including motions to dismiss and motions for summary judgment, and shall endeavor to decide such motions as would a Federal District Judge sitting in the jurisdiction whose substantive law governs as set forth in Section 13.3.7. The arbitrator(s) may engage an independent expert with experience in the subject matter of the dispute to advise the arbitrator(s), but final decision-making authority shall remain in the arbitrator(s).

-105-

13.3.7 <u>Decision of the Arbitrator(s)</u>. The arbitrator(s) shall decide the issues presented in accordance with the substantive law of New York and may not apply principles such as "amiable compositeur" or "natural justice and equity." The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. No punitive or exemplary damages may be granted by the arbitrator(s). The Parties agree that the decision of the arbitrator(s) shall be the sole, exclusive and binding remedy between them regarding any and all disputes, controversies, claims and counterclaims presented to the arbitrator(s). The arbitration hearings and award shall not be made public by either Party without the joint consent of the Parties, except to the extent either Party is required to disclose such information by applicable Laws (or applicable rules of a public stock exchange). The costs of such arbitration, including administrative and arbitrator(s)' fees, and the fees of any expert retained by the arbitrator(s), shall be shared equally by the Parties, and each Party shall bear its own expenses and attorney's fees incurred in connection with the arbitration.

13.3.8 <u>Courts</u>. Any award of the arbitrator(s) may be entered in any court of competent jurisdiction for a judicial recognition of the decision and applicable orders of enforcement, and each Party may apply to any court of competent jurisdiction for appropriate temporary injunctive relief to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, in each case pending resolution of any arbitration proceeding. Without limiting the foregoing, the Parties consent to the jurisdiction of the Federal District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder.

13.3.9 EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL BY JURY OF ANY ISSUE WITHIN THE SCOPE OF THE AGREEMENT TO ARBITRATE AS SET FORTH IN SECTION 13.3.1.

#### ARTICLE XIV MISCELLANEOUS

14.1 **Assignment; Successors**. This Agreement shall not be assignable by either Party without the written consent of the other Party; <u>provided</u>, <u>however</u>, that either Party may assign this Agreement, without such consent (but with notice to the other Party following such assignment): (a) in whole or in part to an Affiliate, as long as the assignee remains an Affiliate of the assigning Party, <u>provided</u> that the assigning Party shall remain responsible for the performance of, and primarily liable under, this Agreement notwithstanding such assignment; or (b) in whole to a Third Party that acquires all or substantially all of the business or assets of such Party (whether by merger, reorganization, acquisition, sale or otherwise), <u>provided</u>, in each case ((a) or (b)), if such assignment would reasonably be expected to cause adverse tax consequences to the non-assigning Party (or such Party's Affiliates), such assignment shall not be made without the non-assigning Party's consent (which consent shall not withheld unreasonably), and the Parties shall cooperate reasonably to enable such assignment in a manner that avoids such adverse tax consequences. No assignment of this Agreement shall be valid and effective unless and until the assignee agrees in writing to be bound by the terms and conditions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties. Any assignment of this Agreement not in accordance with this Section 14.1 shall be null and void.

-106-

14.2 **Legend Change of Control**. In the event that a transaction to effect a Change of Control of Legend is consummated during the Term (a "**Legend Change of Control**"), the following provisions of this Section 14.2 shall apply.

14.2.1 <u>Reimbursement of Excess Amounts</u>. Within [\*\*\*] after such Change of Control, Legend shall reimburse Janssen for all outstanding Excess Amounts under Section 7.3.5 that have not previously been recouped by Janssen or reimbursed as set forth therein, together with interest thereon as set forth in Section 7.3.5.

## 14.2.2 Treatment of Acquirer Intellectual Property.

(a) All Legend Intellectual Property Controlled by Legend immediately prior to such Change of Control shall continue to be Legend Intellectual Property for purposes of this Agreement.

(b) Patent Rights, Know-How or other intellectual property rights that were owned or controlled by the Acquirer in such Change of Control shall not be included within the Legend Intellectual Property, unless such intellectual property rights are used by Legend or the Acquirer (or any of their respective equivalents) on or after such Change of Control to Exploit any Product being Developed, Manufactured or Commercialized under this Agreement.

(c) With respect to any Patent Rights, Know-How or other intellectual property rights that are developed, made or otherwise acquired by such Acquirer following such Change of Control, such Patent Right, Know-How or other intellectual property right shall not be deemed to be Controlled by Legend or its Affiliates for purposes of the definition of "Legend Intellectual Property" unless (i) such intellectual property rights are used by Legend or the Acquirer (or any of their respective Affiliates) on or after such Change of Control to Exploit any Product being Developed, Manufactured or Commercialized under this Agreement or (ii) such Patent Right, Know-How or other intellectual property was made with material use of Legend Know-How or Janssen Know-How; provided that the Legend Acquirer Segregates the program and activities related to Products from any Competing BCMA CAR-T programs and activities of the Acquirer. Such Segregation shall include using Diligent Efforts to:

(i) adopt reasonable procedures to prevent the Acquirer's use of Confidential Information relating to the Products in the Exploitation of such Competing BCMA CAR-T;

(ii) ensure that no personnel working on the program and activities related to such Competing BCMA CAR-T have access to non-public clinical data or technical Know-How, the GDP, the CMC Development Plan, the Manufacturing Plan or the Commercialization Plans, relating to the Products being Developed, Manufactured or Commercialized by the Parties under this Agreement;

(iii) ensure that no personnel working on the program and activities related to Products being Developed, Manufactured or Commercialized by the Parties under this Agreement have access to non-public clinical data or technical Know- How, or the marketing and commercialization plans, relating to such Competing BCMA CAR-T; and

-107-

(iv) require employees and contractors of the Acquirer who have day-to-day responsibilities for such Competing BCMA CAR-T to recuse themselves from meetings and conference calls between Legend and Janssen relating to this Agreement if such Competing BCMA CAR-T is expected to be discussed during such meeting or call.

14.2.3 Effect on Certain Agreement Provisions. From and after the effective date of a Change of Control of Legend:

(a) the provisions of Sections 3.6.2 and 3.6.3 shall no longer apply; and

(b) the provisions of Sections 5.3.3(b) shall no longer apply.

14.3 **Choice of Law**. This Agreement shall be governed by and interpreted under, and any court action in accordance with Section 14.10 shall apply, the laws of the State of New York excluding: (i) its conflicts of laws principles; (ii) the United Nations Conventions on Contracts for the International Sale of Goods; (iii) the 1974 Convention on the Limitation Period in the International Sale of Goods (the "**1974 Convention**"); and (iv) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.

14.4 **Notices**. All notices, requests, demands, waivers and other communications required or permitted to be given under this Agreement shall be in writing and deemed given if delivered personally or sent by facsimile or by overnight courier to the parties hereto, in each case with a copy sent via electronic mail (if an electronic mail address of the party to whom the relevant communication is being made has been designated pursuant hereto and remains a working electronic mail address), at the following addresses (or at such other addresses as shall be specified by like notice):

<u>If to Legend:</u> [\*\*\*] with a copy to: [\*\*\*] <u>If to Janssen</u>: [\*\*\*] with copies to: [\*\*\*]

-108-

All such notices, requests, demands, waivers and other communications shall be deemed to have been received, if by personal delivery or overnight courier, on the day delivered or, if by facsimile, on the next Business Day following the day on which such facsimile was sent; <u>provided</u>, in each case that a copy is also sent by electronic mail in accordance with the first sentence of Section 14.4.

14.5 **Severability**. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application of such provision to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application of such provision, in any other jurisdiction. In the event Janssen or any of its Affiliates seeks to avoid the enforcement against Janssen or any of its Affiliates of Section [3.6.1 or 3.6.2] of this Agreement by asserting, in writing, in a litigation or other legal or governemental proceeding that such provision is invalid or unenforceable, Legend may [\*\*\*] by providing [\*\*\*] written notice to Janssen, which notice shall (i) expressly reference this Section 14.5, and (ii) clearly state [\*\*\*]. The termination shall become effective at the end of the notice period unless Janssen or the applicable Affiliate withdraws or eliminates such assertion and cures any effect of such assertion during such [\*\*\*] period.

14.6 **Force Majeure**. Any delay in performance by any Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by a Force Majeure Event. The Party suffering such occurrence shall immediately notify the other Party, including the details of the Force Majeure Event, and use Diligent Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. Any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence.

14.7 Captions. All captions herein are for convenience only and shall not be interpreted as having any substantive meaning.

14.8 **Integration**. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral. Notwithstanding the authority granted to the Committees and any Subcommittees and Working Groups under this Agreement, this Agreement may be amended only in writing signed by properly authorized representatives of each of Legend and Janssen. In the event of a conflict between the GDP, CMC Development Plan, Manufacturing Plan or a Commercialization Plan, on the one hand, and this Agreement, on the other hand, the terms of this Agreement shall govern.

14.9 **Independent Contractors; No Agency**. Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party, including the Legend Sales Representatives, shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Janssen's legal relationship under this Agreement to Legend shall be that of independent contractor and shall not constitute a partnership (except to the extent provided in Section 7.8.1), joint venture or agency.

-109-

14.10 **Submission to Jurisdiction**. Each Party (i) submits to the jurisdiction of the state and federal courts sitting in New York, New York with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (ii) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court and (iii) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 13.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 14.4. Nothing in this Section 14.10, however, shall affect the right of any Party to serve legal process in any other manner permitted by Law.

14.11 **Execution in Counterparts; Facsimile Signatures**. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or by email of a .pdf attachment shall be deemed to be original signatures.

## 14.12 No Consequential or Punitive Damages.

14.12.1 NEITHER PARTY HERETO NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR ANY LOSS OR INJURY TO A PARTY'S OR ITS AFFILIATES' PROFITS, BUSINESS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

14.12.2 NOTHING IN THIS SECTION 14.12 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS.

14.13 **Performance by Affiliates**. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Each Party may use one or more of its Affiliates to perform its obligations and duties hereunder, provided that such Party provides prompt written notice to the other Party (subject to Section 3.3) and, further provided that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

14.14 **Construction**. The Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. References to Sections include subsections, which are part of the related Section. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (ii) references to a particular statute or regulation include all rules and regulations thereunder and any successor statute,

-110-

rules or regulations then in effect, in each case, including the then-current amendments thereto; (iii) words in the singular or plural form include the plural and singular form, respectively; (iv) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (v) terms "including," "include(s)," "such as," and "for example" as used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (vi) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified; (vii) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (viii) all words used in this Agreement will be construed to be of such gender or number as the circumstances require; (ix) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits), and (x) neither Party or its Affiliates shall be deemed to be acting "on behalf of" the other Party hereunder, except to the extent expressly otherwise provided.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative under seal, in duplicate on the Effective Date.

# LEGEND BIOTECH USA, INC.

By: /s/ Frank Zhang

Name: Frank Zhang Title: Chairman

LEGEND BIOTECH IRELAND LIMITED

By: /s/ Frank Zhang

Name: Frank Zhang Title: Chairman

[Signature Page to the Collaboration and License Agreement]

JANSSEN BIOTECH, INC.

By: /s/ Thomas M. Cavanaugh

Name: Thomas M. Cavanaugh Title: VP, JBI Oncology

[Signature Page to the Collaboration and License Agreement]

Legend Biotech Corporation (Cayman) ("**Legend Cayman**") hereby agrees to unconditionally guarantee the obligations and liabilities of Legend U.S. and Legend Ireland under this Agreement, including the obligations of Legend Biotech Corporation(Cayman) under Section 14.13 to cause its Affiliates to perform obligations imposed on such Affiliates. Legend Cayman hereby acknowledges and agrees that (a) Legend U.S. and Legend Ireland, on one hand, and Janssen, on the other hand, may amend or modify this Agreement without the requirement of providing notice of such amendment or modification to Legend Cayman or obtaining Legend Cayman's consent thereto and (b) Janssen shall be entitled to interact and deal with Legend U.S. and Legend Ireland on all matters relating to this Agreement (and any modifications and amendments hereto) without regard to the guaranty made by Legend Cayman hereunder, and that in each such case, the obligations and liabilities of Legend Cayman under this guaranty shall not be released or otherwise affected or impaired as a result thereof.

Legend Cayman represents and warrants to Janssen that, as of the Effective Date: (i) Legend U.S. and Legend Ireland, together with their Affiliates, have access to sufficient cash or lines of credit or other sources of funds, including the amounts available to Legend U.S. and Legend Ireland under Section 7.3.5, to satisfy their financial obligations under this Agreement; and (ii) all of the interests, assets and rights of Legend U.S. and Legend Ireland, and their Affiliates, related to the Licensed CARs and Products are owned by Legend U.S., Legend Ireland or Legend Cayman or by a subsidiary corporation all of the equity securities of which are owned by Legend U.S., Legend Ireland or Legend Cayman.

## LEGEND BIOTECH CORPORATION (CAYMAN)

By: /s/ Frank Zhang Name: Frank Zhang

Title: Chairman

[Signature Page to the Collaboration and License Agreement]

EXHIBIT A

r

[\*\*\*]

<u>EXHIBIT B</u>

FINANCIAL EXHIBIT

[\*\*\*]

E

<u>EXHIBIT C</u>

INITIAL GDP1

[\*\*\*]

<sup>1</sup> For purposes of the GDP, [\*\*\*].

EXHIBIT C-1

[\*\*\*]

### FIRST AMENDMENT TO THE COLLABORATION AND LICENSE AGREEMENT

This First Amendment to the Collaboration and License Agreement (the "**First Amendment**") effective as of March 12, 2018 (the "**First Amendment Effective Date**") amends that certain Collaboration and License Agreement dated December 21, 2017 by and among Legend Biotech USA, Inc., a Delaware corporation ("**Legend U.S.**"), Legend Biotech Ireland Limited, an Irish entity ("**Legend Ireland**") and Janssen Biotech, Inc., a Pennsylvania corporation, ("**Janssen**") (the "**Agreement**").

WHEREAS, Section 14.8 of the Agreement provides that the Agreement may be amended only in writing signed by properly authorized representatives of each of Legend and Janssen;

WHEREAS, prior to the First Amendment Effective Date, Janssen paid Legend U.S. the U.S. Upfront Payment in accordance with Section 7.1 of the Agreement; and

WHEREAS, Legend and Janssen have agreed to amend certain provisions of the Agreement relating to the Upfront Payment and Milestone Payments as further described herein.

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein and in the Agreement, Legend and Janssen hereby agree as follows:

- 1. <u>Definitions</u>. Any capitalized terms that are not defined in this Amendment shall have the meaning set forth in the Agreement; references below to Sections of the Agreement are references to such Sections of the Agreement.
- 2. <u>Amendments</u>.
  - a. Section 7.1 of the Agreement shall be amended and restated in its entirety as follows:

"7.1 **Upfront Payments**. In partial consideration of the rights granted to Janssen under this Agreement, Janssen shall make a non-refundable, non-creditable payment of [\*\*\*] to Legend U.S. with respect to the United States (the "**U.S. Upfront Payment**") and a non-refundable, non-creditable payment of [\*\*\*] to Legend Ireland with respect to the Janssen Territory and Greater China (the "**Ireland Upfront Payment**", and together the "**Upfront Payment**"). [\*\*\*] of the U.S. Upfront Payment has been paid by Janssen and received by Legend prior to the First Amendment Effective Date. Janssen shall pay the remainder of the U.S. Upfront Payment to Legend U.S. (i.e. [\*\*\*]) and the entire Ireland Upfront Payment to Legend Ireland within [\*\*\*] after the First Amendment Effective Date."

b. Section 7.2.9 of the Agreement shall be amended and restated in its entirety as follows:

[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

"7.2.9 <u>Allocation of Certain Milestone Payments</u>. Milestone Payments for Milestone Events 1, 2, 5, 12 and 13 will be allocated [\*\*\*] and payable to [\*\*\*]. Milestone Payments for Milestone Events 3, 4, 6 and 9 shall be payable to [\*\*\*] Milestone Payments for Milestone Events 7, 8, 10 and 11 shall be payable to [\*\*\*]."

c. Sections 7.7.3 and 7.7.4 of the Agreement shall be amended and restated in their entirety as follows:

"7.7.3

(a) If Payor had a duty to withhold Taxes in connection with any payment it made to Payee under this Agreement (other than the Ireland Upfront Payment) but Payor failed to withhold, and such Taxes were assessed against and paid by Payor, then Payee will indemnify and hold harmless Payor from and against such Taxes, except to the extent such Taxes resulted from Payor's negligent failure to withhold; provided, however, that Payor shall only be responsible for such Taxes to the extent such Taxes do not exceed the amount of Tax that Payor would have withheld if it had received from Payee the documentation necessary to secure any available reduction in the rate of applicable Taxes.

(b) If withholding Taxes (including, for the avoidance of doubt, any penalties, additions to tax and interest thereon) are assessed against Janssen with respect to the Ireland Upfront Payment and paid by Janssen, then (i) Legend will indemnify and hold harmless Janssen from and against such Taxes and (ii) Janssen shall control, and shall have the right to settle without Legend's consent, any proceeding with any Governmental Authority relating to such Taxes.

(c) If Payor makes a claim under this Section 7.7.3, it will comply with the obligations imposed by Section 7.7.1 as if Payor had withheld Taxes from a payment to Payee.

7.7.4 The Parties acknowledge that Legend has provided to Janssen an IRS Form W-9 with respect to Legend U.S. and agree that no Tax will be withheld from the U.S. Upfront Payment. [\*\*\*]. [\*\*\*]."

- d. The third paragraph of the definition "Allowable Expenses" in Section 2 (Definitions) of Exhibit B (Financial Exhibit) shall be amended and restated in its entirety as follows:
- "[\*\*\*]."

3. <u>Effect</u>. The amendments to the Agreement set forth in Section 2 of this First Amendment shall take effect on the First Amendment Effective Date.

4. <u>No Other Amendments</u>. This First Amendment shall be deemed a part of and incorporated into the Agreement. Except as expressly amended by this First Amendment, all of the other provisions of the Agreement shall remain unchanged and are ratified, confirmed in all respects and remain in full force and effect.

<sup>5. &</sup>lt;u>Counterparts</u>. This First Amendment may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmissions or by email of a .pdf attachment shall be deemed to be original signatures.

IN WITNESS WHEREOF, each Party has caused this First Amendment to be executed by their duly authorized representatives as of the First Amendment Effective Date.

# LEGEND BIOTECH USA, INC.

By: /s/ Frank Zhang

Name: Frank Zhang Title: Chairman

LEGEND BIOTECH IRELAND LIMITED

By: /s/ Frank Zhang

Name: Frank Zhang Title: Chairman

JANSSEN BIOTECH, INC.

By: /s/ Alyson P. Lawrence

Name: Alyson P. Lawrence Title: Assistant Secretary

[Signature Page to the First Amendment to the Collaboration and License Agreement]

Genscript Biotech Corporation ("**Genscript**") hereby agrees to unconditionally guarantee the indemnity obligations of Legend U.S. and Legend Ireland under Section 7.7.3(b) of the Agreement (as amended by this First Amendment). Genscript hereby acknowledges and agrees that (a) Legend U.S. and Legend Ireland, on one hand, and Janssen, on the other hand, may amend or modify Section 7.7.3(b) of the Agreement without the requirement of providing notice of such amendment or modification to Genscript or obtaining Genscript's consent thereto and (b) Janssen shall be entitled to interact and deal with Legend U.S. and Legend Ireland on all matters relating to Section 7.7.3(b) of the Agreement (and any modifications and amendments thereto) without regard to the guaranty made by Genscript hereunder, and that in each such case, the obligations and liabilities of Genscript under this guaranty shall not be released or otherwise affected or impaired as a result thereof.

# GENSCRIPT BIOTECH CORPORATION

By: /s/ Frank Zhang

Name: Frank Zhang Title: Chairman Private & Confidential

# DATED 25 November 2019

### LEGEND BIOTECH USA, INC

and

### LEGEND BIOTECH IRELAND LIMITED

and

### JANSSEN BIOTECH, INC.

### AMENDMENT NO. 1 TO

# COLLABORATION AND LICENSE

### AGREEMENT

# DATED DECEMBER 21, 2017

[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

THIS AMENDMENT is made and entered into as of the 25 November 2019 (the "Effective Date"), by and between:

- (1) LEGEND BIOTECH USA, INC., a Delaware corporation ("Legend U.S.")
- (2) LEGEND BIOTECH IRELAND LIMITED, an Irish entity ("Legend Ireland"); together "Legend" and
- (3) JANSSEN BIOTECH, INC., a Pennsylvania corporation ("Janssen")

Legend and Janssen are each referred to herein by name or as a "Party" or, collectively, as "Parties".

#### BACKGROUND

- A. By an agreement dated December 21, 2017, Legend and Janssen entered into a Collaboration and License Agreement to develop, manufacture, and commercialize LCAR-B38M and products containing LCAR-B38M ("the Agreement");
- B. The Parties wish to amend the Agreement to change the Milestone Event 5 as set forth in Section 7.2.1 for the Additional Development Event Milestone titled [\*\*\*]

Now, therefore, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. DEFINITIONS

For purposes of this Amendment, the capitalized terms used herein shall have the defined meanings specified in the terms below or elsewhere herein. Unless otherwise defined herein, each capitalized term used in this Amendment shall have the meaning assigned to it in the Agreement, as modified hereby.

2. Amendments

2.1 Section 7.2.1 of the Agreement is deleted in its entirety and replaced with the following:

<u>7.2.1 Milestone Events</u>. Janssen shall make the non-refundable, non-creditable payments (each, a "**Milestone Payment**") to Legend set forth in the table below not later than [\*\*\*] after Legend delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below (each, a "**Milestone Event**"), subject to Sections 7.2.2 through 7.2.8 below. Janssen shall provide notice to Legend within [\*\*\*] after Janssen's or its Affiliates' achievement of any of the Milestone Events.

Mil	estone Event		Milestone Payment	
		Initial Milestone Even		
1.	[***] Milestone Event		[***]	
2.	[***] Milestone Event		[***]	
3.	Dosing of the fifth (5th) patient in a Phase 1 Clinical Study in the United States with United States subjects (the " <b>Phase I Milestone</b> ")		US\$25 million	
4.				
a.	Receipt of response data readout from 20 patients in the first Phase 1 Clinical Study in the United States with United States subjects showing at least 50% ORR (the " <b>Initial ORR</b> <b>Milestone</b> ")		a. US\$25 million b. [***]	
b.	[***]			
		Additional Development E	vents	
		<u>First</u>		
		<u>Original</u>	Second	
		<u>GDP</u>	<u>Original GDP</u>	
_		<u>Indication</u>	<u>Indication</u>	[ <u>***]</u> [ <u>***]</u> [ <u>***]</u>
5.	Dosing of the fifth (5th) patient in a			[***]
	Registration Study of a Product in	US\$30 million	US\$30 million	[***] [***]
	the United States, EU or Japan	Regulatory Filing Even		
		[ <u>***]</u>	[ <u>***</u> ]	[ <u>***]</u> [ <u>***]</u> [ <u>***]</u>
6.	[***]	[***]	[***]	[***] [***] [***]
7.	[***]	[***]	[***]	[***] [***] [***]
8.	[***]	[***]	[***]	[***] [***] [***]

	Commercialization Approval Ex [ <u>***</u> ]	/ents [ <u>***</u> ]	[ <u>***</u> ]. [ <u>***</u> ]. [ <u>***</u> ].
9. [***]	[***]	[***]	[***] [***] [***]
10. [***]	[***]	[***]	[***] [***] [***]
11. [***]	[***]	[***]	[***] [***] [***]
12. [***]	Additional Milestone Events	[***]	
13. [***]		[***]	

2.2 Section 7.2.4 is hereby deleted and replaced with the following text:

<u>7.2.4 Milestone Payments for Additional Development Events</u>. Subject to Section 7.2.7, with respect to each Additional Development Event, such Milestone Event shall be deemed to occur:

(a) for the First Original GDP Indication when the fifth (5<sup>th</sup>) patient is dosed in the first Registration Study of a Product in the United States, EU or Japan for [\*\*\*];

(b) for the Second Original GDP Indication when the fifth (5<sup>th</sup>) patient is dosed in the first Registration Study of a Product in the United States, EU or Japan for [\*\*\*] other than the First Original GDP Indication with respect to which the Additional Development Event previously occurred;

(c) [\*\*\*]; and

(d) [\*\*\*]; and

(e) [\*\*\*].

3. The Agreement shall be deemed to have been amended in accordance with Section 14.8 of the Agreement. Except as expressly modified hereby, the Agreement shall remain in full force and effect as originally executed by the Parties. This Amendment supersedes any other prior writing and prior or contemporaneous oral agreements or understandings between the Parties that relate to or arise out of this Amendment and any related matters. This Amendment, together with the Agreement, fully integrates the Parties' agreement and understanding with respect to all matters covered by it.

4. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Amendment in duplicate originals by their duly authorized representatives as of the date and year first above written.

LEGEND BIOTECH USA, INC.

By:	/s/ Yuan Xu
Name:	Yuan Xu
Title:	CEO
Date:	December 18, 2019

JANSSEN BIOTECH, INC.

By:	/s/ Thomas Cavanaugh
Name:	Thomas Cavanaugh
Title:	President
Date:	December 18, 2019

# LEGEND BIOTECH IRELAND LIMITED

By: /s/ Yuan Xu

Name: Yuan Xu

Title: CEO

Date: December 18, 2019

#### EMPLOYMENT CONTRACT FOR CHIEF EXECUTIVE OFFICER

THIS EMPLOYMENT AGREEMENT (the "Agreement") is executed on the 28th day of March 2018 by and between Legend Biotech USA Inc. (hereinafter referred to as "Employer" or "Legend Biotech") with a business address of 860 Centennial Ave, Piscataway, NJ 08854 and Yuan Xu, residing at 403 Country Club Drive, Apt 101, Simi Valley, CA 93065 (hereinafter referred to as "Employee").

Employer has hired Employee as its Chief Executive Officer, directly reporting to the Chairman of Legend Biotech's Board of Directors (the "Board"). The purpose of this Agreement is to set forth the terms and conditions of Employee's employment. Therefore, Employer and Employee agree to the following terms and provisions:

#### ARTICLE I. TERM OF EMPLOYMENT

#### Section 1.01 Specified Period

Employer employs Employee and Employee accepts employment with Employer for a period of six (6) years, beginning on March 28, 2018 and terminating on March 27, 2024. However, said specified period may be terminated prior to the end date specified or the end date of any renewal in accordance with the terms identified below.

#### Section 1.02 Automatic Renewal

This Agreement shall be renewed automatically for succeeding terms of one (1) year unless either party gives notice to the other at least ninety (90) days prior to March 27, 2024 (or March 27 of any succeeding one (1) year renewal term, as applicable).

#### Section 1.03 "Employment Term" Defined

"Employment Term" refers to the entire period of employment of Employee by Employer, whether for the periods provided above, or whether terminated earlier as hereinafter provided or extended by mutual agreement between Employer and Employee.

### ARTICLE II. DUTIES AND OBLIGATIONS OF EMPLOYEE

#### Section 2.01 General Duties

Employee shall serve as the Chief Executive Officer of Legend Biotech. In her capacity as Chief Executive Officer of Legend Biotech, Employee shall do and perform all services, acts, or things necessary or advisable to manage and conduct the business of Employer. As CEO, Employee will have overall strategic and operational responsibility for Legend Biotech. Her duties will include but are not limited to: providing coordination for the senior leadership team; serving as liaison to Legend Biotech's clients, vendors and partners; working with Legend Biotech's leadership team to keep them abreast of strategies and challenges; providing leadership to the strategic planning process; implementing new strategic initiatives; managing the annual budget, etc.

Page 1 | 26

### Section 2.02 Employment Authorization

Employee's employment is contingent upon Employee's ability to present documentation to establish that Employee is in compliance with the employment authorization provisions of the Immigration Reform and Control Act of 1986. Employee is responsible for obtaining an employment authorization document corresponding to Employee's current immigration status.

### Section 2.03 Place of Performance

Employee's base office will be in New Jersey, USA. Frequent travel will be required, including but not limited to travel to China and work in China, with total travel time up to 5 months per year, as needed.

### Section 2.04 Devotion to Employer's Business

(a) Employee shall devote her full business time, ability, and attention to the business of Employer during the Employment Term, except as stated in EXHIBIT A attached hereto.

(b) During the Employment Term, Employee shall not engage in any other business duties or pursuits whatsoever, or directly or indirectly render any services of a business, commercial, or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Board; however, it is agreed and acknowledged that the foregoing prohibitions shall not apply to those businesses or pursuits listed in EXHIBIT A. For the avoidance of doubt, Employee's other business duties or pursuits relating to for-profit enterprises involved in the same or related industry as the Employer currently include those activities set forth in EXHIBIT A. In the event that information contained or not contained in EXHIBIT A changes, Employee shall have the duty to revise EXHIBIT A so that it remains accurate and up-to-date.

(c) This Agreement shall not prohibit Employee from making passive personal investments or conducting private business affairs if those activities do not materially interfere with the services required under this Agreement. However, Employee shall not directly or indirectly acquire, hold, or retain any interest in any business competing with or similar in nature to the business of Employer, except as set forth in EXHIBIT A attached hereto. The foregoing shall not prohibit Employee from owning, as a passive portfolio investment, less than 1 % of the outstanding common stock of any publicly traded company.

### Section 2.05 Competitive Activities

The Employee is required to sign the INTELLECTUAL PROPERTY RIGHTS ASSIGNMENT, NON-COMPETITION AND CONFIDENTIALITY AGREEMENT with Legend Biotech (the "Restrictive Covenant Agreement") attached hereto as EXHIBIT B, the terms of which are incorporate herein.

Page 2 | 26

#### ARTICLE III. OBLIGATIONS OF EMPLOYER

#### Section 3.01 General Description

Employer shall provide Employee with the compensation, incentives, benefits, indemnification and business expense reimbursements specified in this Agreement.

### Section 3.02 Office and Staff

Employer shall provide Employee with equipment, office space, and administrative support suitable to Employee's position and adequate for the performance of her duties.

#### ARTICLE IV. INTRODUCTORY PERIOD

Section 4.01 Employee will have an introductory period of three (3) months, from March 28, 2018 until June 27th, 2018 (the "Introductory Period").

#### ARTICLE V. COMPENSATION OF EMPLOYEE

#### Section 5.01 Annual Salary

(a) During the Employment Term, Employee shall receive a base salary of \$470,000 per year. Employee shall be paid semi-monthly on Employer's regularly scheduled pay dates. Employee will be eligible for consideration for annual merit-increase.

(b) Employee shall be eligible to earn an annual, year-end performance-based bonus for each calendar year of the Employment Term. Employee's target-level bonus shall be 55% of Employee's base salary for the applicable year. The annual bonus is discretionary, and will be based on employee's performance rating. The bonus accrual for 2018 will be prorated based on days employed and will include the Introductory Period. Each annual bonus will be paid not later than a date which complies with US tax law under IRC Section 409A.

#### Section 5.02 Stock Option Plan

Employee will participate in Legend Biotech's stock option plan, which is a performance-based incentive plan. Employee will be granted 4,400,000 option shares of Legend Biotech (among the current total of 200,000,000 shares of Legend Biotech stock outstanding). The grant is subject to Board approval and will be made at the end of the Introductory Period. The purchase price per share will be the Fair Market Value of one share on the grant date (currently is \$1.00 per share), with "Fair Market Value" being determined in a manner consistent with the requirements of Section 409A ("Section 409A") of the US Internal Revenue Code of 1986, as amended (the "IRC"), and the option terms shall otherwise be compliant with the requirements of Section 409A. The option shares will vest in five (5) equal annual installments of up to 880,000 shares per year, on each of the first five (5) anniversaries of the grant date. The option shares will be subject to performance-based vesting criteria to be developed jointly between the Board and Employee, and annual vesting will be determined as follows:

(a) If the performance rating for the applicable annual performance period is A (Exceed Expectations) or S (Substantially Exceed Expectations), 880,000 option shares will vest for that period.

Page 3 | 26

(b) If the performance rating for the applicable annual performance period is B (Meet Expectations), 720,000 option shares will vest for that period, and the remaining 160,000 option shares will be cancelled.

As long as the Employee remains employed and the performance rating is B, A, or S, the options will continue to vest in accordance with the abovereferenced schedule. If the Employee's performance fails to meet minimum expectations, Employee will be provided notice, in writing of the deficiencies and Employee will have ninety (90) days to cure such deficiencies. At the end of the ninety (90) day cure period, if Employee's performance has improved to meet minimum expectations (to be decided at the discretion of the Board), Employee's employment will remain. In such case, Employee's right to earn and vest in option shares for current and any subsequent annual performance period should not be affected.

In the case of any stock split, the number of option shares covered by the grant will be adjusted equitably to maintain Employee's percentage ownership of the current total of 200,000,000 outstanding shares. The foregoing shall not apply to shares issued for fair value in arms-length capital raising transactions.

Options will expire 10 years from the date of the grant.

If Employee's employment is terminated, by Employer or by Employee, for any reason other than Employee's death or disability, the vested option shares will remain exercisable for 90 days following the date of termination. If such employment is terminated due to Employee's death or disability, vested option shares will remain exercisable for 12 months after the date of termination.

The options may be subject to other customary terms and conditions, not inconsistent with the terms hereof or with Section 409A. Shares of Legend Biotech acquired by Employee upon exercise shall be fully-vested and non-forfeitable, and shall not be subject to any "call rights" or similar repurchase rights in favor of Legend Biotech or any of its affiliates.

### ARTICLE VI. EMPLOYEE BENEFITS

### Section 6.01 Company Benefits

Employee is eligible for the following standard Company benefits: health, dental, and vision coverage, as well as subsidized coverage for family members. Employee is also eligible for Accidental Death and Dismemberment, Long Term Disability and Life Insurance coverage. Additionally, Employee will be eligible to participate in Employer's 401(k) plan.

#### Section 6.02 Relocation Assistance

A one-time payment of \$20,000 will be paid to Employee as a relocation allowance. Also, Employer will provide up to 30 days hotel stay coverage to aid in Employee's transition.

Page 4 | 26

### ARTICLE VII. BUSINESS EXPENSES

Section 7.01 Employee's business expenses will be reimbursed in accordance with Employer's policy, which will be provided to the Employee.

### ARTICLE VIII. TERMINATION OF EMPLOYMENT

#### Section 8.01 Termination during Introductory Period

If Employee's employment is terminated for any reason during. the Introductory Period, no severance will be paid. The only compensation to be paid will be as outlined in the Restrictive Covenant Agreement attached hereto as EXHIBIT B.

#### Section 8.02 Termination for Cause

(a) Employer reserves the right to terminate Employee's employment for "Cause". Employer shall have "Cause" to terminate Employee only if Employee commits an act of willful and material dishonesty, fraud, or misrepresentation, or other willful and material misconduct, in each case causing demonstrable and material harm to Employer or its affiliates.

(b) If Employer wishes to terminate Employee for "Cause," Employer will give Employee written notice, which shall state in reasonable details the specific conduct and facts alleged to constitute Cause.

Upon termination for Cause, no severance will be provided and all unvested option shares shall lapse immediately.

#### Section 8.03 Termination for Performance

If the Employee's performance fails to meet minimum expectations, Employee will be provided notice, in writing of the deficiencies and Employee will have ninety (90) days to cure such deficiencies.

(a) At the end of the ninety (90) day cure period, if Employee's performance has not met minimum expectations, Employee's employment will be terminated. Upon termination for performance, all unvested option shares will be forfeited except that the unvested options for the period between the last vesting date and the performance notice date will be prorated at performance level "B" and be vested immediately. Employee will receive severance equal to twelve (12) months of Employee's base salary, paid in twelve (12) equal monthly installments immediately following the date of termination.

(b) At the end of the ninety (90) day cure period, if Employee's performance has improved to meet minimum expectations (to be decided at the discretion of the Board), Employee's employment will remain. Employee shall remain the right to earn and vest in option shares, as well as annual bonus, at performance level "B" for the applicable annual performance period.

Page 5 | 26

### Section 8.04 Termination without Cause

Employer may terminate Employee's employment without Cause. If Employee's employment is terminated by Employer without Cause at any time after the Introductory Period, (i) Employee will receive severance equal to twelve (12) months of Employee's base salary, paid in twelve (12) equal monthly installments immediately following the date of termination; (ii) option shares which are then eligible to vest at performance level "B" during the 18 month period following the termination date will become immediately vested and exercisable, irrespective of whether performance criteria are otherwise met; and (iii) any remaining unvested option shares will be forfeited.

A termination of Employee's employment without Cause means any termination which (i) is not a voluntary resignation by Employee, and (ii) fails to meet the conditions of termination "for Cause" as set forth in Section 8.02, and includes the following:

(a) The death of Employee.

(b) Termination of Employee by reason of disability, which shall include any physical or mental disability that prevents Employee from being able to perform her essential job duties under this Agreement, unless reasonable accommodation can be made to allow Employee to continue working. Such a termination shall be effected by Employer giving 30 days written notice of termination to Employee.

(c) If in the opinion of the Board, for any other reason, Employee should no longer occupy the CEO position. Employer will give Employee at least ninety (90) days' notice of termination without Cause as under this clause (c).

### Section 8.05 Employee's Resignation for Good Reason

If Employee terminates her employment for "Good Reason", as defined below, Employee will receive severance equal to the severance payout set forth in Section 8.04, and her option shares will vest or expire as set forth in Section 8.04.

Employee shall have "Good Reason" to terminate her employment if, without Employee's express written consent, one or more of the following occurs: (a) a ten percent (10%) or greater reduction of Employee's base salary; (b) a failure of the Board to timely approve and grant the option shares as set forth in Section 5.02; (c) a change of Employee's base office to any location outside the USA; or (d) Employer's material breach of the terms of this Agreement or any other material written agreement/covenant with Employee related to Employee's provision of services to Employer. In order for an event to qualify as Good Reason, Employee must not terminate employment with Employer without first providing Employer with written notice of the acts or omissions constituting the grounds for "Good Reason" within three (3) months of her first becoming aware of such grounds. Employer shall have thirty (30) days following such written notice to cure such acts or omissions (the "Cure Period"). If Employer has not cured such acts or omissions by the last day of the Cure Period, Employee's employment shall be deemed terminated for Good Reason immediately following the Cure Period.

Page 6 | 26

### Section 8.06 Change in Control

For purposes of this Agreement, a "Change in Control" is defined as: (i) Any voluntary or involuntary dissolution of Employer resulting from either a merger or consolidation in which Employer is not the consolidated or surviving corporation; (ii) a transfer or sale of all or substantially all of the assets of Employer; or (iii) any disposition of the equity interests in the Employer to any one Person or to more than one Person acting as a group which acquires more than fifty percent (50%) of either the total fair market value or total voting control of the Employer. In the event of a Change in Control, if the new ownership of Employer decides to terminate and/or not hire Employee under terms substantially similar in all material respects to her employment prior to the Change in Control, then (1) Employee shall receive severance equal to 24 months of base salary, payable in equal monthly installments immediately following the termination date, and (2) all unvested options will become immediately and fully vested and exercisable, irrespective of whether performance criteria are otherwise met. Employer shall require any successor or acquirer in a Change in Control transaction to expressly assume and perform the Employer's obligations under this Agreement.

### Section 8.07 Bonus upon Termination

If, after the Introductory Period, Employee is terminated without Cause or resigns for Good Reason, and at such time Employee has worked for at least six (6) months of the calendar year, a determination regarding the amount of the performance based bonus referenced in Section 5.01 (b) will be established. The Employee will be paid a prorated share of the determined bonus based on the number of months worked in the calendar year, such amount to be paid when annual bonuses are otherwise paid, and in any event no later than a date which complies with US tax law under IRC Section 409A. In addition, if Employee has earned an annual bonus for a preceding calendar year which has not been paid as of the termination date, such bonus shall be paid at the time otherwise due.

### Section 8.08 COBRA

Employee shall be entitled to COBRA benefits (for continued health, dental and vision plan coverage) upon termination of employment as provided under applicable law. Upon a termination by Employer without Cause, termination for performance, or a termination by Employee for Good Reason, Employer will pay the applicable premiums (inclusive of premiums for Employee's dependents for such health, dental, and vision plan coverage as is effect immediately prior to the date of the termination) for such continued health, dental, and vision plan coverage following the date of the termination for up to 12 months (but in no event after such time as Employee is eligible for coverage under a health, dental and vision insurance plan of a subsequent employer or as Employee and Employee's dependents are no longer eligible for COBRA coverage). Employer shall have no obligation in respect of any premium payments (or any other payments in respect of health, dental, and vision coverage from Employer) following the date of Employee's coverage by a health, dental, and vision insurance plan of a subsequent employer. Employee shall be required to notify Employer immediately if Employee becomes covered by a health, dental, and vision insurance plan of a subsequent employer. If the termination is due to circumstances described in Sections 8.06, Employer will pay up to 24 months of COBRA coverage.

Page 7 | 26

#### Section 8.09 Termination by Employee

Employee may terminate her employment without Good Reason by giving Employer at least ninety (90) days' notice in advance. In such event, Employee shall not receive severance, and all unvested options shall be cancelled.

### ARTICLE IX. GENERAL PROVISIONS

#### Section 9.01 Notices

Any notices to be given hereunder by either party to the other shall be in writing and may be transmitted by personal delivery, electronic mail, or by mail, registered or certified, postage prepaid with return receipt requested. Mailed notices shall be addressed to the parties at the addresses appearing in the introductory paragraph of this Agreement, but each party may change that address by written notice in accordance with this Section. Notices delivered personally shall be deemed communicated as of the date of actual receipt; mailed notices shall be deemed communicated as of the date of mailing.

#### Section 9.02 Arbitration

The parties agree to execute the Arbitration Agreement attached here to as EXHIBIT C, the terms of which are incorporated herein.

### Section 9.03 Attorneys' Fees and Costs

If any legal action is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fee, costs, and necessary disbursements in addition to any other relief to which the prevailing party may be entitled. This provision shall be construed as applicable to the entire Agreement, including the Restrictive Covenant Agreement and any dispute involving the option shares. A prevailing party shall be defined as the party who is entitled to affirmative relief, recovers at least fifty (50%) of any money requested, or owes no affirmative relief/action which was requested by the moving party.

### Section 9.04 Entire Agreement

(a) This Agreement supersedes any and all other agreements, either oral or in writing, between the parties with respect to the employment of Employee by Employer, and, together with the Restrictive Covenant Agreement, contains all of the covenants and agreements between the parties with respect to that employment in any manner whatsoever.

(b) Each party to this Agreement acknowledges that no representations, inducements, promises, or agreements, orally or otherwise, other than those set forth herein, have been made by any party, or anyone acting on behalf of any party, and that no other agreement, statement, or promise not contained in this Agreement shall be valid or binding.

#### Section 9.05 Modifications

Any modification of this Agreement will be effective only if it is in writing and signed by all the parties to this Agreement.

Page 8 | 26

### Section 9.06 Copies

This Agreement may be executed in counterparts, and each counterpart, when executed, shall have the efficacy of a signed original. Photostatic, facsimile and email copies of such signed counterparts may be used in lieu of the originals for any purpose.

### Section 9.07 Effect of Waiver

The failure of either party to insist on strict compliance with any of the terms, covenants, or conditions of this Agreement by the other party shall not be deemed a waiver of that term, covenant, or condition, nor shall any waiver or relinquishment of any right or power at any one time or times be deemed a waiver or relinquishment of that right or power for all or any other times.

### Section 9.08 Partial Invalidity

If any provision in this Agreement is held by a court or arbitrator of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall nevertheless continue in full force without being impaired or invalidated in any way. This Agreement was negotiated at arms-length and shall not be construed against its drafter as each party participated equally in its drafting.

#### Section 9.09 Law Governing Agreement

This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey.

#### Section 9.10 Sums due Deceased Employee

If Employee dies prior to the expiration of the term of her employment, any sums that may be due her from Employer under this Agreement as of the date of death shall be paid to Employee's executors, administrators, heirs, personal representatives, successors, and assigns.

#### Section 9.11 Section Titles

The heading and subheadings herein are inserted as a matter of convenience only and do not define, control or limit the scope of this Agreement or the intent or the provisions thereof.

### Section 9.12 Warranty of Capacity to Execute Agreement

Employer and Employee represent and warrant that they have the mental capacity to understand the terms and conditions of this Agreement.

#### Section 9.13 Compliance with Section 409A and Section 280G

(i) *General*. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A, Section 280G and Section 4999 of the IRC and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. In the event of a Change in Control or similar

Page 9 | 26

transaction involving Employer or any its affiliates which could cause any portion of the compensation (including compensation attributable to option shares) or benefits provided to Employee hereunder to be subject to the excise tax imposed under Section 4999 of the IRC, Employer shall take, upon mutual agreement, reasonable and necessary actions to help minimize the risk of such taxes being imposed.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon Employee's termination of employment shall be payable only upon Employee's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service").

(iii) *Specified Employee*. Notwithstanding anything in this Agreement to the contrary, if Employee is deemed by Employer at the time of Employee's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's Separation from Service with Employer or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Employee (or Employee's estate or beneficiaries), and any remaining payments due to Employee under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements*. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to Employee shall be paid to Employee no later than December 31 of the year following the year in which the expense was incurred; provided, that Employee submits Employee's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and Employee's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments*. Employee's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Employer's payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

Page 10 | 26

THE PARTIES ACKNOWLEDGE THAT EACH HAS READ THIS AGREEMENT IN ITS ENTIRETY, UNDERSTAND ALL OF THE TERMS AND FREELY, VOLUNTARILY AND KNOWINGLY, WITHOUT DURESS OR COERCION, CONSENT TO ALL THE TERMS AND CONDITIONS CONTAINED THEREIN.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date set forth herein.

### EMPLOYEE

/s/ Yuan Xu Yuan Xu

March 23, 2018

EMPLOYER

/s/ Frank Zhang

Frank Zhang

Chairman of the Executive Board Legend Biotech

Page 11 | 26

# EXHIBIT A TO EMPLOYMENT AGREEMENT

Employee's other business duties or pursuits relating to for-profit enterprises involved in the same or related industry as the Employer:

1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
None		

/s/ Yuan Xu

March 23, 2018

Page 12 | 26

#### EXHIBIT B TO EMPLOYMENT AGREEMENT

#### INTELLECTUAL PROPERTY RIGHTS ASSIGNMENT, NON-COMPETITION AND CONFIDENTIALITY AGREEMENT

As a condition of my employment with Legend Biotech (the "**Company**") pursuant to my employment agreement with the Company dated March 28, 2018 (the "**Employment Agreement**"), and in consideration of my employment with the Company and my receipt of the compensation now and hereafter paid to me by the Company, I agree to the following provisions of this Intellectual Property Rights Assignment, Non-Competition and Confidentiality Agreement (this "**Agreement**"):

### 1. Confidential Information

1.1 Legend Biotech Confidential Information. "Legend Biotech Confidential Information" means any non-public information that relates to the actual or anticipated business, research or development of the Company, its subsidiaries and affiliates (collectively the "Legend Biotech Group"), or that relates to the Legend Biotech Group's technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Legend Biotech Group's products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Legend Biotech Group on which I called or with which I may become acquainted during the term of my employment), software, developments, inventions, ideas, processes, formulas, technologies, designs, drawings, engineering, specifications, information regarding routes of synthesis, patent analyses relating to products, test results, reports, studies, analyses, hardware configuration information, marketing, distribution and sales, finances, projects, strategies, opportunities, and all other information which if disclosed would materially adversely affect the Legend Biotech Group or would aid or benefit its competitors; provided, however, Legend Biotech Confidential Information does not include any of the foregoing items to the extent the same have become publicly known and made generally available through no wrongful act of mine or of others.

1.2 Use of Legend Biotech Confidential Information. I agree that during and after my employment with the Company, I shall use the Legend Biotech Confidential Information for the sole and exclusive benefit of the Legend Biotech Group. I agree not to otherwise use or exploit the Legend Biotech Confidential Information without the Company's prior written consent, which consent may be withheld in the Company's sole and absolute discretion.

1.3 Confidentiality. During and after my employment with the Company, I agree to hold in the strictest confidence, and will not, either directly or indirectly, disclose any Legend Biotech Confidential Information to any third party except as may be authorized by the Company in writing. I understand that the absence of any marking or legend indicating that any particular information disclosed by the Legend Biotech Group is to be treated as confidential shall not limit or diminish my obligation to treat such information as confidential information. I understand that my unauthorized use or disclosure of Legend Biotech Confidential Information during my employment may lead to disciplinary action, up to and including immediate termination and legal action by the Company. I understand that nothing in this Agreement is intended to limit my rights to discuss the terms, wages, and working conditions of my employment, as protected by applicable law.

Page 13 | 26

1.4 Former Employer Information. I agree that during my employment with the Company, I will not improperly use, disclose, or induce the Legend Biotech Group to use any proprietary information or trade secrets of any former or concurrent employer or other person or entity. I further agree that I will not bring onto the premises of the Legend Biotech Group or transfer onto the Legend Biotech Group's technology systems any unpublished document, proprietary information, or trade secrets belonging to any such employer, person, or entity unless consented to in writing by both the Company and such employer, person, or entity.

1.5 Third Party Information. I recognize that the Legend Biotech Group may have received and in the future may receive from third parties associated with the Legend Biotech Group, e.g., the Legend Biotech Group's customers, suppliers, licensors, licensees, partners, or collaborators ("Associated Third Parties"), their confidential or proprietary information ("Associated Third Party Confidential Information"). By way of example, Associated Third Party Confidential Information may include the habits or practices of Associated Third Parties, the technology of Associated Third Parties, requirements of Associated Third Parties, and information related to the business conducted between the Legend Biotech Group and such Associated Third Parties. I agree at all times during my employment with the Company and thereafter to hold in the strictest confidence, and not to use or, directly or indirectly, to disclose to any third party, any Associated Third Party Confidential Information, except as necessary in carrying out my work for the Legend Biotech Group consistent with the Legend Biotech Group's agreement with such Associated Third Parties. I further agree to comply with any and all of the Legend Biotech Group's policies and guidelines that may be adopted from time to time regarding Associated Third Parties and Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information. I understand that my unauthorized use or disclosure of Associated Third Party Confidential Information or violation of any Legend Biotech Group's policie

#### 2. Inventions

2.1 Inventions Retained and Licensed. I have attached hereto as Exhibit A, a list describing all inventions, patents, discoveries, original works of authorship, developments, improvements, and trade secrets that were conceived in whole or in part by me prior to my employment with the Company ("Prior Inventions"), which belong solely to me or belong to me jointly with others, and which relate to the Company's proposed business, products, or research and development; or, if no such list is attached, I represent and warrant that there are no such Prior Inventions. Furthermore, I represent and warrant that if any Prior Inventions are included on Exhibit A, they will not materially affect my ability to perform all obligations under this Agreement. If, in the course of my employment with the Company, I incorporate into or use in connection with any product, process, service, technology, or other work by or on behalf of the Company any Prior Inventions, I hereby grant to the Legend Biotech Group a non-exclusive, royalty-free, fully paid-up, irrevocable, perpetual, transferable, worldwide license, with the right to grant and authorize sublicenses, to make, have made, modify, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions without restriction, including, without limitation, as part of or in

Page 14 | 26

connection with such product, process, service, technology, or other work, and to practice any method related thereto. I agree not to incorporate or use of any Prior Inventions without written consent of the Company. I further represent and warrant that the incorporation and use of any Prior Inventions will not infringe upon any party or person's rights or interests in the Prior Inventions, including but not limited to their intellectual property rights. Moreover, I agree to fully indemnify the Company, its directors, officers, agents, employees, investors, shareholders, administrators, affiliates, divisions, subsidiaries, predecessor and successor corporations, and assigns for all verdicts, judgments, settlements, and other losses incurred by any of them resulting from my incorporation or use of any Prior Inventions, as well as any reasonable attorneys' fees and costs.

<u>2.2</u> Assignment of Inventions. I agree that I will promptly make full written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and agree to assign and hereby do irrevocably assign to the Company, or its designee, all my right, title, and interest in and to any and all inventions, original works of authorship, developments, concepts, improvements, designs, discoveries, ideas, trademarks, or trade secrets, whether or not patentable or registrable under patent, copyright, or similar laws, which I may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, during the period of time I am in the employ of the Company (including during my off-duty hours), or with the use of Company's equipment, supplies, facilities, resources, or Legend Biotech Confidential Information (collectively referred to as "**Inventions**"). I further acknowledge that all original works of authorship that are made by me (solely or jointly with others) within the scope of and during the period of my employment with the Company and that are protectable by copyright are "works made for hire," as that term is defined in the United States Copyright Act. I understand and agree that the decision whether or not to commercialize or market any Inventions is within the Company's sole discretion and for the Company's sole benefit, and that no royalty or other consideration will be due to me as a result of the Company's efforts to commercialize or market any such Inventions.

2.3 Moral Rights. Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "Moral Rights"). To the extent that Moral Rights cannot be assigned under applicable law, I hereby waive and agree not to enforce any and all Moral Rights, including, without limitation, any right to identification of authorship or limitation on subsequent modification that I may have in the assigned Inventions.

2.4 Maintenance of Records. I agree to keep and maintain adequate, current, accurate, and authentic written records of all Inventions made by me (solely or jointly with others) during the term of my employment with the Company. The records will be in the form of notes, sketches, drawings, electronic files, reports, or any other format that may be specified by the Company. The records are and will be available to and remain the sole property of the Company at all times.

2.5 Further Assurances. I agree to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in the Inventions and any rights relating thereto in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments, and all other instruments that the Company shall deem proper

Page 15 | 26

or necessary in order to apply for, register, obtain, maintain, defend, and enforce such rights, and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title, and interest in and to such Inventions and any rights relating thereto, and testifying in a suit or other proceeding relating to such inventions and any rights relating thereto. I further agree that my obligations under this Section 2.5 shall continue after the termination of this Agreement. If the Company is unable because of my mental or physical incapacity or for any other reason to secure my signature with respect to any Inventions, including, without limitation, to apply for or to pursue any application for any United States or foreign patents or copyright registrations covering such Inventions, then I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, to act for and in my behalf and stead, to execute and file any papers and oaths, and to do all other lawfully permitted acts with respect to such Inventions with the same legal force and effect as if executed by me.

#### 3. Conflicting Employment

*3.1 Current Obligations.* I agree that during the term of my employment with the Company, I will not engage in or undertake any other employment, occupation, consulting relationship, or commitment that is directly related to the business in which the Company is now involved or becomes involved or has plans to become involved, nor will I engage in any other activities that conflict with my obligations to the Company.

3.2 Prior Relationships. Without limiting Section 3.1, I represent that I have no other agreements, relationships, or commitments to any other person or entity that conflict with my obligations to the Company under this Agreement or my ability to become employed and perform the services for which I am being hired by the Company. I further agree that if I have signed a confidentiality agreement or similar type of agreement with any former employer or other entity, I will comply with the terms of any such agreement to the extent that its terms are lawful under applicable law. I represent and warrant that after undertaking a careful search (including searches of my computers, cell phones, electronic devices, and documents), I have returned all property and confidential information belonging to all prior employers. Moreover, I agree to fully indemnify the Company, its directors, officers, agents, employees, investors, shareholders, administrators, affiliates, divisions, subsidiaries, predecessor and successor corporations, and assigns for all verdicts, judgments, settlements, and other losses incurred by any of them resulting from my breach of my obligations under any agreement to which I am a party or obligation to which I am bound, as well as any reasonable attorneys' fees and costs if the plaintiff is the prevailing party in such an action, except as prohibited by law.

### 4. Non-Competition

4.1 I agree that, during the term of my employment with the Company, and for a period of twelve (12) months immediately following the termination of my employment for any reason, I will not, without the prior written consent of the Company, serve as a partner, member, owner, employee, consultant, officer, director, manager, agent, associate, investor or otherwise for any company whose work involves CAR-T Drug Discovery and Cell therapy: provided, however, that if my employment is terminated during the Introductory Period (as defined in the Employment Agreement), (a) such twelve (12) month non-compete requirement shall not apply, and (b) the Company may, in its discretion, require me to refrain from competition for period of three (3) months following termination, by continuing to pay me 60% of my regular base salary, as defined in Section 5.01 of the Employment Agreement, for a period of three (3) months.

Page 16 | 26

4.2 I acknowledge that I will have access to Legend Biotech Confidential Information during my employment to enable me to optimize the performance of my duties for the Company. I further acknowledge that my fulfillment of the obligations contained in this Agreement, including, but not limited to, my obligation neither to disclose nor to use the Legend Biotech Confidential Information other than for the exclusive and sole benefit of the Legend Biotech Group and my obligation not to compete contained in Section 4.1 above, is necessary, reasonable, and required to protect the Legend Biotech Confidential Information and, consequently, to preserve and protect the value, interest, and goodwill of the Company. I further acknowledge the time, geographic and scope limitations of my obligations under Section 4.1 above are reasonable, especially in light of the Company's legitimate interest to protect Legend Biotech Confidential Information, and that I will not be precluded from gainful employment if 1 am obligated not to compete with the Company during the period and within the Territory as described above. I further agree that the salary and compensation I receive during my employment with the Company reasonably and adequately compensate my obligation under Section 4, and such obligation under Section 4 will not impose undue burden on me.

4.3 I acknowledge and agree that monetary damages would be an insufficient remedy for any violation or breach of the non-compete obligation under Section 4 and any such violation or breach will cause irreparable harm to the Company, its subsidiaries and affiliates. I agree that the Company, on its own behalf or on behalf of its affiliates or subsidiaries, shall be entitled to specific performance and injunctive relief as remedies for such breach or any threatened breach. Such remedies shall not be deemed the exclusive remedies for a breach of the covenants set forth in Section 4, but shall be in addition to all remedies available at law or in equity to the Company, including, without limitation, the recovery of damages from me.

#### 4.4 Compensation for Non-Competition; Termination Certificate

(a) Following my termination of employment, unless my employment is terminated during the Introductory Period, I agree that I will sign and execute the Termination Certification attached as Exhibit B. If I am leaving to accept a new position, and if the Company reasonably determines that the new position (as described in the Termination Certification) is in competition with the Company within the meaning of Section 4.1, I agree to not accept the new position within the 12- month non-compete period.

(b) If my employment was terminated (i) by the Company for Cause, or (ii) by me without Good Reason, then in consideration for my non-competition obligation, the Company will pay me an amount equal to seven (7) months' base salary, based on my base salary for the twelve (12) month period immediately preceding my termination date (the "Compensation"). The Compensation will be paid in equal monthly installments over the twelve-month period immediately following my employment termination date; provided, however, that the Company may thereafter, in its discretion, waive the non-competition obligation by providing me with one-month's advance notice in writing, and following such notice the Company shall no longer be obligated to pay me the Compensation, and I shall no longer be subject to the non-competition obligation. If my

Page 17 | 26

employment was terminated by the Company for Performance, terminated without Cause, terminated due to Change in Control, or if I resigned for Good Reason, in each case as defined in the Employment Agreement, I will be paid severance as provided in the Employment Agreement, and will not be entitled to the Compensation outlined above, and will still be required to comply with the non-competition obligation set forth in Section 4.1.

(c) I agree that if I fail to execute and deliver the Termination Certification required under Section 4.4(a), my right to the Compensation shall be deemed waived, but such waiver shall not release or diminish my non-competition obligation under Section 4.1 of this Agreement.

### 5. Returning Company Documents and Property

Upon termination of or resignation from employment with the Company, or on demand by the Company during my employment, I shall immediately deliver to the Company, and shall not keep in my possession, recreate, or deliver to anyone else, any and all Company property, including, but not limited to, Legend Biotech Confidential Information, Associated Third Party Confidential Information, as well as all devices and equipment belonging to the Company, its subsidiaries and affiliates (including computers, handheld electronic devices, telephone equipment, and other electronic devices), credit cards, records, data, notes, notebooks, reports, files, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, photographs, charts, any other documents and property, and reproductions of any and all of the aforementioned items that were developed by me pursuant to my employment with the Company, obtained by me in connection with my employment with the Company, or otherwise belonging to the Company, its subsidiaries or affiliates. I also consent to an exit interview to confirm my compliance with this Section 5.

### 6. Home or Business Address

I agree to keep the Company advised of my home and business address for a period of three (3) years after termination of my employment with the Company, so that the Company can contact me regarding my continuing obligations provided by this Agreement.

### 7. Notification of New Employer

In the event that I leave the employment of the Company, I hereby grant consent to notification by the Company to my new employer about my obligations under this Agreement.

#### 8. Non-solicitation of Employees

I agree that for a period of twelve (12) months immediately following the termination of my relationship with the Company for any reason, whether voluntary or involuntary, with or without cause, I shall not either directly or indirectly solicit any of the Company's employees to leave their employment, or attempt to solicit employees of the Company, either for myself or for any other person or entity. I agree that nothing in this Section 8 shall affect my continuing obligations under this Agreement during and after this twelve (12) month period, including, without limitation, my obligations under Section 1.

Page 18 | 26

#### 9. Conflict of Interest Guidelines

I agree to diligently adhere to all policies of the Company, including the Company's insider's trading policies and the Company's Conflict of Interest Guidelines. A copy of the Company's current Conflict of Interest Guidelines is attached as Exhibit C hereto, but I understand that these Conflict of Interest Guidelines may be revised from time to time during my employment.

#### 10. Representations

I agree to execute any proper oath or verify any proper document required to carry out the terms of this Agreement. I represent that my performance of all the terms of this Agreement will not breach any agreement prior to my employment by the Company in which I am a party. I hereby represent and warrant that I have not entered into, and I will not enter into, any oral or written agreement in conflict with this Agreement.

### 11. Audit

I acknowledge that I have no reasonable expectation of privacy in any computer, technology system, email, handheld device, telephone, or documents that are used to conduct the business of the Company. As such, the Company has the right to audit and search all such items and systems, without further notice to me, to ensure that the Company is licensed to use the software on the Company's devices in compliance with the Company's software licensing policies, to ensure compliance with the Company's policies, and for any other business-related purposes in the Company's sole discretion. I understand that I am not permitted to add any unlicensed, unauthorized, or non-compliant applications to the Company's technology systems, including, without limitation, open source or free software not authorized by the Company, and that I shall refrain from copying unlicensed software onto the Company's technology systems or using non-licensed software or websites. I understand that it is my responsibility to comply with the Company's policies governing use of the Company's documents and the internet, email, telephone, and technology systems to which I will have access in connection with my employment.

### 12. Voluntary Nature of Agreement

I ACKNOWLEDGE AND AGREE THAT I VOLUNTARILY ENTER INTO THIS AGREEMENT WITHOUT ANY DURESS OR UNDUE INFLUENCE BY THE COMPANY OR ANYONE ELSE. I FURTHER ACKNOWLEDGE AND AGREE THAT I HAVE CAREFULLY READ THIS AGREEMENT AND THAT I COMPLETELY UNDERSTAND THE TERMS, CONSEQUENCES, AND BINDING EFFECT OF THIS AGREEMENT. I HAVE BEEN PROVIDED AN OPPORTUNITY TO SEEK THE ADVICE OF AN ATTORNEY OF MY CHOICE BEFORE SIGNING THIS AGREEMENT.

#### General Provisions.

12.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by the laws of the State of New Jersey without giving effect to any choice-of-law rules or principles that may result in the application of the laws of any jurisdiction other than New Jersey. I hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in New Jersey for any lawsuit filed against me by the Company.

12.2 Entire Agreement. This Agreement, together with the Exhibits herein and any executed written offer letter between me and the Company, to the extent such materials are not in conflict with this Agreement, sets forth the entire agreement and understanding between the Company and me relating to the subject matter herein and supersedes all prior discussions or representations between us, including, but not limited to, any representations made during my interview(s) or relocation negotiations, whether written or oral. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing signed by the chairman of the Board and me.

12.3 Severability. If one or more of the provisions in this Agreement are deemed void by law, the remaining provisions will continue in full force and effect.

12.4 Successors and Assigns. This Agreement will be binding upon my heirs, executors, assigns, administrators, and other legal representatives, and will be for the benefit of the Company, its subsidiaries and affiliates, and their successors and assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated herein. Notwithstanding anything to the contrary herein, Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of the Company's relevant assets, whether by merger, consolidation, sale of assets or stock, or otherwise.

12.5 Waiver. Waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach. Any waiver must be in writing.

12.6 Survivorship. The rights and obligations of the parties to this Agreement will survive termination of my employment with the Company.

12.7 Signatures. This Agreement may be signed in two counterparts, each of which shall be deemed an original, with the same force and effectiveness as though executed in a single document.

March 23, 2018

**Employee:** 

/s/ Yuan Xu

Legend Biotech:

/s/ Frank Zhang

Signature

FRANK ZHANG Name (typed or printed) and Title

Page 20 | 26

Yuan Xu

Name of Employee (typed or printed)

Signature

### <u>Exhibit A</u>

# LIST OF PRIOR INVENTIONS

# AND ORIGINAL WORKS OF AUTHORSHIP

Identifying Number or Brief

Title

Date

None

\_\_No inventions or improvements\_\_\_ Additional Sheets Attached

Signature of Employee: /s/ Yuan Xu

Print Name of Employee: Yuan Xu

Date: March 23, 2018

Page 21 | 26

#### Exhibit B

### TERMINATION CERTIFICATION

This is to certify that I do not have in my possession, nor have I failed to return, Legend Biotech Confidential Information as defined in Section 1.1 of the Intellectual Property Rights Assignment, Non-Competition and Confidentiality Agreement (the "Agreement") and the Company Documents and Property as set forth in Section 5 of the Agreement, any other documents or property, or reproductions of any and all aforementioned items belonging to Legend Biotech USA Incorporated, its subsidiaries, affiliates, their successors or assigns (together, the "Company").

I further certify that I have complied with all the terms of the Agreement signed by me, including the reporting of any inventions and original works of authorship (as defined therein) conceived or made by me (solely or jointly with others), as covered by the Agreement.

I further agree that, in compliance with the Agreement, I will preserve as confidential all Legend Biotech Confidential Information and Associated Third Party Confidential Information, including trade secrets, confidential knowledge, data, or other proprietary information relating to products, services, processes, know-how, designs, formulas, developmental or experimental work, computer programs, databases, other original works of authorship, customer lists, business plans, financial information, or other subject matter pertaining to any business of the Company, its subsidiaries, affiliates, or any of its employees, clients, consultants, or licensees.

I further agree that, in compliance with the non-competition provisions under Section 4 of the Agreement and within twelve (12) months from the termination date, I will not directly or indirect compete with the Company within the scope and territory set forth in Section 4 of the Agreement.

I also agree that for twelve (12) months from this date, I will not either directly or indirectly solicit any of the Company's employees (i) to leave their employment, or (ii) to enter into an employment, consulting, contractor, or other relationship with any other person, firm, business entity, or organization (including with myself). I agree that nothing in this paragraph shall affect my continuing obligations under the Agreement during and after this twelve (12) month period, including, without limitation, my obligations under Section 1 thereof.

After leaving the Company's employment, I will be employed by in the position of:

Date:

Signature of employee: Print name:

Address for Notifications:

Page 22 | 26

#### Exhibit C

### CONFLICT OF INTEREST GUIDELINES

It is the policy of Legend Biotech USA Incorporated to conduct its affairs in strict compliance with the letter and spirit of the law and to adhere to the highest principles of business ethics. Accordingly, all officers, employees, and independent contractors must avoid activities that are in conflict, or give the appearance of being in conflict, with these principles and with the interests of the Company. The following are potentially compromising situations that must be avoided:

- 1. Revealing confidential information to outsiders or misusing confidential information. Unauthorized divulging of information is a violation of this policy whether or not for personal gain and whether or not harm to the Company is intended. (The Intellectual Property Rights Assignment, Non-Competition and Confidentiality Agreement elaborate on this principle and is a binding agreement.)
- 2. Accepting or offering substantial gifts, excessive entertainment, favors, or payments that may be deemed to constitute undue influence or otherwise be improper or embarrassing to the Company.
- 3. Participating in civic or professional organizations that might involve divulging confidential information of the Company.
- 4. Initiating or approving personnel actions affecting reward or punishment of employees or applicants where there is a family relationship or is or appears to be a personal or social involvement.
- 5. Initiating or approving any form of personal or social harassment of employees.
- 6. Investing or holding outside directorship in suppliers, customers, or competing companies, including financial speculations, where such investment or directorship might influence in any manner a decision or course of action of the Company.
- 7. Borrowing from or lending to employees, customers, or suppliers.
- 8. Acquiring real estate of interest to the Company.
- 9. Improperly using or disclosing to the Company any proprietary information or trade secrets of any former or concurrent employer or other person or entity with whom obligations of confidentiality exist.
- 10. Unlawfully discussing prices, costs, customers, sales, or markets with competing companies or their employees.
- 11. Making any unlawful agreement with distributors with respect to prices.

Page 23 | 26

13. Engaging in any conduct that is not in the best interest of the Company.

Each officer, employee, and independent contractor must take every necessary action to ensure compliance with these guidelines and to bring problem areas to the attention of higher management for review. Violations of this conflict of interest policy may result in discharge without warning.

<sup>12.</sup> Improperly using or authorizing the use of any inventions that are the subject of patent claims of any other person or entity.

#### EXHIBIT C TO EMPLOYMENT AGREEMENT

#### ARBITRATION AGREEMENT

This Arbitration Agreement ("Agreement") is entered into by and between Legend Biotech USA Inc., (the "Employer"), and Yuan Xu (the "Employee") (the Employer and the Employee are collectively referred to herein as the "Parties") as of <u>March 28, 2018</u> (the "Effective Date").

In consideration of the Employee's continued employment by the Employer, which the Employee acknowledges to be for good and valuable consideration for her obligations hereunder, Employer and the Employee hereby agree as follows:

Both Parties recognize that differences may arise between them. The Parties mutually consent to the resolution by arbitration of any and all claims/controversies/disputes arising out of this Agreement or the Employee's employment with Employer, including, but not limited to, any and all claims by the Employee against Employer (including, but not limited to, harassment, discrimination, whistleblower, wage and hour claims, and leave issues), and any and all claims by Employer against the Employee.

Both Parties understand that federal, state and administrative avenues to resolve disputes/claims exist. Both parties are waiving their right to pursue those avenues, specifically, both Parties are waiving their right to a jury trial. This waiver is made voluntarily, knowingly and free from duress or coercion. The Parties understand that any other avenues/forums/jurisdictions/remedies are forever precluded and regardless of the nature of the claim/dispute, the Parties understand that any claim/controversy/dispute can only be resolved through arbitration.

There will be a single arbitrator to be selected and agreed upon by the Parties. The arbitration shall be in accordance with the then current rules of the AAA (American Arbitration Association). The arbitration will take place in Piscataway, New Jersey.

The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) of New Jersey. The Arbitrator, and not a federal, state or local court or agency, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability or formulation of this Agreement, including, but not limited to, any claim that all or any part of this Agreement is void.

The arbitration shall be final and binding upon the Parties.

Except as provided in the Employment Agreement between the Parties dated March 28, 2018, each party shall bear its own costs and fees (including, but not limited to, attorneys' fees) for the arbitration unless same are awarded by the arbitrator. Further, the parties shall equally share/be responsible for the costs and fees of the arbitration and arbitrator unless same are awarded by the arbitrator.

Employee and Employer represent and warrant that they have the mental capacity to understand the terms and conditions of this Agreement.

Page 25 | 26

THE PARTIES ACKNOWLEDGE THAT THEY HAVE READ THIS AGREEMENT IN ITS ENTIRETY, UNDERSTAND ALL OF THE TERMS AND FREELY, VOLUNTARILY AND KNOWINGLY, WITHOUT DURESS OR COERCION, CONSENT TO ALL THE TERMS AND CONDITIONS CONTAINED THEREIN.

## EMPLOYEE

/s/ Yuan Xu Yuan Xu

March 23, 2018

EMPLOYER

/s/ Frank Zhang Frank Zhang

Chairman of the Executive Board Legend Biotech

Page 26 | 26

#### Ying Huang, PhD

#### 908-307-8008

#### vhuang1992@gmail.com

#### Dear Ying,

Congratulations! We are pleased to offer you the full time position of Chief Financial Officer at Legend Biotech USA, Inc. (referred to as "the Company" in the rest of this document.) We trust that your knowledge, skills and experience will be among our most valuable assets. The following is a summary of your compensation package.

#### Location: New Jersey, USA

**Remuneration:** The base salary for this position is **\$450,000** per year, plus **40%** of annual base salary as the year-end performance-based bonus target. The year-end bonus is based on employee's performance rating. The first year's bonus accrual is prorated based on percentage of time employed.

#### Long-term Incentive Plan:

You will be eligible to participate in Legend Biotech share option plan, which is a performance-based incentive plan. You will be granted a total of 1,000,000 option shares in the year of 2019, and the options will be vested evenly in 5 years starting from the first anniversary of the grant date. The purchase price per share for these total 1,000,000 shares will be at the fair market value on the grant date upon the board of Legend Biotech's approval. The terms of the grants will be in accordance with the LEGEND BIOTECH CORPORATION SHARE OPTION SCHEME.

In the event that Legend is acquired by another company, if the new ownership of the employer decides to terminate and/or not hire you under terms substantially similar in all material respects to your employment prior to the acquisition, then you will receive severance pay equal to 6 months of thencurrent base salary and all unvested options will vest immediately upon the board of Legend Biotech's approval provided that same would not violate the option scheme at that time.

**Company Benefits:** You will be eligible for Health, Dental and Vision coverage, as well as subsidized coverage for family members. You will be automatically enrolled in Accidental Death and Dismemberment, Long Term Disability and life Insurance. You will also be eligible to participate in Employer's 401(k) plan.

**Non-competition:** You are required to sign the "INTELLECTUAL PROPERTY RIGHTS ASSIGNMENT, NON-COMPETITION AND CONFIDENTIALITY AGREEMENT" with Legend Biotech prior to the employment.

Legend Biotech USA. Inc. 10 Knightsbridge Rd, Piscataway, NJ 08854 | 2101 Cottontail Lane, Somerset NJ 08873 Commencement Date: Your employment will commence on July 22nd, 2019. This offer is valid for THREE business days from the date of issuance.

At will: Your employment with the Company is at-will.

This summary supersedes all other commitments either verbal or written that may have been made to you before.

Your offer is contingent upon the followings: 1) satisfactory reference check and background check, including, but not limited to: verification of education, previous employment, personal history verification, and criminal history; 2) your employment with the company will be confirmed only after we receive the results of a drug-screening procedure. Please complete your drug screen within 72 hours from the receipt of the email from our vendor; 3) verification of your right to work in the United States. The 1986 Immigration Reform and Control Act requires U.S. employers to ensure that all candidates for employment are legally authorized to work. Therefore, you must furnish documentation of your identity and authorization to work in the U.S.

Sincerely,

/s/ Yuan Xu

Yuan Xu Chief Executive Officer, Legend Biotech

#### **Offer Confirmation**

I, Ying Huang, hereby accept the offer by Legend Biotech USA, Inc.

/s/ Ying Huang Candidate Employee Signature 4/20/2019 Date

Legend Biotech USA. Inc. 10 Knightsbridge Rd, Piscataway, NJ 08854 | 2101 Cottontail Lane, Somerset NJ 08873

Exhibit 10.5

## **LEGEND BIOTECH CORPORATION** (incorporated in the Cayman Islands with limited liability)

## SHARE OPTION SCHEME

Adopted by the resolutions of the shareholders of Legend Biotech Corporation on 2 December 2017 and approved by the resolutions of the shareholders of Genscript Biotech Corporation at the extraordinary meeting on 21 December 2017

## TABLE OF CONTENT

1.	DEFINITIONS	3
2.	ADOPTION OF THIS SCHEME	7
3.	PURPOSE, DURATION AND ADMINISTRATION	7
4.	GRANT OF OPTION	8
5.	SUBSCRIPTION PRICE	9
6.	EXERCISE OF OPTIONS	10
7.	INCENTIVE STOCK OPTIONS	12
8.	LAPSE OF OPTION	13
9.	MAXIMUM NUMBER OF SHARES SUBJECT TO OPTIONS	14
10.	REORGANISATION OF CAPITAL STRUCTURE AND SPECIAL DIVIDENDS	15
11.	SHARE CAPITAL	15
12.	ALTERATION OF THIS SCHEME	16
13.	TERMINATION	16
14.	MISCELLANEOUS	16
EX	EXHIBIT A PROXY FORM	
ΕX	HIBIT B NOTICE OF GRANT	20
EX	HIBIT C NOTICE OF EXERCISE	25
ΕX	HIBIT D INVESTMENT REPRESENTATION STATEMENT	30

**LEGEND BIOTECH CORPORATION** (incorporated in the Cayman Islands with limited liability)

## SHARE OPTION SCHEME

#### **DEFINITIONS** 1.

1.1 In this Scheme, save where the context otherwise requires, the following expressions have the respective meanings set opposite them:-

"Adoption Date"	21 December 2017, being the date of adoption of this Scheme pursuant to the resolutions of the shareholders of the Listco at the extraordinary general meeting on 21 December 2017;		
"associate"	has the meaning ascribed to it in the Listing Rules;		
"Auditors"	the auditors of the Company from time to time;		
"Board"	the board of directors of the Company from time to time or a duly authorised committee of the Board or such other committee as the Board may authorise for the purpose of administering this Scheme;		
"Business Day"	any day on which the Stock Exchange is open for the business of trading in securities;		
"Cause"	has the meaning ascribed to such term in any written agreement between the Participant and the Company or any Subsidiary of the Company defining such term as applicable to an Option and, in the absence of such an agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony; (ii) such Participant's commission of a crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof that is reasonably likely to result in material adverse effects on the Company; (iii) such participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct that is reasonably likely to result in material adverse effects on the Company. The determination that a termination or cessation of a Participant's employment or engagement for Cause or without Cause will be made by the Board, at its sole discretion;		
"close associate"	has the meaning ascribed to it in the Listing Rules;		

"Company"	Legend Biotech Corporation, an exempted company incorporated under the laws of the Cayman Islands with limited liability on 27 May 2015, which is a direct non-wholly owned Subsidiary of the Listco;
"Companies Law"	the Companies Law (as revised) of the Cayman Islands, as amended, supplemented or otherwise modified from time to time;
"connected person"	has the meaning ascribed to it in the Listing Rules;
"Date of Grant"	in respect of an Option, subject as mentioned in paragraph 9.5 and the approval of the directors and shareholders of the Listco (if required), the date on which the Board resolves to make an Offer of that Option to the Participant, which date must be a Business Day;
"Director"	a director of the Company;
"Disability"	the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances;
"Fair Market Value"	as of any date, the value of a Share determined by the Board in good faith with reference to a valuation report to be obtained from time to time and in a manner that complies with Sections 409A and 422 of the Internal Revenue Code;
"GEM"	Growth Enterprise Market, an alternative stock market operated by the Stock Exchange
"Grantee"	any Participant who accepts an Offer in accordance with the terms of this Scheme, or (where the context so permits) any person who is entitled to any such Option in consequence of the death of the original Grantee, or the legal personal representative of such person;
"Group"	the Listco and its Subsidiaries;
"HK\$"	Hong Kong dollar, the lawful currency of Hong Kong;
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China;
	4

"Individual Limit"	has the meaning ascribed to it in paragraph 9.5;
"Internal Revenue Code"	the United States Internal Revenue Code of 1986, as amended from time to time, and the rules and regulations thereunder;
"ISO" or "Incentive Stock Option"	an Option granted under this Scheme that is intended to be, and that qualifies as, an "incentive stock option" within the meaning of Section 422 of the Internal Revenue Code; (note)
"ISO Period"	has the meaning ascribed to it in paragraph 3.2;
"Listco"	Genscript Biotech Corporation (金斯瑞生物科技股份有限公司), an exempted company incorporated under the laws of the Cayman Islands with limited liability on 21 May 2015, whose shares are listed on the main board of the Stock Exchange (Stock Code: 1548);
"Listing Rules"	the Rules Governing the Listing of Securities on the Main Board of the Stock Exchange (as amended from time to time);
"Market Standoff Period"	has the meaning ascribed to it in paragraph 14.1;
"Nonstatutory Option"	means an Option granted under this Scheme to a U.S. Participant that does not qualify as an Incentive Stock Option; (note)
"Offer"	the offer of the grant of an Option made in accordance with paragraph 4.1;
"Option"	a right granted for the subscription of a Share pursuant to this Scheme, which, for U.S. Participants may be an Incentive Stock Option or a Nonstatutory Option;
"Option Period"	a period to be notified by the Board to each Grantee at the time of making an Offer, which shall not expire later than ten years from the Date of Grant (or five years in the case of an Incentive Stock Option granted to a U.S. Participant who is a Ten Percent Shareholder);
"Participants"	any directors (including executive directors, non-executive directors and independent non-executive directors) and employees of any member of the Group; <u>provided</u> , that for any Participant who is subject to the tax laws of the United States of America, such Participant must be a natural person and a director or employee of the Company or a Subsidiary that is at least 50% (or such lesser percentage as may be determined in accordance with Section 409A of the Internal Revenue Code and the final regulations and guidance thereunder) owned by the Company;
	5

"Related Corporation"	any parent corporation or subsidiary corporation as defined in Section 1.424-1(f)(1) and (2) of the U.S.		
	Treasury Regulations;		
"Scheme"	this share option scheme in its present form or as amended from time to time in accordance with the provisions hereof;		
"Scheme Limit"	the meaning given to that term in paragraph 9.1;		
"Scheme Mandate Limit"	the meaning given to that term in paragraph 9.2;		
"Securities Act"	The United States Securities Act of 1933, as amended;		
"Shareholders"	holders of the Shares;		
"Share(s)"	ordinary shares of par value US\$0.0001 each in the share capital of the Company;		
"Stock Exchange"	The Stock Exchange of Hong Kong Limited;		
"Subscription Price"	the price per Share at which a Grantee may subscribe for Shares on the exercise of an Option as described in paragraph 5;		
"Subsidiary"	has the meaning ascribed to it in the Listing Rules or a subsidiary corporation as defined in Section $1.424-1(f)(1)$ and (2) of the U.S. Treasury Regulations (as the case may be);		
"substantial shareholder"	has the meaning ascribed to it in the Listing Rules;		
"Ten Percent Shareholder"	means an employee of the Company or a subsidiary corporation (as defined in Section 1.424-1(f)(1) and (2) of the U.S. Treasury Regulations) of the Company who owns (or is treated as owning) stock possessing more than 10 percent of the total combined voting power of all classes of stock of the corporation employing the Grantee or of a Related Corporation;		
"US\$"	U.S. dollar, the lawful currency of the United States of America; and		
"U.S. Participant"	means a Participant who is subject to the tax laws of the United States of America.		

Note:

The main difference between an Incentive Stock Option and a Nonstatutory Option is that a U.S. Participant may receive more favorable tax treatment at the time of grant, exercise, and sale of Shares of Legend Cayman received upon the exercise of an Incentive Stock Option (as described in 26 U.S. Code Sec. 422 and the related U.S. Treasury Regulations), depending on the U.S. Participant's tax situation. An Incentive Stock Option must meet certain specific requirements to receive preferential tax treatment.

- 1.2 In this Scheme, save where the context otherwise requires:-
  - (a) the headings are inserted for convenience only and shall not limit, vary, extend or otherwise affect the construction of any provision of this Scheme;
  - (b) references to paragraphs are references to paragraphs of this Scheme;
  - (c) references to any statute or statutory provision shall be construed as references to such statute or statutory provision as respectively amended, consolidated or re-enacted, or as its operation is modified by any other statute or statutory provision (whether with or without modification), and shall include any subsidiary legislation enacted under the relevant statute;
  - (d) expressions in the singular shall include the plural and vice versa;
  - (e) expressions in any gender or the neuter shall include other genders and the neuter; and
  - (f) references to persons shall include bodies corporate, corporations, partnerships, sole proprietorships, organisations, associations, enterprises, branches and entities of any other kind whether or not having separate legal identity.

#### 2. ADOPTION OF THIS SCHEME

- 2.1 This Scheme shall become valid and effective upon adoption by the resolutions of the shareholders of the Company and approval by the resolutions of the shareholders of the Listco at the extraordinary meeting.
- 2.2 The approval in Section 2.1 above must comply with all applicable provisions of the corporate charter, bylaws, and applicable state law prescribing the method and degree of stockholder approval required for the issuance of corporate stock or options.

#### 3. <u>PURPOSE, DURATION AND ADMINISTRATION</u>

- 3.1 The purpose of this Scheme is to provide Participants with the opportunity to acquire proprietary interests in the Company and to encourage Participants to work towards enhancing the value of the Company and its Shares for the benefit of the Company and its Shareholders as a whole. This Scheme will provide the Company with a flexible means of either retaining, incentivising, rewarding, remunerating, compensating and/or providing benefits to Participants.
- 3.2 Subject to paragraphs 13 and 14, this Scheme shall be valid and effective for a period of ten years commencing on the Adoption Date. After the expiry of the ten-year period, no further Options shall be offered or granted, but in all other respects the provisions of this Scheme shall remain in full force and effect; <u>provided</u>, that no Incentive Stock Options may be granted under the Scheme after the tenth anniversary of the earlier of (a) the date the Scheme is adopted by the Board and (b) the date the Scheme is approved by the Company's Shareholders (such period, the "<u>ISO</u> <u>Period</u>"). Options complying with the provisions of Chapter 17 of the Listing Rules which are granted during the life of this Scheme shall continue to be exercisable in accordance with their terms of issue after the end of the ten-year term of this Scheme.

- 3.3 This Scheme shall be subject to the administration of the Board, and the decision of the Board shall be final and binding on all parties. The Board shall have the right to (i) interpret and construe the provisions of this Scheme, (ii) determine the persons who will be offered Options under this Scheme, the terms on which Options are granted, the number of Shares and the Subscription Price, subject to paragraph 5, in relation to such Options, (iii) subject to paragraphs 10 and 12, make such adjustments to the terms of this Scheme and to the terms of the Options granted under this Scheme as it deems necessary, including providing for the accelerated vesting and/or exercisability of Options as it deems appropriate, and shall notify the relevant Grantee(s) of such adjustment(s) by written notice, and (iv) make such other decisions or determinations as it shall deem appropriate in the administration of this Scheme.
- 3.4 No member of the Board shall be personally liable by reason of any contract or other instrument executed by such member or on his behalf in his capacity as a member of the Board or for any mistake of judgment made in good faith for the purposes of this Scheme, and the Company shall indemnify and hold harmless each employee, officer or director of the Company to whom any duty or power relating to the administration or interpretation of this Scheme may be allocated or delegated, against any cost or expense (including legal fees) or liability (including any sum paid in settlement of a claim with the approval of the Board) arising out of any act or omission to act in connection with the Scheme unless arising out of such person's own fraud or bad faith.

#### 4. GRANT OF OPTION

- 4.1 On and subject to the terms of this Scheme, the Board shall be entitled at any time within ten years after the Adoption Date (or, in the case of an Incentive Stock Option, within the ISO Period) to make an Offer to any Participant, as the Board may at its absolute discretion select, to take up an Option pursuant to which such Participant may, during the Option Period, subscribe for such number of Shares as the Board may determine at the Subscription Price. The Offer shall specify the terms on which the Option is to be granted, including the number of Shares that may be subscribed for, and the Subscription Price, and may include at the discretion of the Board other terms either on a case by case basis or generally.
- 4.2 Each grant of Options to any director, chief executive or substantial shareholder of the Listco (or any of their respective associates) shall be subject to the prior approval of the independent non-executive directors of the Listco (excluding any independent non-executive director of the Listco who is a proposed recipient of the grant of Options). Where any grant of Options to a substantial shareholder or an independent non-executive director of the Listco, or any of their respective associates, would result in the Shares issued and to be issued upon exercise of all Options already granted and to be granted (including Options exercised, cancelled and outstanding) to such person in the 12-month period (or such other period as may from time to time be specified by the Stock Exchange) up to and including the Date of Grant, representing in aggregate over 0.1 % (or such other percentage as may from time to time be specified by the Stock Exchange) of the Shares in issue, such grant of Options shall be subject to prior approval by the Listco's shareholders (voting by way of poll). The Grantee, his associates and all core connected persons (as defined in the Listing Rules) of the Listco shall abstain from voting at such general meeting, except that any such person may vote against the relevant resolution at the general meeting, provided that his intention to do so has been stated in the circular to be sent to the Listco's shareholders in connection therewith.

- 4.3 No Offer shall be made and no Option shall be granted to any Participant after inside information has come to the knowledge of the Listco and the Company until the Listco has announced the information. In particular, the Company shall not grant any Option during the period commencing one month immediately preceding the earlier of:-
  - (1) the date of the board meeting of the Listco (as such date is first notified to the Stock Exchange in accordance with the requirements of the Listing Rules) for the approval of the Listco's results for any year, half year, quarter or any other interim period (whether or not required under the Listing Rules); and
  - (2) the deadline for the Listco to publish an announcement of its results for any year or half-year under the Listing Rules, or quarter or any other interim period (whether or not required under the Listing Rules),

and ending on the date of the results announcement. For the avoidance of doubt, the period during which no Option shall be granted mentioned above shall include any period of delay in the publication of a results announcement.

- 4.4 An Offer shall be made to a Participant by a letter in duplicate in such form as the Board may from time to time determine requiring the Participant to undertake to hold the Option on the terms on which it is to be granted and to be bound by the provisions of this Scheme and shall remain open for acceptance by the Participant to whom the Offer is made for a period of 21 days from the date on which the letter containing the Offer is delivered to that Participant, <u>provided</u> that no such Offer shall be open for acceptance after the tenth anniversary of the Adoption Date (or, in the case of an Offer for an ISO, after the ISO Period) or after this Scheme has been terminated in accordance with the provisions hereof or after the person/entity to whom the Offer is made has ceased to be a Participant.
- 4.5 An Offer shall be deemed to have been accepted and the Option to which the Offer relates shall be deemed to have been granted and to have taken effect when the duplicate of the offer letter comprising acceptance of the Offer duly signed by the Grantee with the number of Shares in respect of which the Offer is accepted clearly stated therein, together with a total remittance in favour of the Company of US\$ 1.00 (or its equivalent in RMB) by way of consideration for the grant thereof, is received by the Company. Such remittance shall not be refundable in any circumstances.
- 4.6 Any Offer may be accepted in respect of less than the number of Shares for which it is offered. To the extent that the Offer is not accepted within 21 days from the date on which the letter containing the Offer is delivered to that Participant in the manner indicated in paragraph 4.5, it shall be deemed to have been irrevocably declined.

## 5. <u>SUBSCRIPTION PRICE</u>

5.1 The Subscription Price payable by any Grantee (including a non-U.S. Participant or a U.S. Participant) shall be no less than the Fair Market Value of a Share of Legend Cayman on the Date of Grant (determined with reference to a valuation report to be obtained in determining the Fair Market Value of a Share of Legend Cayman from time to time), subject to rounding adjustments (that the Subscription Price as determined pursuant to this paragraph shall be rounded to the nearest ten), provided that with respect to the period from the date when the Company resolves to seek a separate listing of Legend Cayman on the Stock Exchange, GEM, or an overseas stock exchange and up to the listing date (if any), the rules under note (2) to rule 17.03(9) of the Listing Rules is complied with.

#### 6. EXERCISE OF OPTIONS

- 6.1 An Option shall be personal to the Grantee and shall not be assignable and no Grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest in favour of any other person over or in relation to any Option, except for the transmission of an Option on the death of the Grantee to his personal representative(s) on terms of this Scheme. Any breach of the foregoing shall entitle the Company to cancel any outstanding Option or part thereof granted to such Grantee without incurring any liability on the part of the Company.
- 6.2 An Option may, subject to the terms and conditions upon which such Option is granted, be exercised in whole or in part in the manner as set out in paragraph 6.3 by the Grantee giving notice in writing to the Company stating that the Option is thereby exercised and the number of Shares in respect of which it is exercised. The notice of exercise shall be in such form as the Board may from time to time determine. Each such notice must be accompanied by a remittance for the aggregate amount of the Subscription Price multiplied by the number of Shares in respect of which the notice is given. Within 15 Business Days after receipt of the notice, the aggregate amount of the Subscription Price, and, where appropriate, receipt of the Auditors' or the relevant financial advisor's (retained for such purpose) certificate pursuant to paragraph 10, the Company shall, at the Board's absolute discretion, allot and issue the relevant number of Shares to the Grantee credited as fully paid and issue to the Grantee a share certificate in respect of the Shares so allotted; provided, that, the issuance of Shares to a U.S. Participant upon exercise of an Option shall be subject to the U.S. Participant satisfying any applicable tax withholding obligations, which may be satisfied by the U.S. Participant in cash or check or any other method permitted by the Company in accordance with applicable law.

Notwithstanding anything to the contrary herein, as to PRC (as hereinafter defined) Participants, the Option may not be exercised, unless otherwise approved by the Board, until all registrations, consents, approvals, filings or waivers required under applicable laws, including the laws of the People's Republic of China (the "PRC"), are duly obtained. In particular, the exercise of Options shall be conditioned by the Grantee's completion of requisite registration by the PRC State Administration of Foreign Exchange ("SAFE") or its authorized institutions under the Notice of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Return on Investment Conducted by Residents in China via Special-Purpose Companies ("Circular 37") with regard to the Shares acquired upon exercise. The Company shall coordinate with the Grantee in connection with handling registrations, approvals, filings or waivers for the exercise of Option only to the extent determined by the Board.

- 6.3 Subject to the terms and conditions upon which such Option was granted, an Option may be exercised by the Grantee at any time during the Option Period, provided that:-
  - (a) unless otherwise provided in an agreement evidencing the grant of an Option, in the event the Grantee (being an employee or a director of any member of the Group with respect to Participants who are not U.S. Participants, or, in the case of U.S. Participants, being an employee or a director of the Company or a Subsidiary of the Company) ceases to be a Participant for any reason other than (i) his or her death, (ii) his or her Disability, or (iii) on one or more of the grounds of termination of employment or engagement specified in paragraph 8(f) the Option shall lapse on the date of cessation of such employment or engagement and not be exercisable unless the Board otherwise determines in which event the Option shall be exercisable to the extent and within such period as the Board may determine; provided that if the Participant is a U.S. Participant and the U.S. Participant ceases employment or engagement for any reason other than Cause, death or Disability, the Option shall lapse 30 days after the date of such cessation of such employment or engagement and shall not be exercisable thereafter. The date of cessation of employment of a Grantee (being an employee and who may or may not be a director of any member of the Group) shall be the last actual working day on which the Grantee was physically at work with the Company or the relevant Subsidiary, whether salary is paid in lieu of notice or not;

- (b) in the event the Grantee (A) dies before exercising the Option in full and none of the events for termination of employment or engagement under paragraph 8(f) then exists with respect to such Grantee, the personal representative(s) of the Grantee shall be entitled within a period of twelve months from the date of death to exercise the Option up to the entitlement of such Grantee as at the date of death, or (B) becomes Disabled before exercising the Option in full and none of the events for termination of employment or engagement under paragraph 8(f) then exists with respect to such Grantee, the Grantee shall be entitled within a period of twelve months from the date of exercise the Option up to the entitlement of such Grantee as at the date when he becomes Disabled to exercise the Option up to the entitlement of such Grantee as at the date when he becomes Disabled;
- (c) if a general offer by way of voluntary offer, takeover or otherwise (other than by way of scheme of arrangement pursuant to paragraph 6.3(d) below) is made to all the holders of Shares (or all such holders other than the offeror, any person controlled by the offeror and any person acting in association or concert with the offeror) and such offer becomes or is declared unconditional prior to the expiry date of the relevant Option, the Company shall forthwith give notice thereof to the Grantee and the Grantee shall be entitled to exercise the Option to its full extent or, if the Company shall give the relevant notification, to the extent notified by the Company pursuant to paragraph 6.4(b) at any time within such period as shall be notified by the Company;
- (d) if a general offer for Shares by way of scheme of arrangement is made to all the holders of Shares and has been approved by the necessary number of holders of Shares at the requisite meetings, the Company shall forthwith give notice thereof to the Grantee and the Grantee may at any time thereafter (but before such time as shall be notified by the Company) exercise the Option to its full extent or, if the Company shall give the relevant notification, to the extent notified by the Company pursuant to paragraph 6.4(b));
- (e) in the event a notice is given by the Company to its Shareholders to convene a Shareholders' meeting for the purpose of considering and, if thought fit, approving a resolution to voluntarily wind-up the Company, the Company shall forthwith give notice thereof to the Grantee and the Grantee may at any time thereafter (but before such time as shall be notified by the Company) exercise the Option to its full extent or, if the Company shall give the relevant notification, to the extent notified by the Company pursuant to paragraph 6.4(b), and the Company shall as soon as possible and in any event no later than three days prior to the date of the proposed Shareholders' meeting, allot, issue and register in the name of the Grantee such number of fully paid Shares which fall to be issued on exercise of such Option; and
- (f) in the event of a compromise or arrangement, other than a scheme of arrangement contemplated in paragraph 6.3(d) above, between the Company and its members and/or creditors being proposed in connection with a scheme for the reconstruction or amalgamation of the Company, the Company shall give notice thereof to all Grantees on the same day as it first gives notice of the meeting to its members and/or creditors to consider such a scheme or arrangement and the Grantee may at any time thereafter but before such time as shall be notified by the Company pursuant to paragraph 6.4(b), and the Company shall as soon as possible and in any event no later than three days prior to the date of the proposed meeting, allot, issue and register in the name of the Grantee such number of fully paid Shares which fall to be issued on exercise of such Option.

6.4 For the purpose of this paragraph 6:-

- (a) any references to exercising an Option shall refer to exercising that Option to the extent not already exercised, notwithstanding that the Option Period has not come into effect;
- (b) pursuant to paragraphs 6.3(c), (d), (e) and (f), the Company may in its discretion notwithstanding the terms of the relevant Option, at the same time as giving the notice provided for under each of those paragraphs, also give notice to a Grantee that his or her Option may be exercised at any time within such period as shall be notified by the Company and/or to the extent (not being less than the extent to which it could then be exercised in accordance with its terms) notified by the Company; and
- (c) if the Company gives notice under paragraph 6.4(b) that an Option can be exercised in part only, the balance of the Option shall lapse.
- 6.5 The Shares to be allotted and issued upon the exercise of an Option shall be subject to all the provisions of the memorandum and articles of association of the Company for the time being in force and will rank pari passu with the fully paid Shares in issue on the date the name of the Grantee is registered on the register of members of the Company. Prior to the Grantee being registered on the register of members of the Company, the Grantee shall not have any voting rights, or rights to participate in any dividends or distributions (including those arising on a liquidation of the Company), in respect of the Shares to be issued upon the exercise of the Option.
- 6.6 Only with respect to Participants who are not U.S. Participants, any Options granted but not exercised may be cancelled if the Grantee so agrees and new Options may be granted to the Grantee provided such new Options are granted within the limits prescribed by paragraph 9 and otherwise comply with the terms of this Scheme.
- 6.7 The Participant shall, concurrently with the exercise of all or any portion of the Option, deliver to the Company an irrevocable proxy in the form attached hereto as Exhibit A.

#### 7. INCENTIVE STOCK OPTIONS

- 7.1 Notwithstanding anything to the contrary in this Scheme, the following shall apply to Options that are intended to be granted as Incentive Stock Options.
  - (a) Eligibility. Incentive Stock Options may be granted only to Participants who are employees of the Company or a "subsidiary corporation" thereof (as such term is defined in Section 424(f) of the Internal Revenue Code). An Incentive Stock Option shall not be exercisable after the expiration of ten years after the Date of Grant.
  - (b) Subscription Price. The Subscription Price of an Incentive Stock Option shall be no less than the Fair Market Value of a Share on the Date of Grant.
  - (c) Terms. The Offer evidencing the grant of each Incentive Stock Option shall provide that the Option is intended to be an Incentive Stock Option and shall provide that the Option shall not be exercisable after the expiration of ten years after the Date of Grant (or five years, in the case of Incentive Stock Options granted to Ten Percent Shareholders).

- (d) Ten Percent Shareholders. Pursuant to U.S. tax laws (26 U.S. Code Sec. 422), a, a Ten Percent Shareholder will not be granted an Incentive Stock Option unless the Subscription Price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the Date of Grant and the Option is not exercisable after the expiration of five years after the Date of Grant.
- (e) Transferability. An Incentive Stock Option will not be transferable except by will or by the laws of descent and distribution and will be exercisable during the lifetime of the Grantee only by the Grantee.
- (f) US\$100,000 Limitation. If the aggregate Fair Market Value (determined at the time of grant) of Shares with respect to which Incentive Stock Options are exercisable for the first time by any Grantee during any calendar year (under all share option schemes of the Company and Related Corporations) exceeds US\$ 100,000 or such other limit established in the Internal Revenue Code) or if an Option grant otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with the rules will be treated as Nonstatutory Options, despite any contrary provisions of the applicable Offer evidencing the grant of such Option.

#### 8. LAPSE OF OPTION

An Option shall lapse automatically (to the extent not already exercised) on the earliest of:-

- (a) the expiry of the Option Period (subject to the provisions of paragraphs 2.2 and 13);
- (b) the expiry of the periods for exercising the Option as referred to in paragraph 6.3(a),(b),(c),(d);
- (c) subject to the scheme of arrangement (referred to in paragraph 6.3(d)) becoming effective, the expiry of the period for exercising the Option as referred to in paragraph 6.3(d);
- (d) subject to paragraph 6.3(e), the date of the commencement of the winding-up of the Company;
- (e) the date on which the Grantee commits a breach of paragraph 6.1;
- (f) the date on which the Grantee (being an employee or a director of any member of the Group) (i) ceases to be a Participant by reason of the termination of his or her employment or engagement for Cause, (ii) has been convicted of any criminal offence involving his or her integrity or honesty, or on any other ground on which an employer would be entitled to terminate his or her employment summarily, or (iii) only with respect to Grantees who are not U.S. Participants, appears either to be unable to pay or to have no reasonable prospect of being able to pay his or her debts or has become
- (g) bankrupt or has made any arrangement or composition with his or her creditors generally;
- (h) where the Grantee is an employee, director, officer or contract consultant of a member of the Group (other than the Company), the date on which such member ceases to be a Subsidiary; and

(i) unless the Board otherwise determines, and other than in the circumstances referred to in paragraph 6.3(a) or (b), the date the Grantee ceases to be a Participant (as determined by a resolution of the Board) for any reason.

Transfer of employment or engagement or relationship from one member of the Group to another member of the Group shall not be considered as a cessation of employment, engagement or relationship; provided, that for U.S. Participants, transfer of employment or engagement or relationship from the Company or a Subsidiary of the Company to Listco shall be deemed to be a termination of employment or engagement for purposes of participation in this Scheme.

#### 9. MAXIMUM NUMBER OF SHARES SUBJECT TO OPTIONS

- 9.1 The overall limit on the number of Shares which may be issued upon exercise of all outstanding Options granted and yet to be exercised under this Scheme and other share option schemes of the Company (and to which the provisions of Chapter 17 of the Listing Rules are applicable) must not exceed 30% of the Shares in issue from time to time (the "Scheme Limit").
- 9.2 The total number of Shares which may be issued upon exercise of all Options to be granted under this Scheme and other share option schemes of the Company shall not in aggregate exceed 10% of the Shares in issue as at the date of the Adoption Date (the "**Scheme Mandate Limit**"), being 200,000,000 Shares multiplied by 10% which equals to 20,000,000, assuming that there is no change in the issued share capital of the Company between the period from the Latest Practicable Date and the Adoption Date. Options lapsed in accordance with the terms of this Scheme will not be counted for the purpose of calculating the Scheme Mandate Limit.
- 9.3 The Company may seek approval of the Shareholders in general meeting for refreshing the Scheme Mandate Limit, under the Share Option Scheme. However, the total number of Shares which may be issued upon exercise of all Options to be granted under all of the schemes of the Company under the Scheme Mandate Limit as refreshed shall not exceed 10% of the Shares in issue as at the date of the aforesaid approval of the Scheme Mandate Limit. Options previously granted under this Scheme and other share option schemes of the Company (including those outstanding, cancelled, lapsed in accordance with its terms or exercised options), will not be counted for the purpose of calculating the limit as refreshed. A circular must be sent to the Listco's shareholders in connection with the meeting at which their approval will be sought.
- 9.4 The Company may also seek separate approval of the Listco's shareholders in general meeting for granting Options beyond the Scheme Mandate Limit provided the Options in excess of the Scheme Mandate Limit are granted only to Participants specifically identified by the Listco before such approval is sought. A circular shall be sent to the Listco's shareholders containing a generic description of the specified Participants who may be granted such Options, the number and terms of the Options to be granted and the purpose of granting Options to the specified Participants with an explanation as to how the terms of the Options serve such purpose.
- 9.5 The total number of Shares issued and to be issued upon exercise of the Options granted to each Participant (including both exercised, cancelled and outstanding Options) in any 12-month period shall not exceed 1% of the Shares in issue (the "**Individual Limit**"). Any further grant of Options to a Participant which would result in the Shares issued and to be issued upon exercise of all Options granted and to be granted to such Participant (including exercised, cancelled and outstanding Options) in the 12-month period up to and including the Date of Grant of such further Options exceeding the Individual Limit shall be subject to the approval of Listco's shareholders in advance with such Participant and his close associates (or his associates if such Participant is a connected

person) abstaining from voting. A circular must be sent to the Listco's shareholders disclosing the identity of such Participant and the number and terms of the Options granted and to be granted. The number and terms of Options to be granted to such Participants shall be fixed before the approval of the Listco's shareholders is sought and the date of the Listco's board meeting for proposing such further grant shall for all purposes be the Date of Grant for the purpose of calculating the Subscription Price.

- 9.6 Subject to paragraph 10, the aggregate maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under this Scheme will be equal to the Scheme Limit, as may be refreshed from time to time.
- 9.7 The maximum number of Shares referred to in paragraph 9 shall be adjusted, in such manner as the Auditors or the financial advisor of the Company retained for such purpose shall certify to be appropriate, fair and reasonable in the event of any alteration in the capital structure of the Company in accordance with paragraph 10 by way of capitalisation of profits or reserves, rights issue, subdivision or consolidation of Shares, reduction of the share capital of the Company.

#### 10. REORGANISATION OF CAPITAL STRUCTURE AND SPECIAL DIVIDENDS

In the event of an alteration in the capital structure of the Company whilst any Option remains exercisable by way of capitalisation of profits or reserves, rights issue, subdivision or consolidation of shares, or reduction of the share capital of the Company, such corresponding alterations (if any) shall be made to:

- (i) the number or nominal amount of Shares subject to the Option so far as unexercised; or
- (ii) the Subscription Price,

or any combination thereof, as the Auditors or a financial advisor engaged by the Company for such purpose shall, at the request of the Company, certify in writing, either generally or as regards any particular Grantee, to be in their opinion fair and reasonable, provided that any such adjustments give a Grantee the same proportion of the equity capital of the Company as that to which that Grantee was previously entitled, but so that no such adjustments be made to the extent that a Share would be issued at less than its nominal value; and further provided that any such adjustments for U.S. Participants shall comply with Section 409A of the Internal Revenue Code. The capacity of the Auditors or financial advisor (as the case may be) in this paragraph is that of experts and not of arbitrators and their certification shall, in the absence of manifest error, be final and binding on the Company and the Grantees. The costs of the Auditors or financial advisor (as the case may be) shall be borne by the Company.

#### 11. SHARE CAPITAL

- 11.1 The exercise of any Option shall be subject to the Shareholders in general meeting approving any necessary increase in the authorised share capital of the Company in accordance with the Companies Law. Subject thereto, the Board shall make available sufficient authorised but unissued share capital of the Company to meet subsisting requirements on the exercise of Options.
- 11.2 Prior to the exercise of the Options and the acquisition of the underlying Shares, the Options do not carry any right to vote in general meeting of the Company, or any right to dividend, or any other rights whether or not arising on the liquidation of the Company.

#### 12. ALTERATION OF THIS SCHEME

- 12.1 Subject to paragraph 12.2 below, the Board may amend any of the provisions of the Scheme (including without limitation amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of the Scheme, which are not found in Chapter 17 of the Listing Rules) at any time (but not so as to affect adversely any rights which have accrued to any Grantee at that date).
- 12.2 Those specific provisions of this Scheme which relate to the matters set out in rule 17.03 of the Listing Rules cannot be altered to the advantage of Participants, and no changes to the authority of the Directors or administrator of this Scheme in relation to any alteration of the terms of this Scheme shall be made, without the prior approval of the Listco's shareholders in general meeting. Any alterations to the terms and conditions of this Scheme which are of a material nature, or any change to the terms of Options granted, must also, to be effective, be approved by the Listco's shareholders in general meeting, except where the alterations take effect automatically under the existing terms of this Scheme. This Scheme so altered must comply with Chapter 17 of the Listing Rules.
- 12.3 Notwithstanding any approval obtained pursuant to paragraph 12.1, no amendment shall operate to adversely affect the terms of issue of any Option granted or agreed to be granted prior to such amendment except with the consent or sanction in writing of such number of Grantees as shall together hold Options in respect of not less than three-fourths in nominal value of all Shares then subject to the options granted under this Scheme, except where such amendment takes effect automatically under the existing terms of this Scheme.

#### 13. TERMINATION

The Company by ordinary resolution in general meeting or the Board may at any time terminate the operation of this Scheme and in such event no further Options will be offered or granted but in all other respects the provisions of this Scheme shall remain in full force and effect. Options which are unexercised and unexpired immediately prior to the termination of the operation of this Scheme shall continue to be exercisable in accordance with their terms of issue after the termination of this Scheme.

#### 14. MISCELLANEOUS

14.1 Lock-Up Period. A Grantee shall agree that, if so requested by the Company in connection with any registration of the offering of any securities of the Company under the Securities Act or any applicable United States state laws, the Grantee shall not sell or otherwise transfer any shares of Shares or other securities of the Company during the 180-day period (or such longer period as may be agreed to in writing by the Company) following the effective date of a registration statement of the Company filed under the Securities Act in connection with any initial public offering of Shares (the "**Market Standoff Period**"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period and these restrictions shall be binding on any transferee of such shares of Shares. Notwithstanding the foregoing, the 180-day period may be extended for up to such number of additional days as is deemed necessary by the Company.

- 14.2 Legends and Stop-Transfer Orders.
  - (a) Legends. The Company shall cause the legends set forth below or legends substantially similar thereto, to be placed upon any certificate(s) evidencing ownership of the shares of Shares acquired upon exercise of an Option together with any other legends that may be required by United States state or federal securities laws:

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") OR ANY APPLICABLE STATE SECURITIES LAWS AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT AND SUCH LAWS OR, IN THE OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION IS IN COMPLIANCE THEREWITH.

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER AND RIGHT OF FIRST REFUSAL AND REPURCHASE RIGHTS HELD BY THE ISSUER OR ITS ASSIGNEE(S) AS SET FORTH IN THE EXERCISE NOTICE BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH TRANSFER RESTRICTIONS AND RIGHT OF FIRST REFUSAL AND REPURCHASE RIGHTS ARE BINDING ON TRANSFEREES OF THESE SHARES.

- (b) Stop-Transfer Notices. In order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.
- (c) Refusal to Transfer. The Company shall not be required (i) to transfer on its books any shares of Shares that have been sold or otherwise transferred in violation of any of the provisions of this Scheme or (ii) to treat as owner of such shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such shares shall have been so transferred.
- 14.3 Grantee's Representations. If the shares of Shares purchasable pursuant to the exercise of an Option have not been registered under the Securities Act or any applicable state laws at the time the Option is exercised, a Grantee shall, if required by the Company, concurrently with the exercise of all or any portion of the Option, deliver to the Company his or her Investment Representation Statement in the form attached hereto as Exhibit A and shall make such other written representations as are deemed necessary or appropriate by the Company and/or its counsel.
- 14.4 To the extent applicable, it is intended that this Scheme and any Options granted hereunder to U.S. Participants are exempt from, or comply with, the provisions of Section 409A of the Internal Revenue Code. This Scheme and any Options granted hereunder will be administered in a manner consistent with this intent.
- 14.5 This Scheme shall not form part of any contract of employment between the any member of the Group and any Grantee, and the rights and obligations of any such Grantee under the terms of his or her office or employment or engagement shall not be affected by his or her participation in this Scheme and this Scheme shall afford such Grantee no additional rights to compensation or damages in consequence of the termination of such office or employment for any reason.

- 14.6 Participation in this Scheme shall be at the Board's absolute discretion and neither participation in this Scheme nor the receipt of an Offer pursuant to this Scheme shall create any right to or expectation of any future participation or offer under this Scheme or any other equity-based incentive plans of the Group.
- 14.7 This Scheme shall not confer on any person any legal or equitable right (other than those rights constituting the Options themselves) against the Company directly or indirectly or give rise to any cause of action at law or in equity against the Company or any Subsidiary.
- 14.8 The Company shall bear the costs of establishing and administering this Scheme.
- 14.9 A Grantee shall be entitled to receive copies of all notices and other documents sent by the Company to holders of Shares generally.
- 14.10 Any notice or other communication between the Company and a Grantee may be given by sending the same by prepaid post or by personal delivery to, in the case of the Company, its principal place of business in Nanjing, the People's Republic of China or such other address as notified to the Grantee from time to time and, in the case of the Grantee, his or her address last notified to the Company.
- 14.11 Any notice or other communication served by post:-
  - (a) by the Company shall be deemed to have been served 24 hours after the same was put in the post; and
  - (b) by the Grantee shall not be deemed to have been received until the same shall have been received by the Company.
- 14.12 All allotments and issues of Shares will be subject to all necessary consents under any relevant legislation for the time being in force in Hong Kong and in the Cayman Islands, and a Grantee shall be responsible for obtaining any governmental or other official consent or approval that may be required by any country or jurisdiction in order to permit the grant, holding or exercise of the Option. The Company shall not be responsible for any failure by a Grantee to obtain any such consent or approval or for any tax or other liability to which a Grantee may become subject as a result of his or her participation in this Scheme.
- 14.13 Each Grantee shall pay all taxes and discharge all other liabilities to which he may become subject as a result of his participation in this Scheme or the exercise of any Option.
- 14.14 The Board shall have the power from time to time to make or vary regulations for the administration and operation of this Scheme, provided that the same are not inconsistent with the provisions of this Scheme. The Board shall also have the power to delegate its powers to grant Options to Participants and to determine the Subscription Price, to the Company's chief executive officer or managing director from time to time.
- 14.15 This Scheme and all Options granted hereunder shall be governed by and construed in accordance with the laws of Hong Kong

#### EXHIBIT A PROXY FORM

The undersigned shareholder (the "**Shareholder**") of Legend Biotech Corporation, an exempted company incorporated in the Cayman Islands (the "**Company**"), hereby irrevocably (to the fullest extent permitted by law) appoints Fangliang Zhang (the "**Proxyholder**") as the sole and exclusive attorney and proxy of the undersigned, with full power of substitution and resubstitution, to vote and exercise all voting and related rights (to the full extent that the undersigned is entitled to do so) with respect to \_\_\_\_\_\_\_ ordinary shares of the Company that now are legally owned or will be owned by the undersigned, and any and all other shares or securities of the Company issued or issuable in respect thereof on or after the date hereof (collectively, the "**Shares**"), in accordance with the terms of this irrevocable proxy (the "**Proxy**"). Upon the undersigned's execution of this Proxy, any and all prior proxies given by the undersigned with respect to any Shares are hereby revoked and the undersigned agrees not to grant any subsequent proxies with respect to the Shares.

This Proxy is coupled with an interest and is given to secure the performance of the Shareholder's obligations under the Notice of Grant pursuant to which the Shares were originally acquired from the Company. This Proxy is irrevocable until the expiration date as set out in the Notice of Grant.

The Proxyholder is hereby authorised and empowered by the undersigned to act as the undersigned's attorney and proxy to vote the Shares, and to exercise all voting, consent and similar rights of the undersigned with respect to the Shares (including, without limitation, the power to execute and deliver written consents) at every annual, special, adjourned or postponed meeting of shareholders of the Company and with respect to every written resolutions in lieu of such meeting in the manner determined by the Proxyholder in his sole discretion.

This Proxy shall be governed by and construed in accordance with the laws of Hong Kong.

This Proxy shall not affect the right to transfer the Shares other than as set forth in the following sentence, the Scheme and the Notice of Exercise and Share Purchase Agreement. Any obligation of the undersigned hereunder shall be binding upon the transferees, heirs, successors, assigns, administrators, executors and other legal representatives of the undersigned.

Shareholder

Mr. Fangliang Zhang

Proxyholder

DATED: <u>MM/DD/YYYY</u>

## EXHIBIT B NOTICE OF GRANT

To:

Mm/dd/yyyy

Dear :

# LEGEND BIOTECH CORPORATION SHARE OPTION SCHEME

## NOTICE OF GRANT OF AN OPTION

We are pleased to inform you that Legend Biotech Corporation (the "**Company**") is granting you an Option to subscribe for ordinary shares in the share capital of the Company (the "**Shares**"). This grant is being made pursuant to the share option scheme adopted by the Company on Dec. 21st 2017 (the "**Scheme**") and is subject to the terms set out in this letter (the "**Notice of Grant**") and the rules of the Scheme (as such rules may be amended from time to time). Capitalized terms not defined in this Notice of Grant shall have the meanings ascribed in the Scheme. The Scheme is enclosed with this Notice of Grant.

## Grant of Option

The terms of the grant of the Option are as follows:

 Type of Option:
 Incentive Stock Option

 Number of Shares subject to the Option:
 Incentive Stock Option

 (Performance A or S is required)
 Incentive Stock Option

 Subscription price
 Incentive Stock Option

 (the price per Share at which you may subscribe for Shares upon exercising the Option).
 Incentive Stock Option

 Expiration date
 mm/dd/yyyy

[Time-Based Vesting: The Option is subject to time-based vesting. Subject to the rules of the Scheme and the conditions set out below, the Option will vest and be exercisable with respect to the number of Shares and on the dates set forth in the following schedule:

<u>Vesting date</u> mm/dd/yyyy	Performance Goal/ Performance Period (if applicable) Performance Period:	Number of Shares	Exercise period mm/dd/yyyy-
	mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy
mm/dd/yyyy	Performance Period: mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy- mm/dd/yyyy
mm/dd/yyyy	Performance Period: mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy- mm/dd/yyyy
mm/dd/yyyy	Performance Period: mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy- mm/dd/yyyy
mm/dd/yyyy	Performance Period: mm/dd/yyyy to mm/dd/yyyy		mm/dd/yyyy- mm/dd/yyyy

[Performance-Based Vesting: The Option is subject to performance-based vesting and, subject to the rules of the Scheme and the conditions set out below, the Option will vest and be exercisable with respect to the number of Shares as follows:

(a) If the KPI rating is B for the performance period, 50% of the options will be vested and the remaining shares will be cancelled.

(b) If the KPI rating is C or D for the performance period, none of shares will be vested and all options will be cancelled.

(c) If the KPI rating is A or S for the performance period, the shares will be 100% vested.

The vesting of the Option shall be conditional upon the Participant being not in violation of any of the Company's policies and/or not acting in any way which is contrary to the best interest of the Company, as determined by the Board in its sole discretion. In addition, the vesting of the Option shall be subject to the Scheme in relation to the termination of employment or engagement of the Participant.

The Option is granted purely at the Company's discretion and does not form part of any contract of employment or engagement for services between you and the Company or any of its Subsidiaries. Your rights and obligations under the terms of your employment or engagement are not affected by your participation in the Scheme and such participation shall not give you any additional rights to compensation or damages in the event of the termination (however caused, and whether lawful or unlawful) of your employment or engagement for services.

This invitation to apply for an option pursuant to the Scheme does not constitute an offer or invitation to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) or the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), and it is made on terms that only the qualifying person (as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance) to whom this invitation has been addressed is eligible to apply. Options offered in relation to the Scheme may not be offered or sold in Hong Kong by means of any document, except in circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance or which do not constitute an offer to the public within the meaning of that Ordinance.

No person may issue or possess for the purposes of issue, whether in Hong Kong or elsewhere, any advertisement, invitation or document relating to options offered in relation to the Scheme, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to options which are or are intended to be disposed of only to persons outside Hong Kong.

You acknowledge receipt of, and understand and agree to, this Notice of Grant and the Scheme. You acknowledge that you have been made aware of the Company's Rule 701(e) Information Statement (the "Information Statement") for the Scheme [and how to access the Information Statement on the Company's [stock plan administration platform]. The Company encourages you to review the Information Statement before exercising the Option. You acknowledge and agree that if you exercise the Option without first reviewing the Information Statement (as drafted at such future date), you are knowingly and voluntarily declining to review the Information Statement. As of the Date of Grant, this Notice of Grant and the Scheme set forth the entire understanding between you and the Company regarding the Option and supersede all prior oral and written agreements with respect to the Option. By accepting the Option, you consent to receive documents governing the Option by electronic delivery and to participate in the Scheme through an on-line or electronic system established and maintained by the Company or another third party designated by the Company from time to time.

[The remaining of this page is intended to be blank.]

Please confirm your acceptance of the grant of the option by signing and returning the duplicate letter together with a payment of the sum of US\$1.00 (or its equivalent in RMB) by no later than <u>mm/dd/yyyy</u>

Yours faithfully,

For and on behalf of

## Legend Biotech Corporation

Name: Fangliang Zhang

Title: Chairman of Legend Biotech Corporation

#### To: Legend Biotech Corporation

I, with address

hereby accept the grant of the option set out above and undertake to hold the option on the terms set out in the letter and to be bound by the terms of the Scheme. I enclose the payment of the sum of US\$1.00 (or its equivalent in RMB) as consideration for the grant of the option.

I confirm that I have read, understand and accept the terms of the Scheme.

Yours faithfully

Name:

Date: mm/dd/yyyy

#### EXHIBIT C

#### LEGEND BIOTECH CORPORATION SHARE OPTION SCHEME

#### NOTICE OF EXERCISE AND SHARE PURCHASE AGREEMENT

(to be executed in duplicate with a copy to each party)

This Notice of Exercise (this "Exercise Notice"), dated as of \_\_\_\_\_\_, 20\_\_ (the "Exercise Date"), constitutes written notice to Legend Biotech Corporation, an exempted company incorporated in the Cayman Islands with limited liability (the "Company") that \_\_\_\_\_ ("Purchaser") hereby elects to purchase the number of ordinary shares of par value US\$\_\_\_\_\_ each in the share capital of the Company ("Ordinary Shares") subject to the Option granted to Purchaser on \_\_\_\_\_\_, 20\_\_ (the "Option"), under the terms of the Notice of Grant of Option (the "Notice of Grant") and the Legend Biotech Corporation Share Option Scheme, adopted by the Company on [\*], 2017 (the "Scheme"). Capitalized terms used in this Exercise Notice, if not defined herein, have the meanings ascribed to them in the Notice of Grant or, as applicable, the Scheme.

As used in this Notice, "**Shares**" refers not only to the Ordinary Shares purchased under this Exercise Notice, but also all securities and property received in respect of those shares in an event described in paragraph 10 of the Scheme, and all new, substituted or additional securities or other property to which Purchaser is entitled by reason of Purchaser's ownership of the purchased Shares.

1. **Exercise Details**. The Subscription Price for the Shares shall be \$\_\_\_\_\_\_ per Share, for a total purchase price of \$\_\_\_\_\_\_. As the Shares are not publicly traded, Purchaser shall pay the full exercise price to the Company in cash, check, bank draft, electronic funds or wire transfer, or money order payable to the Company. The purchase and sale of the Shares shall occur simultaneously with the execution and delivery of this Exercise Notice, the payment of the aggregate Subscription Price, and the satisfaction of any applicable tax withholding obligations, all in accordance with the provisions of the Notice of Grant and the Scheme.

2. Limitations on Transfer.<sup>1</sup> No Shares purchased pursuant to this Exercise Notice, nor any beneficial interest in such Shares, shall be sold, gifted, transferred, encumbered or otherwise disposed of in any way (whether by operation of law or otherwise) by Purchaser or any subsequent transferee other than in compliance with this Exercise Notice. The Shares remain subject to the Lock-Up Period described in paragraph 14.1 of the Scheme and the restrictions on transfer described in [\_\_\_\_\_], which provisions are incorporated by reference herein. Purchaser acknowledges that Purchaser may be required to hold the Shares purchased hereunder indefinitely.

3. **Investment and Taxation Representations**. In connection with the purchase of the Shares, simultaneously with the delivery of this Exercise Notice, the Purchaser shall deliver the Investment Representation Statement, attached as Exhibit D to the Scheme.

#### 4. Restrictive Legends and Stop-Transfer Orders.

(a) **Restrictive Legends**. Purchaser understands and agrees that the Company shall place the legends set forth below or similar legends on any stock certificate(s) evidencing the Shares, together with any other legends that may be required by state or federal securities laws, the Company's organizational documents or bylaws, any other agreement between Purchaser and the Company or any agreement between Purchaser and any third party.

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") OR ANY APPLICABLE STATE SECURITIES LAWS AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT AND SUCH LAWS OR, IN THE OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION IS IN COMPLIANCE THEREWITH.

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER AND RIGHT OF FIRST REFUSAL AND REPURCHASE RIGHTS HELD BY THE ISSUER OR ITS ASSIGNEE(S) AS SET FORTH IN THE EXERCISE NOTICE BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH TRANSFER RESTRICTIONS AND RIGHT OF FIRST REFUSAL AND REPURCHASE RIGHTS ARE BINDING ON TRANSFEREES OF THESE SHARES.

(b) **Stop-Transfer Notices**. Purchaser agrees that, in order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) **Refusal to Transfer**. The Company shall not be required (i) to transfer on its books any shares of Shares that have been sold or otherwise transferred in violation of any of the provisions of this Scheme or (ii) to treat as owner of such shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such shares shall have been so transferred.

(d) **Lock Up**. Purchaser agrees that Purchaser will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of or enter into any hedging or similar transaction with the same economic effect as a sale, any Shares or other securities of the Company held by the Purchaser during the 180-day period (or such longer period as may be agreed to in writing by the Company) following the effective date of a registration statement of the Company filed under the Securities Act in connection with any initial public offering of Shares (the "**Market Standoff Period**"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period and these restrictions shall be binding on any transferee of such shares of Shares. Notwithstanding the foregoing, the 180-day period may be extended for up to such number of additional days as is deemed necessary by the Company or the Managing Underwriter to continue coverage by research analysts in accordance with NASD Rule 2711 or any successor rule.

#### 5. Tax Consequences.

(a) Purchaser hereby agrees that the Company does not have a duty to design or administer the Scheme or its other compensation programs in a manner that minimizes Purchaser's tax liabilities. Purchaser will not make any claim against the Company, or any of its officers, directors, employees or affiliates related to tax liabilities arising from this Exercise Notice.

(b) Purchaser has reviewed with his own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Exercise Notice. Purchaser is relying solely on such advisors and not on any statements or representations of the Company or any other person. Purchaser understands that Purchaser (and not the Company or any other person) shall be responsible for Purchaser's own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

(c) Purchaser understands that the Shares have been valued by the Company's Board of Directors for the purpose of this sale, and that the Company believes this valuation represents a fair appraisal of its worth. Purchaser also understands, however, that the Company can give no assurances that such price is in fact the fair market value of the Shares and that it is possible that the United States Internal Revenue Service would successfully assert that the value of the Shares on the date of purchase is substantially greater than so determined. If the United States Internal Revenue Service were to succeed in a determination that the Shares had value greater than the purchase price, the additional value would constitute income as of the date of its receipt. The additional taxes (and interest) due would be payable by Purchaser, and there is no provision for the Company to reimburse him for that tax liability. Purchaser assumes responsibility for such potential tax liability.

6. Additional Agreements. At the request of the Company from time to time, as a condition to the exercise of the Option, Purchaser agrees to provide such additional documents as the Company may reasonably require.

#### 7. Miscellaneous.

(a) **No Employment Rights**. Nothing in this Exercise Notice shall affect in any manner whatsoever the right or power of the Company, or a parent or subsidiary of the Company, to terminate Purchaser's service relationship, for any reason, with or without Cause.

(b) **Governing Scheme Document**. This Exercise Notice is subject to all the provisions of the Scheme, the provisions of which are hereby made a part of this Exercise Notice, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Scheme. [In addition, the Shares issued under this Agreement are subject to recoupment in accordance with The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or for a "constructive termination" (or similar term) under any agreement with the Company.]

(c) **Entire Agreement**. This Exercise Notice, together with all of its Exhibits, the Notice of Grant and the Scheme constitute the full and entire understanding and agreement between the parties with regard to the subject matter hereof and supersede all prior understandings and agreements, whether oral or written, between the parties with regard to the subject matter hereof, and may only be modified or amended in writing signed by both parties.

(d) **Severability**. If all or any part of this Exercise Notice, the Notice of Grant or the Scheme is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Exercise Notice, the Notice of Grant or the Scheme not declared to be unlawful or invalid. Any provision of this Exercise Notice (or part of such a provision) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

(e) **Counterparts**. This Exercise Notice may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same agreement. Facsimile copies of signed signature pages will be binding originals.

(f) **Effect on Other Employee Benefit Plans**. The value of the Shares will not be included as compensation, earnings, salaries, or other similar terms used when calculating Purchaser's benefits under any employee benefit plan sponsored by the Company or any Subsidiary or affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify or terminate any of the Company's or any of its Subsidiary's or Affiliate's employee benefit plans.

(g) **Successors and Assigns**. The rights and benefits of this Exercise Notice shall inure to the benefit of, and be enforceable by the Company's successors and assigns. The rights and obligations of Purchaser under this Notice may only be assigned with the prior written consent of the Company.

(h) **Legal Representation**. Purchaser has reviewed the provisions of this Exercise Notice, has had an opportunity to obtain the advice of counsel prior to executing this Notice and fully understands and agrees to the provisions hereof. Purchaser understands that the law firm of Jones Day represents the Company and not any purchaser individually.

IN WITNESS WHEREOF, the parties have duly executed this Exercise Notice as of the Exercise Date.

## THE COMPANY:

LEGEND BIOTECH CORPORATION

(Signature)

Name: Fangliang Zhang Title: <u>Chairman of Legend Biotech Corporation</u>

#### **PURCHASER:**

(Signature)

Name:

## EXHIBIT D INVESTMENT REPRESENTATION STATEMENT

GRANTEE	:	
COMPANY	: LEGEND BIOTECH CORPORATION	
SECURITY	: ORDINARY SHARES OF PAR VALUE US\$[ ]	
AMOUNT	:	_
DATE	:	_

In connection with the purchase of the above-listed shares of Shares (the "<u>Securities</u>") of Legend Biotech Corporation (the "<u>Company</u>"), the undersigned (the "<u>Grantee</u>") represents to the Company the following:

(a) Grantee is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Securities. Grantee is acquiring these Securities for investment for Grantee's own account only and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the United States Securities Act of 1933, as amended (the "Securities Act").

(b) Grantee acknowledges and understands that the Securities constitute "restricted securities" under the Securities Act and have not been registered under the Securities Act or qualified under the California Corporate Securities Law of 1968, as amended (the "<u>California Securities Law</u>"), in each case, in reliance upon specific exemptions therefrom, which exemptions depend upon, among other things, the bona fide nature of Grantee's investment intent as expressed herein. Grantee understands that the Securities must be held indefinitely unless they are subsequently registered under the Securities Act and qualification under the California Securities Law, or an exemption from such registration and qualification is available. Grantee further acknowledges and understands that the Company is under no obligation to register the Securities. Grantee understands that the certificate evidencing the Securities will be imprinted with a legend which prohibits the transfer of the Securities unless they are registered and qualified, or such registration and qualification is not required in the opinion of counsel satisfactory to the Company. Grantee acknowledges and understands that the California of determination relating to the fairness for investment of the Securities offered by the Company and that the Commissioner has not and will not recommend or endorse the Securities.

(c) Grantee is familiar with the provisions of Rule 701 and Rule 144, each promulgated under the Securities Act, which, in substance, permit limited public resale of "restricted securities" acquired, directly or indirectly from the issuer thereof, in a non-public offering subject to the satisfaction of certain conditions. Rule 701 provides that if the issuer qualifies under Rule 701 at the time of the grant of the Option to Grantee, the exercise will be exempt from registration under the Securities Act. In the event the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the United States Securities Exchange Act of 1934 (the "Exchange Act"), ninety (90) days thereafter (or such longer period as any market stand-off agreement may require) the Securities exempt under Rule 701 may be resold, subject to the satisfaction of certain of the conditions specified by Rule 144, including: (1) the resale being made through a broker in an unsolicited "broker's transaction" or in transactions directly with

a market maker (as said term is defined under the Exchange Act); and, in the case of an affiliate, (2) the availability of certain public information about the Company, (3) the amount of Securities being sold during any three (3) month period not exceeding the limitations specified in Rule 144(e), and (4) the timely filing of a Form 144, if applicable.

(d) In the event that the Company does not qualify under Rule 701 at the time of grant of the Option, then the Securities may be resold in certain limited circumstances subject to the provisions of Rule 144, which requires (i) the resale to occur not less than six months, or, in the event the Company is not subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, not less than one year, after the later of the date the Securities were sold by the Company or the date the Securities were sold by an affiliate of the Company, (ii) in the case of resales by persons who are not affiliates of the Company (within the meaning of Rule 144), the satisfaction of the conditions set forth in section (2) of the paragraph immediately above, and (iii) in the case of resales by affiliates of the Company, the satisfaction of the conditions set forth in sections (1), (2), (3) and (4) of the paragraph immediately above. Grantee acknowledges that a copy of Rule 144 will be delivered to Grantee upon request.

(e) Grantee further understands that in the event all of the applicable requirements of Rule 701 or 144 are not satisfied, registration under the Securities Act, compliance with Regulation A, or some other registration exemption will be required; and that, notwithstanding the fact that Rules 144 and 701 are not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rules 144 or 701 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their respective brokers who participate in such transactions do so at their own risk. Grantee understands that no assurances can be given that any such other registration exemption will be available in such event.

(f) Grantee is a resident and domiciliary of the state or other jurisdiction hereinafter set forth opposite the Grantee's signature.

(g) Grantee understands and acknowledges that the Company will rely upon the accuracy and truth of the foregoing representations and Grantee hereby consents to such reliance.

IN WITNESS WHEREOF, the undersigned Grantee has executed this Investment Representation Statement as of

By:

Name:

Address:

#### LEASE

## AGREEMENT

## BETWEEN

## GENSCRIPT USA HOLDING, INC.

## LANDLORD,

## -AND-

#### LEGEND BIOTECH USA INC.

## DATED: February 8, 2018

## LEASE AGREEMENT

This LEASE AGREEMENT (this "Lease") is dated February 8, 2018 and is between GENSCRIPT USA HOLDING, INC. ("Landlord"), and LEGEND BIOTECH USA INC. ("Tenant").

# BASIC LEASE PROVISIONS

(1)	Land:	The township of Piscataway, Block No. 6102, Tax Lot1.01
(2)	Building:	860 Centennial Avenue aka 10 Knightsbridge Road, Piscataway, New Jersey
(3)	Premises:	22,000 rentable square feet
(4)	Term:	One year
(5)	Estimated Commencement Date:	February 9, 2018
(6)	Termination Date:	February 8, 2019
(7)	Basic Rent:	\$60,000 per month
(8)	Rentable Size of Building:	66,058 square feet.
(9)	Rentable Size of Premises:	22,000 square feet.
(10)	Tenant's Proportionate Share	33.30%. If the rentable size of Building increases, the Tenant's Proportionate Share shall be adjusted accordingly.
(11)	Parking Spaces:	117 unassigned parking spaces.
(12)	Security:	None
(13)	Base Period:	Calendar year 2018 and 2019.
(14)	Permitted Use:	General office and laboratory space and any other lawful ancillary use permitted by zoning.
(15)	Brokers:	None
(16)	Governing Law:	This Lease is governed by the laws of the State of New Jersey.
(17)	Landlord's Notice Address:	GenScript USA Holding, Inc. 860 Centennial Avenue New Jersey 08854 Attn:
(18)	Tenant's Notice Address:	Legend Biotech USA Inc. 860 Centennial Avenue New Jersey 08854 Attn:

#### ARTICLE 1 DEFINITIONS

1.1 Unless otherwise defined herein, capitalized terms used in this Lease shall have the same meanings as those defined in Basic Lease Provisions.

## ARTICLE 2 DEMISE, TERM

2.1 <u>Demise of Premises</u>. Landlord hereby leases and demises to Tenant, and Tenant hereby hires and takes from Landlord, upon the terms and conditions set forth herein, the Premises for the Term. Landlord and Tenant hereby agree that for all purposes of this Lease, the Premises contains 22,000 rentable square feet set forth in the Basic Lease Provisions. Tenant shall also have the right to use all Common Areas of the Building in a similar manner as other tenants in the Building.

#### 2.2 Term.

(a) Term: The Term of this Lease will commence on the Commencement Date and end on the Termination Date.

(b) Commencement Date. The "*Commencement Date*" will be the earlier to occur of (i) the date Tenant takes occupancy of the Premises for the purposes of conducting its business, and (ii) five (5) days after Landlord notifies Tenant in writing that the Finish Work is Substantially Completed, provided. The "*Commencement Date*" will be as set forth in the Basic Lease Provisions, notwithstanding the date Tenant actually completes the Finish Work. From and after the date hereof, Tenant will have the right to enter upon the Premises for the purposes of constructing the Finish Work. Such occupancy by Tenant is expressly subject to all of the terms and conditions of this Lease, except Tenant's obligation to pay Basic Rent.

(c) "Substantially Completed" or "Substantial Completion" means that (i) Landlord has completed the Finish Work in accordance with the Working Plans in a good and workmanlike manner, except for (x) minor details of construction that will not unreasonably interfere with Tenant's use of the Premises (collectively, "Punch List Items"), and (y) any part of the Finish Work that is not completed due to any act or omission of Tenant or Tenant's Visitors; and (ii) Landlord has obtained a valid temporary or permanent certificate of occupancy for the Premises or, alternatively, Landlord has completed all Finish Work necessary to entitle Landlord to the issuance of a temporary or permanent certificate of occupancy other than any Finish Work that is not completed due to any act or omission of Tenant or Tenant's Visitors. If the completion of the Finish Work is delayed due to any act or omission by Tenant or Tenant's Visitors, including, but not limited to, delays due to changes in or additions to the Finish Work requested by Tenant, delays in submission of information or estimates, delays in giving authorizations or approvals, or delays due to the postponement of any work at the request of Tenant, then the Commencement Date will be accelerated by the number of days of delay caused by Tenant and Tenant's Visitors (any such delay being referred to herein as a "*Tenant Delay*").

3

(d) Landlord shall use all reasonable and good faith efforts to have the Tenant Finish Work Substantially Completed before February 8, 2018. If the Finish Work is not Substantially Completed on or before February 8, 2018, Tenant shall be entitled to a one day abatement of Basic Rent for each day thereafter that the Finish Work is not Substantially Completed. Any such accrued abated amounts shall be credited against the first and subsequent installments of Basic Rent coming due under this Lease for Premises until the entire abated amount has been fully credited. If Landlord does not Substantially Complete the Finish Work within thirty (30) days after receipt of Tenant's termination notice, then this Lease shall terminate and be of no further force and effect. If, however, Landlord Substantially Complete the Finish Work within thirty (30) are the sole remedies of Tenant with respect to Landlord's failure to timely Substantially Complete the Finish Work.

(e) <u>ASIS</u>. Tenant acknowledges that neither Landlord nor any employee, agent or representative of Landlord has made any express or implied representations or warranties, other than as expressly set forth in this Lease, with respect to the physical condition of the Building or the Premises, the fitness or quality thereof or any other matter or thing whatsoever with respect to the Building or the Premises or any portion thereof, and that Tenant is not relying upon any such representation or warranty in entering into this Lease. Tenant has inspected the Building and the Premises and is thoroughly acquainted with their respective condition and agrees to take the same "ASIS", except for the Finish Work which Landlord has agreed to complete pursuant to the terms of Section 2.6.

2.3 <u>Occupancy of Premises</u>. Tenant's occupancy of the Premises will be deemed to conclusively establish that the Finish Work is Substantially Completed and that the Premises are in satisfactory condition as of the date of such occupancy, unless, within fifteen (15) days of such occupancy, Tenant delivers to Landlord a written notice specifically identifying all unsatisfactory conditions.

2.4 <u>Commencement Date Agreement</u>. When the Commencement Date occurs, Landlord and Tenant shall enter into an agreement memorializing the Commencement Date and Termination Date of this Lease.

2.5 <u>Move-In Day.</u> Tenant may move into the Premises at any time on or after the Commencement Date, provided that Tenant's move in date is approved by Landlord at least one week in advance. If the move is not completed by 4:00 PM, Tenant shall pay to Landlord, on the next Basic Rent Payment Date, an overtime charge of \$50.00 per hour or part thereof until 11:00 PM. No moving will be permitted after 11:00 PM. If applicable, Landlord will attempt to provide one (1) elevator for Tenant's exclusive use during Tenant's move. Tenant shall be responsible for any damage caused to the Premises, the Building and/or the Property by Tenant or its moving contractors.

2.6 <u>Finish Work:</u> Landlord shall construct the Finish Work in a good and workmanlike manner. Landlord further warrants to the Tenant that all materials incorporated in the Finish Work will be new unless otherwise specified, and that all work on the Finish Work will be of good quality, free from known faults and defects, and in substantial conformity with Working Plans.

4

IN WITNESS WHEREOF, the parties have executed this Lease as of the date first above written.

WITNESS:

WITNESS:

Landlord:

# GENSCRIPT USA HOLDING, INC.

By: /s/ Rita Tsai

Name: Rita Tsai Title: Director of US Site Operation Dept. OU

Tenant:

# LEGEND BIOTECH USA, INC.

By: /s/ Aimee Fan

Name: Aimee Fan Title: Accountant

# COLLABORATIVE RESEARCH AND LICENSE AGREEMENT

BY AND BETWEEN Noile-Immune Biotech, Inc. AND Legend Biotech USA, Inc.

April 27, 2020

[\*\*\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

# **Table of Contents**

1.	DEFINITIONS	1
2.	GOVERNANCE	11
3.	TARGET NOMINATION, SELECTION AND SUBSTITUTE	12
4.	RESEARCH AND DEVELOPMENT (R&D) PLAN	14
5.	DEVELOPMENTS AND REGULATORY APPROVAL	16
6.	COMMERCIALIZATION	17
7.	GRANT OF LICENSE	18
8.	TECHNOLOGY TRANSFER	19
9.	CONSIDERATION	20
10.	PAYMENTS BY LEGEND	21
11.	INTELLECTUAL PROPERTY AND PATENT INFRINGEMENT	23
12.	CONFIDENTIAL INFORMATION	25
13.	PUBLICATION	27
14.	REPRESENTATIONS AND WARRANTIES	27
15.	DISCLAIMER AND LIMITATION OF LIABILITY	29
16.	INDEMNIFICATION	30
17.	TERM AND TERMINATION	31
18.	MISCELLANEOUS PROVISIONS	33

# EXHIBITS

EXHIBIT B Noile's Bank Account

- i -

## **COLLABORATIVE RESEARCH AND LICENSE AGREEMENT**

THIS COLLABORATIVE RESEARCH AND LICENSE AGREEMENT (this "<u>Agreement</u>") is made as of April \_\_\_, 2020 (the "<u>Effective</u> <u>Date</u>") by and between **Noile-Immune Biotech, Inc.**, a Japanese corporation having its principal place of business at 2-12-10 Shiba-Daimon, Minato-ku, Tokyo 105-0012, Japan ("<u>Noile</u>"), and **Legend Biotech USA, Inc.**, a company incorporated under the laws of New York having its principal place of business at 10 Knightsbridge Road, Piscataway, NJ 08854, USA ("<u>Legend</u>"). Noile and Legend are sometimes referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

## RECITALS

**WHEREAS**, Noile, a biopharmaceutical company focused on the development of novel cancer immunotherapy products, is developing proprietary Products;

WHEREAS, Legend is a pharmaceutical company focused on discovering and developing cutting-edge cell-based therapies with the ultimate goal of changing the way life-threatening diseases are treated;

WHEREAS, Noile and Legend desire to perform certain research works and are willing to enter into Initial Research to apply their collective expertise, capabilities and resources to develop Products and novel CAR-T platforms based on technology owned or controlled by Noile; and

WHEREAS, in connection with such Initial Research, Legend wishes to be granted, and Noile desires to grant, certain license and option rights under certain patents, patent applications, know-how, and other proprietary information related to Noile Platform, Licensed Compounds and Licensed Products;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, Noile and Legend agree as follows:

## 1. DEFINITIONS

As used in this Agreement, capitalized terms have the meanings given them below or elsewhere in this Agreement:

1.1. "<u>7x19 CAR-T</u>" means Noile's proprietary CAR-T technology, including a construct expressing a CAR directed against a given target, the cytokine IL-7, and the chemokine CCL19.

1.2. "<u>Affiliate</u>" means, with respect to a Party, any entity that, directly or indirectly, controls, is controlled by or is under common control with such Party for so long as such control exists. For purposes of this definition, an entity has "control" of another entity if it has the direct or indirect ability or power to direct, or cause the direction of management policies of such other entity or otherwise direct the affairs of such other entity, whether through ownership of [\*\*\*] fifty percent (50%) of the voting securities of such other entity, by contract or otherwise.

- 1 -

1.3. "<u>Alliance Manager</u>" means an alliance leader appointed by each Party to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement. Detailed information of the Alliance Manager is described in Section 2.4.

1.4. "<u>Applicable Laws</u>" mean any laws, regulations, guidelines, or standards applicable to the conduct of the collaboration or other activities under this Agreement.

1.5. "<u>Calendar Half Year</u>" means a period of six (6) consecutive calendar months ending on June 30 and December 31, respectively; <u>provided that</u> (a) the first Calendar Half Year of the term shall extend from the Effective Date to the end of the next complete Calendar Half Year thereafter; and (b) the last Calendar Half Year of the term shall end upon the expiration or termination of this Agreement.

1.6. "<u>Calendar Quarter</u>" means a period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, respectively; <u>provided that</u> (a) the first Calendar Quarter of the term shall extend from the Effective Date to the end of the subsequent complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the term shall end upon the expiration or termination of this Agreement.

1.7. "CAR" means a chimeric antigen receptor.

1.8. "CAR-T" means engineered T-cells that express a CAR on their cell membrane which have [\*\*\*].

1.9. "Clinical Trial" means any human clinical study or trial of the Licensed Product in the Territory.

1.10. <u>"Combination Product</u>" means a Licensed Product containing a Licensed Compound as well as at least one other active pharmaceutical ingredient. For the avoidance of doubt, all Combination Products are also Licensed Products.

1.11. "Combinational Target" means any Target having a specific combination of [\*\*\*] therein.

1.12. "Commercial License" has the meaning as set forth in Section 7.3.

1.13. "<u>Commercialization</u>" means, with respect to a Licensed Product, any and all activities (whether before or after Regulatory Approval) directed to the marketing, promotion and sale of such Licensed Product after Regulatory Approval for commercial sale has been obtained, including pre-launch and post-launch marketing, promoting, marketing research, distributing, offering to commercially sell and commercially selling such Licensed Product, importing, exporting or transporting such Licensed Product for commercial sale, medical education activities with respect to such Licensed Product, conducting Clinical Trials that are not required to obtain or maintain Regulatory Approval for such Licensed Product for an indication, which may include epidemiological studies, modeling and pharmacoeconomic studies, post-marketing surveillance studies, investigator sponsored studies and health economics studies and regulatory affairs (including interacting with Regulatory Authorities) with respect to the foregoing. When used as a verb, "Commercialize" means to engage in Commercialization activities.

- 2 -

1.14. "<u>Commercially Reasonable Efforts</u>" means, with respect to a Party and a product owned by it or to which it otherwise has rights, the efforts which are reasonable for [\*\*\*] in accordance with its business, legal, medical, and scientific judgment, and the efforts and resources that it would use for a [\*\*\*], taking into account the [\*\*\*]. For the clarity, "Commercially Reasonable Efforts" shall be evaluated or determined on a country-by-country and Product-by-Product basis, as applicable.

1.15. "<u>Confidential Information</u>" means all information pertinent to this Agreement, Initial Research, information in project proposals and project charters, and activities made with regard to this Agreement, in whatever form, oral, written, electronic or otherwise, that is (a) marked or designated as confidential, (b) defined as confidential in this Agreement, or (c) of the type that would generally be regarded as confidential or proprietary in the scientific, academic or healthcare communities, and in each case, (a)–(c), that is disclosed or provided by or on behalf of a disclosing Party, including its Affiliates, to a receiving Party, including its Affiliates or to any of the receiving Party's or its Affiliates' directors, officers, faculty, employees, contractors, consultants, advisors or agents pursuant to or in connection with this Agreement. The contents of this Agreement shall also be treated as the Confidential Information of each Party under this Agreement. Notwithstanding the foregoing, Confidential Information shall not include (i) information that was received by or becomes generally available to the public other than as a result of any action or inaction by the receiving Party, (ii) information that was received by or becomes available to the receiving Party on a non-confidential basis from a source other than the disclosing Party; provided however, that the source of such information was not bound by a confidentiality agreement with, or other contractual, legal or fiduciary obligation of confidentiality to, any person or entity with respect to such information, or (iii) information that was known prior to the disclosure or is developed independently by or on behalf of the receiving Party or any of its Affiliates without reference to or use of the information supplied by the disclosing Party that owns such Work Results in accordance with Section 11.1.

1.16. "<u>Control</u>" or "<u>Controlled</u>" means, with respect to any Intellectual Property right and a Party, possession by such Party or an Affiliate of such Party of the ability to grant the right to access or use, or to grant a license or a sublicense to, such Intellectual Property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.17. "Data Protection" means the situation where any regulation, law or statute of a government authority:

(a) exists in any country in the Territory; and

## - 3 -

(b) directly or indirectly protects (regardless of whether any Valid Claim exists in that country), the exclusive sale of any Licensed Product from the sale in that country of a Third Party's pharmaceutical product containing the same active pharmaceutical ingredient that is contained in such Licensed Product.

1.18. "<u>Data Protection Period</u>" means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period in which Data Protection with respect to a Licensed Product exists in such country. For the avoidance of doubt, Data Protection Period includes "Re-examination Period" (*saishinsa kikan*) in Japan.

1.19. "<u>Development</u>" means all research, non-clinical and clinical drug development activities, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, formulation development, delivery system development, the performance of any such research or Clinical Trials, including the manufacturing of Licensed Compounds or Licensed Products for use in Clinical Trials, or other activities reasonably necessary in order to obtain, but not maintain, Regulatory Approval of Licensed Compounds or Licensed Products in the Territory. "Development" shall exclude all Commercialization activities. When used as a verb, "Develop" means to engage in Development activities.

1.20. "Disputes" has the meaning as set forth in Section 18.2(a).

1.21. "Excluded Target" has the meaning as set forth in Section 3.3.

1.22. "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.23. "Field" means all indications and uses, including the diagnosis, prognosis, prevention, and treatment of human diseases and human conditions.

1.24. "<u>First Commercial Sale</u>" means, on a country-by-country basis, the first sale of a Licensed Product under this Agreement by Legend, its Affiliates or Sublicensees to an end user or prescriber for use, consumption or resale of the Licensed Product in a country in the Territory where Regulatory Approval of the Licensed Product has been obtained and where the sale results in a recordable Net Sale. Sale of a Licensed Product under this Agreement by Legend to an Affiliate of Legend or a Sublicensee of Legend shall not constitute a First Commercial Sale unless such Affiliate or such Sublicensee is the end user of such Licensed Product and such sale results in a Net Sale. Also, sale of a Licensed Product under this Agreement by Legend, its Affiliates or Sublicensees in a jurisdiction where Regulatory Approval for that Licensed Product has not yet been attained shall not constitute a First Commercial Sale under this Agreement.

1.25. "Force Majeure" has the meaning as set forth in Section 18.6.

1.26. "<u>Generic/Biosimilar Competition Period</u>" means a period during the portion of the applicable Royalty Term in a particular country where there are one or more products being sold in such country that are Generic/Biosimilar with respect to such Licensed Product, and where such sales of such product(s), [\*\*\*] of the sales of the Licensed Product. As used herein, "<u>Generic/Biosimilar</u>" means any drug or biological product that [\*\*\*] under the FD&C Act or the PHS Act and related rules and regulations, or the corresponding or similar laws, rules and regulations of any other jurisdiction and where such drug or biological product obtains

- 4 -

Regulatory Approval based on[\*\*\*] to a Licensed Product hereunder. For purposes of this definition, (a) "<u>FD&C Act</u>" means the United States Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder from time to time and (b) "<u>PHS Act</u>" means the Public Health Services Act, as amended, and the regulations promulgated thereunder from time to time.

1.27. "<u>GLP</u>" means all applicable current Good Laboratory Practice standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58 and/or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which the relevant activity under this Agreement is being performed.

1.28. "<u>GMP</u>" means all current Good Manufacturing Practices applicable to biopharmaceuticals in the US and/or in the European Union, as are in effect from time to time during the effective term of this Agreement and in each case as applicable to the activities being carried out under this Agreement.

1.29. "GxP" means any of the following as applicable to this Agreement: GLP and GMP.

1.30. "<u>IND</u>" means (a) an Investigational New Drug application as defined in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA, (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.31. "Indemnitee" has the meaning as set forth in Section 16.3.

1.32. "Indemnitor" has the meaning as set forth in Section 16.3.

1.33. "<u>Initial Payment</u>" means the initial payment paid upon each Legend Selected Target having been formally designated in accordance with Section 3.4, which detail is described in Section 9.1.

1.34. "<u>Initial Research</u>" means the research activities to be performed mainly within the Initial Research Term on a Target-by-Target or Product-by-Product basis, but sometimes performed before the IND at the latest for each Product generated from a Licensed Target.

1.35. "Initial Research Term" means the period of [\*\*\*] following the Effective Date, as may be modified as described in Section 3.4, during which any of the Legend Selected Targets shall be selected and nominated.

- 5 -

1.36. "Intellectual Property." means the following subsisting throughout the world (a) patents, patent applications, utility models, design registrations and certificates of invention and other governmental grants for the protection of inventions or industrial designs (including all related continuations, continuations-in-part, divisionals, reissues and reexaminations); (b) copyrights, designs, data and database rights and registrations and applications for registration thereof; (c) inventions, invention disclosures, statutory invention registrations, whether patentable or nonpatentable, whether copyrightable or noncopyrightable and whether or not reduced to practice; (d) trade secret and proprietary know-how; and (e) any other proprietary rights relating to any of the foregoing (including remedies against infringement thereof and rights of protection of interest therein under the laws of all jurisdictions).

1.37. "Legend Personnel" means directors, officers, employees, contractors and subcontractors of Legend.

1.38. "Legend Selected Target" has the meaning as set forth in Section 3.4.

1.39. "Licensed Compound" means any construct that is designed to secrete both cytokine IL-7 and chemokine CCL19 in a CAR-T or TCR-T that binds to a Legend Selected Target or a Licensed Target.

1.40. "Licensed Know-How" means all technology, data, information, know-how, trade secrets, materials (including biological materials), compounds and inventions that are necessary or reasonably useful for the Development, manufacture and/or Commercialization of Licensed Compounds and/or Licensed Products in the Field in the Territory that are proprietary to and owned or Controlled by Noile as of the Effective Date. Licensed Know-How includes all chemical, structural, manufacturing process, biological, target, pharmacological, toxicological, clinical, assay and other methods of screening, structure activity relationship information or other information that relates to any Legend Selected Target, Licensed Target, Licensed Compound and/or Licensed Product (including in each case its composition, formulation, or method of use, manufacture, preparation or administration). Noile shall, to the extent reasonably practicable, notify Legend [\*\*\*] in relation to those Licensed Know-How which [\*\*\*] to the Development, manufacture and/or Commercialization by Legend of Licensed Product in the Field. In such case, [\*\*\*], the Parties shall discuss in good faith (i) regarding [\*\*\*], and (ii) regarding the terms and conditions for [\*\*\*]. For the avoidance of doubt, nothing under this Section 1.40 shall require Noile to breach its confidentiality obligations to any third party under non-disclosure agreements or other similar agreements. To the extent that [\*\*\*].

- 6 -

1.41. "Licensed Patents" mean any and all patents and patent applications (including all claims and the entire scope of claims therein) owned or Controlled by Noile, as of the Effective Date, as listed in <u>Exhibit A</u>, and all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, supplemental protections, complementary certificates, and the like thereof, and all foreign counterparts thereof, that are owned or Controlled by Noile as of the Effective Date claiming a Legend Selected Target, a Licensed Target, a Licensed Compound and/or a Licensed Product (including in each case its composition, formulation, combination, product by process, or method of use, manufacture, preparation or administration), or otherwise claiming inventions that are necessary or reasonably useful for the Development, manufacture and/or Commercialization of Licensed Compounds and/or Licensed Products in the Field in the Territory.

1.42. "<u>Licensed Product</u>" means any pharmaceutical preparation containing the Licensed Compound, alone or in combination with one or more additional active ingredients, for sale by prescription, over-the-counter, or any other method. For clarification, a Licensed Product shall be [\*\*\*].

1.43. "Licensed Target" means the Legend Selected Target which becomes a Target for Developing and Commercializing Licensed Compounds and/or Licensed Products under the Commercial License, as designated by Legend in accordance with Section 3.1(b). The total number of Licensed Targets hereunder shall not be more than two (2).

1.44. "List" has the meaning set forth in Section 3.3.

1.45. "Loss" or "Losses" has the meaning as set forth in Section 16.1.

1.46. "<u>MAAs</u>" or "<u>Marketing Approval Application</u>" means a BLA, sBLA, NDA, sNDA and any equivalent thereof in the USA or any other country or jurisdiction. As used herein: "BLA" means a Biologics License Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 et seq., for FDA approval of a Product and "sBLA" means a supplemental BLA; and "NDA" means a New Drug Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 314 et seq., for FDA approval of a Product and "sNDA" means a supplemental NDA.

1.47. "Major Country" means each country of USA, a Major European Country, [\*\*\*].

1.48. "<u>Major European Country</u>" means [\*\*\*].

1.49. "Milestone Payment" means each milestone payment as described in Section 9.2.

- 1.50. "Net Sales"
  - (i) Licensed Products other than Combination Products

- 7 -

The term "Net Sales" of a Licensed Product (other than a Combination Product) shall mean the gross invoice amount (not including value added taxes, sales taxes, or similar taxes) of the Licensed Product sold by Legend, its Affiliates or Sublicensees to the first Third Party after deducting the following, if not previously deducted, from the amount invoiced or received:

- a) trade and quantity discounts other than early payment cash discounts;
- b) returns, rebates, chargebacks, and other allowances;
- c) retroactive price reductions that are actually allowed or granted;
- d) [\*\*\*]; and
- e) [\*\*\*].

Net Sales shall be calculated on a country-by-country and Licensed Product-by-Licensed Product basis, so that a separate figure for Net Sales is calculated for each Licensed Product in each country in which it is sold.

For the purpose of calculating the Net Sales of a Licensed Product (other than a Combination Product), any deductions shall be limited to those applied under Legend's standard operating procedures.

Sales of Licensed Products (other than Combination Products) between Legend and Legend's Affiliates and/or Sublicensees shall be excluded from the computation of Net Sales.

[\*\*\*].

Notwithstanding any deductions referred to in a) to e) above, the Net Sales of a Licensed Product (other than a Combination Product) shall

(ii) Combination Products (where an invoice price for a Licensed Product containing the Licensed Compound sold as a single agent exists)

In the case of a Combination Product (where an invoice price for a Licensed Product containing the Licensed Compound sold as a single agent exists), Net Sales shall be calculated on the basis of the gross invoice amount of a Licensed Product [\*\*\*].

The deductions referred to in a) to e) of part (i) above shall be calculated and deducted from the gross invoice amount of the Combination Product on the basis of a Licensed Product [\*\*\*].

For the purpose of calculating Net Sales of a Combination Product, any deductions shall be limited to those applied under Legend's standard operating procedures.

Sales of Combination Products between Legend and Legend's Affiliates and/or Sublicensees shall be excluded from the computation of Net Sales.

Notwithstanding any deductions referred to in a) to e) of part (i) above (as adjusted according to this part (ii)), the Net Sales of a Combination Product shall [\*\*\*].

(iii) Combination Products (where an invoice price for the Licensed Product sold as a single agent does not exist)

If only Combination Products are sold in a particular country, an adjusted gross invoice amount for the Combination Products sold within that country shall be calculated [\*\*\*].

- 8 -

1.51. "Noile Platform" means Noile's 7x19 CAR-T platform that can be applied to CAR-T/TCR-T [\*\*\*] cell therapy.

1.52. "Noile Research" has the meaning as set forth in Section 3.3.

1.53. "<u>Noile Technology</u>" means technology created or developed by Noile outside the performance of this Agreement, including without limitation the Noile Platform, Licensed Know-How and Licensed Patents. In principle, Noile Technology as used under this Agreement shall refer to those technology as of the Effective Date; provided, however, that Noile shall, to the extent practicable, notify Legend [\*\*\*] with respect to advances and/or improvements in relation to those Noile Technology which [\*\*\*] to the Development, manufacture and/or Commercialization by Legend of Licensed Compounds and/or Licensed Products in the Field, based on which the Parties shall discuss in good faith regarding potential addition of such advances and/or improvements to the scope of the Research License and/or the Commercial License and the terms and conditions for such addition, including without limitation [\*\*\*]. For the avoidance of doubt, nothing under this Section 1.53 shall require Noile to breach its confidentiality obligations to any third party under non-disclosure agreements or other similar agreements.

1.54. "<u>Phase II Clinical Trial</u>" means a Clinical Trial of a Licensed Product with the endpoint of evaluating its effectiveness for a particular indication or indications in one or more specified doses or its short-term tolerance and safety, as well as its pharmacokinetic and pharmacodynamic information in patients with the indications under study.

1.55. "Priority Date" has the meaning as set forth in Section 3.2.

1.56. "Product" means a pharmaceutical or biologic product containing CAR-T or TCR-T directed against a particular Target.

1.57. "Noile Materials" has the meaning as set forth in Section 8.2.

1.58. "<u>Project Team</u>" means a team of the personnel involved in managing and/or executing the Initial Research. The Project Team may be established on a project-by-project basis, each of such projects shall be identified in the Research and Development Plan.

1.59. "<u>Regulatory Approval</u>" means any approval (including supplement, amendment, pre- and post-approval, pricing approval and reimbursement approval), licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other government authority, that is necessary for the commercialization of Licensed Product under this Agreement.

- 9 -

1.60. "<u>Regulatory Authority</u>" means the FDA or any other regulatory authority or body with regulation or governance over the performance of any part of the activities under this Agreement.

1.61. "<u>Research License</u>" has the meaning as set forth in Section 7.1.

1.62. "<u>Research and Development Plan</u>" means a written research and development plan of the Development ending in Regulatory Approval of Licensed Products Targeting a Legend Selected Target describing (i) the collaborative research activities to be pursued by the Parties under this Agreement, (ii) allocation of responsibilities or roles of each Party, (iii) the anticipated timeline, (iv) [\*\*\*], in each case with respect to the Legend Selected Target and development activities related to Licensed Compounds and Licensed Products, as amended from time to time [\*\*\*].

1.63. "<u>Royalty Term</u>" means, on a country-by-country, Licensed Product-by-Licensed Product and Licensed Target-by-Licensed Target basis, the period commencing on the First Commercial Sale of a Licensed Product in a country in the Territory and ending upon the later of: (i) expiration of the Data Protection Period with respect to such Licensed Product in such country or (ii) expiration of the last to expire Valid Claim covering such Licensed Product in such country or (iii) [\*\*\*] of the First Commercial Sale of the first Licensed Product Targeting such Licensed Target in such country.

1.64. "<u>SAE</u>" means a serious adverse event, as defined and revised by the U.S. FDA, resulting from any Clinical Trial or administration of a Product.

1.65. "<u>Sublicensee</u>" means a Third Party or Affiliate of Legend which has been granted a sublicense under the Commercial License by Legend [\*\*\*].

1.66. "Substitute Option Right" has the meaning as set forth in Section 3.6(a).

1.67. "Substituted Target" has the meaning as set forth in Section 3.6(d).

1.68. "SUSAR" means a suspected unexpected serious adverse reaction resulting from any Clinical Trial or administration of a Product.

1.69. "<u>Target</u>" means, [\*\*\*]. If a Target is [\*\*\*], and if a Target is [\*\*\*]. A Target shall [\*\*\*]. By way of example, if a Target is [\*\*\*], it includes: (a) [\*\*\*] such Target [\*\*\*], and (b) [\*\*\*] of such Target or variant thereof. "Target", "Targeting" or "Targeted" means, when used as a verb, [\*\*\*].

- 10 -

1.70. "Target Candidate" means any candidate Target which Legend nominates and makes notice in writing to Target Reviewer for review.

1.71. "Target Reviewer" means an independent reviewer [\*\*\*].

1.72. "Taxes" has the meaning as set forth in Section 10.7.

1.73. "TCR-T" means engineered T-cells that express a T-cell receptor on their cell membrane, which [\*\*\*].

1.74. "Territory" means worldwide.

1.75. "Third Party" means a person or entity other than the Parties and their respective Affiliates.

1.76. "Third Party Claims" has the meaning as set forth in Section 16.1.

1.77. "<u>Treaty</u>" has the meaning as set forth in Section 10.7.

1.78. "<u>Valid Claim</u>" means an issued and unexpired claim of a Licensed Patent, including any additional term provided by a SPC (supplementary protection certificate or its equivalent), existing in a country or area in the Territory that claims the composition of matter of the applicable Licensed Compound or Licensed Product in that country and that 1) has not been revoked or held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction, and 2) has not been denied or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise by Noile.

1.79. "<u>Work Results</u>" means any Intellectual Property and any source information and data relevant to such Intellectual Property invented, developed or otherwise made by or on behalf of a Party (or Parties) in the course of all activities under this Agreement including but not limited to the Initial Research, Development and Commercialization activities (whether or not patentable or subject to copyright or trade secret protection). For clarity, Work Results shall include raw data, laboratory notebooks and materials, if any.

## 2. GOVERNANCE

Legend and Noile agrees to cooperate with each other in good faith [\*\*\*] in accordance with the terms and conditions of this Agreement. Without limiting the generality of the foregoing and any other obligations of Legend under this Agreement, Legend will notify Noile, [\*\*\*] any milestone achievement [\*\*\*]. In addition, Noile is entitled to request Legend to disclose [\*\*\*] which Legend will not unreasonably reject or withhold, [\*\*\*].

- 11 -

# 3. TARGET NOMINATION, SELECTION AND SUBSTITUTE

## 3.1. Legend's Right.

(a) Subject to Section 3.6, during the Initial Research Term, Legend has the right to nominate up to two (2) Legend Selected Targets for evaluating, researching or developing Licensed Compounds and/or Licensed Products. For clarity, and notwithstanding anything to the contrary in this Agreement, Legend is [\*\*\*]

(b) During the valid term of the Substitute Option Right, Legend shall have the right to convert each Legend Selected Target into a Licensed Target by providing written notice to Noile, which Licensed Target fully enjoys the Commercial License with sublicensing right under Section 7.4, provided however, it will automatically lose the Substitute Option Right with respect to the converted Legend Selected Target after such conversion.

(c) Furthermore, Legend shall have the right within the valid term to exercise the Substitute Option Right by substitution from any Legend Selected Target based upon the provisions set forth in Section 3.6(a).

3.2. <u>Nomination.</u> Following the Effective Date, Legend may nominate Target Candidates by providing written notice to the Target Reviewer of such Target Candidates, that Legend proposes to become Licensed Targets finally. This right of nomination is exercisable by Legend throughout the Initial Research Term until all Legend Selected Targets have been finally determined in accordance with this Agreement, subject to Section 3.6; provided, however, that such right of nomination shall be exercised at any one time only in relation to a maximum number of Target Candidates which is equal to the number of Legend Selected Targets which remain unselected at the time of the exercise. Upon receiving a written notice from Legend which is compliant with this Section 3.2, the Target Reviewer shall promptly (and in no event later than [\*\*\*] days after such receipt) make written notice, with a copy to Legend, to Noile of the fact of the nomination, the date on which the Target Reviewer received the written notice from Legend (the "<u>Priority</u> <u>Date</u>"), and the number of Target Candidates nominated by Legend in its written notice to the Target Reviewer, without disclosing to Noile [\*\*\*] such Target Candidates.

3.3. <u>Selection.</u> Upon notice to Noile by the Target Reviewer under Section 3.2, Noile shall [\*\*\*] provide the Target Reviewer with a list of all Targets, (a) to which Noile has licensed exclusive rights to a Third Party, or is otherwise contractually restricted from licensing any right to Legend, evidenced by the relevant exclusive license agreements or other contracts; (b) which Noile has entered into (and has maintained ongoing) active discussions with a Third Party with respect to a potential agreement, which when executed, would be described in sub-Section (a) above, with such discussions being evidenced by [\*\*\*] ("<u>Ongoing Bona Fide Discussions</u>"); and (c) to which Noile has itself already initiated and maintained [\*\*\*] specific to a Product Targeting such Target, as evidenced by [\*\*\*] ("<u>Noile Research</u>"); in each case

- 12 -

of sub-Sections (a) through (c) above, as of the Priority Date (the "List", and the Targets on the List, the "Excluded Targets"). The Target Reviewer shall verify the list and the evidence provided by Noile, select the Target(s) among the Target Candidates which do not fall under the Excluded Targets, and notify Legend, in writing with a copy to Noile, of the result of the selection operation.

3.4. <u>Designation of Each Legend Selected Target</u>. Immediately upon the notification from the Target Reviewer under Section 3.3 that a Target Candidate nominated by Legend is not an Excluded Target, such Target shall be deemed a "<u>Legend Selected Target</u>". For clarification, this event shall be the direct trigger for the Initial Payment for the applicable Legend Selected Target under Section 9.1. For clarity, and subject to Section 3.6, Legend has the right to nominate any Legend Selected Target only within the Initial Research Term, that is [\*\*\*] after the Effective Date; provided, however, that the period during which Legend has the right to nominate any Legend Selected Target shall be tolled for [\*\*\*] and the Initial Research Term shall be extended by such duration.

3.5. <u>Updated Arrangements.</u> Unless and until two (2) Legend Selected Targets have been finally selected in accordance with this Agreement, Legend may continue exercising the right of nomination provided for in Section 3.2, within the Initial Research Term only (but subject to Section 3.6), by providing written notice to the Target Reviewer of new Target Candidates and/or past Excluded Targets in accordance with Section 3.2. The Target Reviewer shall follow the procedure set forth in Section 3.2 in notifying Noile of any and all new nominations made by Legend, and Noile shall follow the procedure set forth in Section 3.3 in providing the Target Reviewer updates to the List upon receiving the notice from the Target Reviewer of new nominations made by Legend. Such updates may include, but are not limited to, addition of new Excluded Targets (with corresponding evidence as required in Section 3.3) and removal of past Excluded Targets from the List (due to, for example, termination of exclusive license agreements or other contracts with Third Parties, termination of Ongoing Bona Fide Discussions, or termination of Noile Research). The Target Reviewer shall then follow the procedure set forth in Section 3.3 in notifying Legend any and all new Target(s) selected by it. Up to two (2) Legend Selected Targets can be initially designated by both Parties during the Initial Research Term. If the number of the Legend Selected Targets initially designated during the Initial Research Term is less than two (2), no extension of the Initial Research Term is permitted for further selection of initial Legend Selected Targets. However, if no Legend Selected Target is selected during the Initial Research Term, both Parties shall consult in good faith to find a solution, including, without limitation, termination of this Agreement.

## 3.6. Substitute of Target.

(a) Notwithstanding anything herein to the contrary, Legend shall have, after the initial designation of a Legend Selected Target, an option to substitute such Legend Selected Target with a new Target, which option may be exercised by Legend [\*\*\*], with respect to each initially designated Legend Selected Target (referred to as "<u>Substitute Option Right</u>"). Any such Substitute Option Right shall be valid and exercisable, on a Legend Selected Target-by-Legend Selected Target basis, [\*\*\*].

- 13 -

(b) Each substitution under Section 3.6(a) shall be [\*\*\*] relating to such Target (or a Licensed Compound or a Licensed Product relating to such Target), based upon which [\*\*\*]. In the case where Legend desires to replace a Target with any proposed Target Candidate, Legend, the Target Reviewer and Noile shall follow the procedures set forth in Sections 3.2-3.4 in selecting the replacement Legend Selected Target. Additionally, Legend shall [\*\*\*] to replace the Target.

(c) For clarity, Legend shall have [\*\*\*]. If Legend desires [\*\*\*] to this Agreement under the terms and conditions to be mutually agreed

upon.

(d) Any Legend Selected Target as replaced with a new Target shall no longer become a Licensed Target (herein referred to as "Substituted Target") nor be covered by the Research License under Section 7.1.

## 4. RESEARCH AND DEVELOPMENT PLAN

4.1. <u>Research and Development Plan</u>. Following the designation of each Legend Selected Target in accordance with Section 3, Legend shall, upon good faith discussion with Noile, use Commercially Reasonable Efforts to determine a Research and Development Plan covering [\*\*\*] research and development activities for Licensed Compounds and Licensed Products Targeting such Legend Selected Target, and as required to enable the filing of an approval by Legend for a Licensed Product Targeting the Licensed Target [\*\*\*]. Legend shall consider in good faith any suggestions or comments from Noile (if any) in relation to the preparation of a Research and Development Plan, but shall have the final decision on all matters of such Research and Development Plan to the extent it is compliant with the terms and conditions of this Agreement; provided, however, that if such Research and Development Plan obligates Noile to perform specific scientific and/or technical activities which are assigned to Noile, Noile's prior consent (which shall not be unreasonably withheld) shall be required with respect to such assignment of activities to Noile.

## 4.2. Performance of Research and Development Plan

(a) Under each Research and Development Plan, Legend shall use Commercially Reasonable Efforts to perform the Research and Development Plan. Legend will provide Noile with [\*\*\*] reports in reasonable form and substance in relation to updates to the progress of the relevant Research and Development Plan.

(b) Upon request by Legend and agreement by Noile (which shall not be unreasonably withheld), Noile shall provide reasonable technical support to facilitate and speed up the research as stated in the relevant Research and Development Plan; provided, however, that [\*\*\*]. Further, both parties shall discuss in good faith considering each other's suggestion in relation to the Research and Development Plan at each stage.

- 14 -

4.3. <u>Subcontractors</u>. Each Party may subcontract portions of its work as necessary under the Research and Development Plan to (i) any Affiliate or (ii) Third Parties; provided in the case of a Third Party, (a) [\*\*\*], and (b) such subcontract is in writing and is consistent with the terms and conditions of this Agreement including the confidentiality provisions of Section 12 and any rights granted to such subcontractor are restricted to only those rights necessary for performance by such subcontractor of the portions of work on behalf of the sub-contracting Party. The sub-contracting Party shall remain fully responsible (at its cost) for all acts or omissions of any subcontractor it appoints (including any acts or omissions which result in a breach of the terms of this Agreement) and shall ensure that each subcontractor complies with the terms and conditions of this Agreement.

4.4. <u>Completion of any Research and Development Plan</u>. The term for a particular Research and Development Plan shall commence on the start date for such Research and Development Plan, and shall continue, unless earlier terminated in accordance with Section 17, until [\*\*\*] in the Research and Development Plan. For the avoidance of doubt, and notwithstanding anything herein to the contrary, under no circumstances shall Legend be obligated to disclose or provide to Noile any of Legend's technology, data, information, know-how, trade secrets, materials (including biological materials), compounds, procedures or inventions, in each case invented, developed, created or otherwise made by, for or on behalf of Legend or its Affiliates prior to the Effective Date or after the Effective Date but independently of this Agreement.

## 4.5. Reports and Records.

(a) <u>Progress Reports</u>. Legend shall keep Noile [\*\*\*] informed of its progress under each relevant Research and Development Plan, including with respect to any milestone achievement. All such reports, information and data provided by a Party shall be considered the providing Party's Confidential Information and, as between the Parties, shall be exclusively owned by the providing Party.

(b) <u>Development Records</u>. Legend shall maintain records of its performance of each Research and Development Plan (or cause such records to be maintained) in sufficient detail and in good scientific manner as shall properly reflect all work done and results achieved in the performance of such Research and Development Plan. All laboratory notebooks shall be maintained for [\*\*\*] of the relevant notebook entry. All other records shall be maintained by each Party during the applicable Research and Development Plan [\*\*\*]. All such records of a Party shall be considered such Party's Confidential Information and, as between the Parties, shall be exclusively owned by such Party.

(c) <u>Quality</u>. Each Research and Development Plan shall be performed at all times in accordance with all Applicable Laws including as applicable requirements of GxP.

- 15 -

4.6. <u>Research Efforts</u>. Each Party may assign such scientific and technical personnel and allocate such other resources as such Party judges are reasonably necessary for performing the activities as are assigned to it in each Research and Development Plan and shall perform such activities in accordance with all Applicable Laws (including GxPs) in each case to the extent applicable to performance of the relevant Research and Development Plan activities by such Party and the terms and conditions of this Agreement. Each Party shall be solely responsible for the safety and health of its employees, consultants and visitors, and for compliance with all Applicable Laws related to health, safety and the environment, including providing its employees, consultants and visitors with all required information and training concerning any potential hazards involved in performing such activities and any precautionary measures to protect its employees from any such hazards at its own facilities and as regards its or its subcontractors' performance of the Research and Development Plan.

4.7. <u>Conduct of Clinical Trials</u>. Legend agrees that any Clinical Trial with respect to a Licensed Product will be conducted under an IND and in accordance with applicable GxPs.

## 5. DEVELOPMENTS AND REGULATORY APPROVAL

5.1. As between the Parties, Legend shall be responsible for holding and applying for any Regulatory Approvals or MAAs in relation to the Licensed Products and the Licensed Compounds, and for sponsoring any Clinical Trials (including holding the IND). Legend shall have sole decision-making authority in relation to any sponsorship of any Clinical Trials or progression of any Licensed Products through Clinical Trials, including the decision on whether to apply for any MAAs.

5.2. Legend shall use Commercially Reasonable Efforts to develop the Licensed Products and obtain Regulatory Approval at its own responsibility and expense in the Territory.

5.3. Legend shall more specifically use Commercially Reasonable Efforts to satisfy the following obligations:

(a) Submit the first (1<sup>st</sup>) IND for a Licensed Compound (or Licensed Product) to a Regulatory Authority in a Major Country within [\*\*\*];

and

(b) Have the First Commercial Sale of a Licensed Compound (or Licensed Product) in a Major Country within [\*\*\*].

For the avoidance of doubt, the above obligations are indicative of Commercially Reasonable Efforts [\*\*\*], and Legend shall still continue to use a reasonably similar level of effort after Legend completes the above obligations.

5.4. In the event that Noile in good faith believes that Legend is not meeting its diligence obligations, and Legend has not achieved one of the above diligence milestones by the corresponding target date, then within [\*\*\*] of Noile's written request for the Parties to meet, the Parties shall [\*\*\*] for the Parties to discuss Legend's progress toward the [\*\*\*]. If, following the [\*\*\*] meeting, [\*\*\*] that Legend is satisfying its diligence obligations despite the fact that Legend has not achieved a development milestone by the corresponding target date, then the Parties shall, in good faith, discuss and mutually agree upon a new target date for the achievement of such development milestone, based upon the then-expected development environment.

5.5. If, following the above [\*\*\*] meeting, Legend [\*\*\*] this Agreement, and, should that [\*\*\*], then Legend shall, [\*\*\*], either (i) [\*\*\*], or (ii) [\*\*\*]. In the event of the above (i), the Parties [\*\*\*].

5.6. Legend shall provide Noile with [\*\*\*] written progress reports summarizing the events, schedule, and progress of the Development, registration, and estimated launch dates for each Licensed Product, [\*\*\*]. Such reports shall be considered Legend's Confidential Information and, as between the Parties, shall be exclusively owned by Legend.

5.7. For the avoidance of doubt, all Licensed Compounds and Licensed Products as necessary for the development hereunder shall be made or had made by Legend at its own responsibility and expense.

## 6. COMMERCIALIZATION

6.1. <u>Commercialization Generally</u>. Legend shall use its Commercially Reasonable Efforts to Commercialize any Licensed Product following its decision to progress filing an IND in relation to such Licensed Product. Legend shall be primarily responsible for and shall have sole decision making authority in relation to the Commercialization and manufacture of the Licensed Product following filing of IND.

6.2. <u>Commercialization Updates</u>. Legend shall keep Noile informed of its Commercialization of any Licensed Product and shall provide [\*\*\*] updates to Noile summarizing progress in the Development and Commercialization of any Licensed Products in relation to which any Research and Development Plan has been completed. All such updates shall be considered Legend's Confidential Information and, as between the Parties, shall be exclusively owned by Legend.

- 17 -

6.3. <u>Safety Event Reporting</u>. Additionally, each Party shall provide to the other Party prompt written notice of any material safety events pertaining to any Product, including a Product developed by any third party, of which it becomes aware including any SUSARs, SAEs or other material events which [\*\*\*]; provided, however, that nothing under this Section 6.3 shall require any Party to breach its obligations to any Regulatory Authority under Applicable Law and/or its confidentiality obligations to any third party under non-disclosure agreements or other similar agreements.

#### 7. GRANT OF LICENSE

7.1. <u>Research License</u>. Noile agrees to grant and hereby grants to Legend, and Legend agrees to accept and hereby accepts from Noile, an exclusive license, without the right to grant sublicense, under the Licensed Patent and the Licensed Know-How, to research and develop Licensed Compounds and Licensed Products targeting any of the Legend Selected Targets or the Licensed Targets in the Field in the Territory (the "<u>Research License</u>").

7.2. Expiration of Research License. The Research License shall terminate upon [\*\*\*].

7.3. <u>Commercial License</u>. With respect to each Legend Selected Target and each Licensed Target, Noile agrees to grant and hereby grants to Legend, and Legend agrees to accept and hereby accepts from Noile, an exclusive license (with the right to grant sublicenses through multiple tiers of sublicensees) under the Licensed Patent and the Licensed Know-How, to research, Develop, make, have made, use, sell, offer for sale, export and import Licensed Compounds and Licensed Products Targeting such Legend Selected Target or the Licensed Target (as applicable) in the Field in the Territory (the "<u>Commercial License</u>"). For the avoidance of doubt, the Commercial License shall immediately be invalidated with respect to any Legend Selected Target upon its becoming a Substituted Target.

7.4. <u>Sublicense</u>. Legend shall be fully responsible for the acts or omissions of its Affiliates under this Agreement, the acts or omissions of the Sublicensees under this Agreement, and the sublicensing of the Licensed Patents and the Licensed Know-How in the Field. Legend shall be obliged to [\*\*\*].

7.5. <u>Target Exclusivity</u>. During the term of this Agreement, neither Noile nor any of its Affiliates shall work independently of this Agreement on any Legend Selected Target (so long as such Legend Selected Target does not become a Substituted Target) or any Licensed Target, for itself or through or with its respective Affiliates or any Third Party (including the grant of any license or option to its Affiliates or any Third Party), to discover or otherwise research and/or Develop and/or Commercialize any Product that binds any Legend Selected Target (so long as such Legend Selected Target does not become a Substituted Target) or any Licensed Target does not become a Substituted Target (so long as such Legend Selected Target does not become a Substituted Target) or any Licensed Target.

- 18 -

# 8. TECHNOLOGY TRANSFER

8.1. <u>Technology Transfer</u>. Within [\*\*\*] days after the date of the designation of each Legend Selected Target, and thereafter during the term of this Agreement pursuant to Section 1.53 in relation to applicable advances and/or improvements after the Effective Date, Noile shall provide access to Legend all available data and know-how applicable to Noile Platform and such Legend Selected Target or Licensed Target, as applicable, that are available to Noile as of the date of the designation of such Legend Selected Target and which are necessary or useful for the research, Development and Commercialization of Licensed Compounds and Licensed Products for such Legend Selected Target or Licensed Target, as applicable; provided, however, that nothing under this Section 8.1 shall require Noile to breach its obligations to any Regulatory Authority under Applicable Law and/or its confidentiality obligations to any third party under non-disclosure agreements or other similar agreements. Such data, know-how and technology shall include but not limited to [\*\*\*].

8.2. <u>Material Transfer</u>. During the Initial Research Term, Noile may, at its discretion, provide Legend with materials (collectively, "<u>Noile</u> <u>Materials</u>"), as is agreed to by the Parties in accordance with the Research and Development Plan. In such event, Noile shall disclose at least reasonably sufficient information to handle or maintain such Noile Materials safely. Other details of the transfer of each of Noile Materials, including quality and quantity thereof, the detailed timing and mode of transfer, shall be separately determined between the Parties; [\*\*\*]. In furtherance of the foregoing, unless otherwise agreed to by the Parties in a separate agreement, it is agreed upon that:

(a) Legend may use Noile Materials for the purpose of the Initial Research or for any other non-commercial or commercial purpose in connection with Licensed Compounds and/or Licensed Products;

(b) Legend shall not transfer Noile Materials in part or whole to any Legend Personnel or Third Party to perform any activities inconsistent with the Research License or the Commercial License (including any sublicense thereof), without the prior written consent of Noile;

(c) Legend's rights under Sections 8.2(a) and 8.2(b) shall not terminate until expiration or termination of the Research License and Commercial License with respect to each Legend Selected Target and Licensed Target; and

(d) unless otherwise specifically provided herein, Noile shall retain all right, title and interest in and to any and all Noile Materials, and Legend shall, upon expiration or termination of the Research License and Commercial License with respect to each Legend Selected Target and Licensed Target: (i) either destroy Noile Materials and provide Noile with written evidence of such destruction or return to Noile, all of the unused Noile Materials; and (ii) cease all work employing such Noile Materials; and

- 19 -

(e) Legend acknowledges that Noile Materials are experimental in nature and they are provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. NOILE MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF NOILE MATERIALS SHALL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS.

## 9. CONSIDERATION

9.1. <u>Initial Payments for each Legend Selected Target</u>. Within [\*\*\*] days after the designation of each Legend Selected Target (under Section 3.4) on a Legend Selected Target-by-Legend Selected Target basis, Legend shall pay to Noile an Initial Payment for each Legend Selected Target in the amount of [\*\*\*] via wire transfer of immediately available funds to the bank account as specified in <u>Exhibit B</u>. The total payments under this Section shall [\*\*\*] and no payments shall be due on designation of any other Target than Legend Selected Target. For clarity, [\*\*\*].

9.2. <u>Notification and Milestone Payments</u>. Legend shall [\*\*\*] notify Noile in writing of the achievement of each milestone event described in the table below and, within [\*\*\*] of the event, shall remit the applicable Milestone Payment to Noile via wire transfer of immediately available funds to the bank account as specified in <u>Exhibit B</u> with respect to any first Licensed Compound or Licensed Product (whichever is earlier) reaching each of the events below for each Licensed Target:

Development Events	Milestone Payments
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	

Milestone payments listed above shall be made only once upon the first achievement of each relevant milestone by the first Licensed Compound or Licensed Product (whichever is earlier) for each Licensed Target, and shall be payable no more than two (2) times each (once per each Licensed Target). For the avoidance of doubt, a Milestone Payment shall be due and payable regardless of whether it is Legend or any Affiliate achieving such milestone event or any Third Party achieving such milestone event on behalf of Legend or its Affiliates.

- 20 -

9.3. <u>Royalties</u>. In partial consideration for the rights and licenses granted herein, Legend shall pay to Noile, during the Royalty Term and on a country-by-country and Licensed Product-by-Licensed Product basis, a running royalty as specified below on the Net Sales of the Licensed Products sold by Legend, its Affiliates and/or Sublicensees, which royalty shall not be refundable nor creditable.

(A) Annual, worldwide Net Sales of all Licensed Products, except for the case [\*\*\*] of Net Sales(B) in the row below.

(B) Annual, worldwide Net Sales of all Licensed Products in the applicable [\*\*\*] of Net Sales Generic/Biosimilar Competition Period.

If, during the applicable Royalty Term, a Licensed Product is not covered by a Valid Claim in a Licensed Patent in a country, the royalties owed by Legend on the Net Sales of such Licensed Product in such country sold by Legend, its Affiliates and/or Sublicensees shall be reduced by [\*\*\*].

In accordance with Section 10.1., Legend shall report to Noile on Net Sales on a Licensed Product-by-Licensed Product and country-by-country basis as long as any obligation to pay royalties for Licensed Products exists.

9.4. <u>Third Party Royalties</u>. If Legend is required to pay patent royalties to a Third Party for an unblocking license permitting the manufacture or sale of Licensed Products, then [\*\*\*]. [\*\*\*] paid by Legend under such third-party license shall be creditable against the royalties due Noile; provided that the royalties payable to Noile in a given calendar year shall [\*\*\*]. For clarification, [\*\*\*]. It is understood that no such royalty deduction may be granted for Third Party royalties due on account of [\*\*\*]. For clarity, Legend would be responsible for the payment of any and all royalties and all other payments owed to Third Parties with respect to Licensed Targets under any agreements between Legend and such Third Parties as of or following the Effective Date.

## 10. PAYMENTS BY LEGEND

10.1. <u>Royalty Payments and Report of Sales Amounts</u>. Within [\*\*\*] days from the end of each Calendar Quarter, Legend shall make payment of the royalties due for such Calendar Quarter. Together with the payment, Legend shall also send Noile a report for such Calendar Quarter setting forth the Net Sales of the Licensed Products in such Calendar Quarter along with its calculation of the royalty due. Legend shall keep accurate records in sufficient detail to enable any payment payable hereunder to be determined.

- 21 -

10.2. <u>Payment Account</u>. The applicable parts of Sections 10.1 through 10.7 shall apply to the Initial Payments under Sections 9.1, the Milestone Payments under Section 9.2, and the royalty payments under Section 9.3. All payments to Noile including the Initial Payments, the Milestone Payments, and royalty payments shall be made by wire transfer to an account of Noile set forth in <u>Exhibit B</u> attached hereto.

10.3. <u>Currency</u>. All amounts payable by Legend under this Agreement shall be paid in United States Dollars. In the case of sales outside the United States, the rate of exchange to be used in computing the amount of royalty payments due Noile shall be made [\*\*\*]. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as provided in this Section 10, the Parties shall consult with a view to finding a prompt and acceptable solution.

10.4. <u>Right to Audit</u>. Noile shall have the right, upon prior written notice to Legend, not more than [\*\*\*], through an independent certified public accountant selected by Noile and reasonably acceptable to Legend, which acceptance shall not be unreasonably withheld or delayed, to inspect or audit the relevant records of Legend to verify that the amounts of royalty payments were correctly determined. The independent certified public accountant shall execute a confidentiality agreement, in a form reasonably acceptable to Legend, with respect to all information provided by Legend. Legend shall grant the independent certified public accountant access during normal business hours to those books and records of Legend concerning Licensed Products as may be reasonably necessary for the sole purposes of verifying the accuracy of the reports required to be furnished by Legend, pursuant to Section 9.3 and Section 10.1; provided, however, that verification shall [\*\*\*]. The records and results of such audits shall be deemed Confidential Information of Legend and, as between the Parties, shall be exclusively owned by Legend. A copy of the independent certified public accountant's report shall be delivered to Legend simultaneously with its delivery to Noile. If the independent certified public accountant's report correctly shows any underpayment of royalties by Legend shall remit to Noile within [\*\*\*] days after Legend's receipt of such report:

- a) the amount of such underpayment;
- b) interest on the underpayment which shall be calculated pursuant to Section 10.5; and
- c) the reasonable fees and expenses of the independent certified public accountant performing the audit, if such underpayment exceeds [\*\*\*].
   Otherwise, Noile's accountant's fees and expenses shall be borne by Noile.

10.5. <u>Overdue Payment</u>. In the case of a delay in payment not caused by Force Majeure, interest on any overdue payments shall accrue at a rate of [\*\*\*], effective for the applicable days of the period of default.

10.6. <u>Record of Sales</u>: Notwithstanding anything herein to the contrary, Legend shall keep, or cause to be kept, records of the sales of the Licensed Products under this Agreement for a period of [\*\*\*]. Upon request by Noile, Legend shall supply Noile with such records, which may be submitted to the tax authority, and shall give Noile any commercially reasonable assistance in relation thereto. Such records shall be deemed Confidential Information of Legend and, as between the Parties, shall be exclusively owned by Legend.

- 22 -

10.7. <u>Taxes</u>: Noile shall be liable for all income and other taxes (including interest) ("<u>Taxes</u>") imposed upon any payments made by Legend to Noile under this Agreement. No Taxes shall be deducted from the payments made under this Agreement, except that Legend may withhold from any amounts payable hereunder any Taxes which are required to be withheld by Applicable Laws. Noile shall cooperate with Legend and make commercially reasonable efforts in order to (i) file certificates and other documentation with tax authorities and (ii) obtain a reduction or elimination of, or credit for, Taxes relating to this Agreement. Without limitation of the generality of the foregoing, in order to eliminate the obligation to withhold Taxes under the United States-Japan Income Tax Treaty effective as of March 30, 2004 (hereinafter referred to as the "<u>Treaty</u>"), Noile may complete the Application Form (ex.W-8BEN) for Income Tax Convention and the Attachment Form For Limitation On Benefits Section and send them to Legend. Legend agrees that, once Noile has taken all steps necessary for applying the Treaty in a timely manner as provided in this Section, Legend shall not withhold such Taxes unless required by Applicable Law. If, however, Legend determines that it is required by Applicable Law to withhold any Taxes, and such Taxes are withheld and paid by Legend to the appropriate tax authority, then Legend shall provide Noile with an official tax receipt or other evidence issued by the tax authority to support a claim for credit by Noile within [\*\*\*] days of Legend's receipt of the official tax receipt or evidence from the tax authority.

## 11. INTELLECTUAL PROPERTY AND PATENT INFRINGEMENT

#### 11.1. Ownership.

(a) Ownership of all Work Results, including any Intellectual Property developed in the course of the preclinical development or clinical development of any Licensed Product, shall be determined by inventorship or authorship, as applicable. Inventorship and authorship determination shall be in accordance with [\*\*\*]. Notwithstanding the above, if the Work Results to the extent [\*\*\*] then Legend shall solely own the Work Results including but not limited to the relevant intellectual property, know-how, trade-secret etc. and administer that on its sole discretion for any purpose and Noile hereby assigns to Legend all of its rights, title and interest in and to such Work Results, and all intellectual property, know-how, trade secret and other proprietary rights therein. [\*\*\*]

(b) For the avoidance of doubt, any background Intellectual Property developed before the Effective Date shall remain separately owned by the Party who independently developed such Intellectual Property, and nothing under this Agreement shall affect or impact any ownership of either Party in relation to such Party's background Intellectual Property.

## 11.2. Intentionally Omitted.

11.3. <u>Prosecution</u>. Legend shall have the first option to institute, prosecute, and control, at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patents relating to the manufacture, use, importation, sale, or offer for sale of any Licensed Product being Developed or Commercialized in the Territory. Legend shall have the sole right to institute, prosecute, and control, at its own expense

- 23 -

and by counsel of its own choice, any action or proceeding with respect to infringement of any of Legend's patents relating to Licensed Products. Any amount recovered by Legend as a result of such an action, by settlement or otherwise, shall be [\*\*\*]. If Legend fails to bring an action or proceeding or otherwise fails to take appropriate action to abate such infringement within a period of [\*\*\*] starting from the giving of notice by Noile to Legend of any infringement or threatened infringement by a Third Party of any Licensed Patent, Noile shall have the right, but not the obligation, to bring and control, at its own expense and by counsel of its own choice, any action or proceeding relating to the Licensed Patent. Any recovery obtained by Noile as a result of such an action, by settlement or otherwise, shall be [\*\*\*]. The Party not taking action to respond to any such action shall provide reasonable assistance to the Party taking such action, including, to the extent necessary to allow the Party taking such action to maintain the action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. Noile shall not be required to join an action as a party if Legend desires to bring an action in court unless such action is taken by Legend, based on reasonable considerations, in a jurisdiction that requires Noile to be a plaintiff.

11.4. <u>Settlement</u>. In no case may Legend enter into any settlement or consent judgment or other voluntary final disposition that: (i) extends, or purports to exercise, Legend's rights under the Licensed Patents beyond the rights granted pursuant to this Agreement, (ii) makes any admission regarding wrongdoing by Noile, or the invalidity, unenforceability or absence of infringement of any Licensed Patent; (iii) [\*\*\*] (iv) subjects Noile to an injunction or other equitable relief; or (v) obligates Noile to make a monetary payment; in all cases without the prior written consent of Noile, which consent shall not be unreasonably withheld or delayed. Similarly, in no case may Noile enter into any settlement or consent judgment or other voluntary final disposition that: (a) limits Legend's rights under the Licensed Patents or under this Agreement other than as expressly stated herein; (b) makes any admission regarding wrongdoing on the part of Legend, an Affiliate or Sublicensee, or the invalidity, unenforceability or absence of infringement of any Intellectual Property right arising hereunder or any Licensed Patent; (c) subjects Legend, an Affiliate or Sublicensee to an injunction or other equitable relief; or (d) obligates Legend, an Affiliate or Sublicensee to make a monetary payment; in all cases without the prior written consent of Legend, which consent shall not be unreasonably withheld or delayed.

- 24 -

11.5. [\*\*\*] shall, at its own cost, maintain responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications included in the Licensed Patents. [\*\*\*] agrees to retain a patent law firm and/or patent agent to handle all preparation, filing, prosecution, and maintenance of the patents and patent applications within the Licensed Patents. [\*\*\*] shall be the client of the patent law firm and/or patent agents. In particular, [\*\*\*] shall keep [\*\*\*] informed of any official communication from [\*\*\*], but only to the extent when such communication relates to matters which would be reasonably expected to adversely affect such Licensed Patents (including any official actions limiting the scope of a claim, citations of prior art, rejections, interferences, oppositions, reexaminations, revocations or nullifications). For the avoidance of doubt, nothing under this Section 11.5 obligates [\*\*\*] to consult, or otherwise requires [\*\*\*] in relation to any preparation, filing, prosecution, and maintenance of patents and patent applications included in the Licensed Patents, which shall be performed under [\*\*\*].

11.6. If reasonably requested by [\*\*\*] shall cooperate fully in the preparation, filing, prosecution and maintenance of the Licensed Patents and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to any Licensed Patents, including executing all papers and instruments, or requiring their respective employees or contractors to execute such papers and instruments, so as to effectuate the ownership of the Licensed Patents.

## 12. CONFIDENTIAL INFORMATION

12.1. <u>Confidentiality</u>. Except as otherwise expressly provided in this Agreement or otherwise agreed to in writing, each Party shall hold, and shall cause its or its Affiliates' directors, officers, faculty, employees, contractors, subcontractors, consultants, advisors and agents to hold, in confidence all Confidential Information of the other Party furnished to it or its Affiliates by or on behalf of the other Party or the other Party's Affiliates, or acquired by it or its Affiliates, or its or its Affiliates' directors, officers, faculty, employees, contractors, subcontractors, consultants, advisors and agents as required or permitted under this Agreement and shall only disclose such Confidential Information to its or its Affiliates' directors, officers, faculty, employees, contractors, consultants, advisors and agents having a need to know such Confidential Information. Except as otherwise expressly provided in this Agreement or otherwise agreed to in writing, neither Party shall use any such Confidential Information except for the purposes contemplated by this Agreement and as set forth in Section 12.2 or release or disclose such Confidential Information to any other person, except its Affiliates or its or its Affiliates or its or its or its affiliates or its or its agreement and as set forth in Section 12.2 or release or disclose such Confidential Information to any other person, except its Affiliates or its or its affiliates' directors, officers, faculty, employees, contractors, consultants, advisors and agents as needed for such Party's performance of the transactions contemplated by this Agreement, and its auditors, attorneys, financial advisors and bankers in the ordinary course of its business, each of whom has agreed in writing to be bound by obligations of confidential Information until [\*\*\*].

- 25 -

12.2. <u>Legal Exclusion</u>. Notwithstanding Section 12.1, either Party may disclose the Confidential Information of the other Party to the extent such disclosure is required by a court or applicable administrative order, law or regulation; <u>provided that</u>, to the extent permitted by Applicable Law, such Party promptly provides written notice to the other Party and cooperates with the other Party to minimize the scope of disclosure, and seeks a protective order to prevent disclosure of such information. If, in the absence of a protective order or other remedy, such Party is[\*\*\*] compelled to disclose any such Confidential Information to any tribunal or other entity, such Party may disclose such Confidential Information without liability hereunder; <u>provided that</u> such Party gives prior written notice (to the extent permitted by Applicable Law) to the other Party and copies of the Confidential Information disclosed under this Section 12.2 shall remain confidential for all other purposes; <u>provided that</u> such information.

12.3. <u>Responsibility</u>. Without limiting the generality of any other clause herein including without limitation Section 7.4, each Party shall be responsible for any breach of this Section 12 by its Affiliates or its or its Affiliates' directors, officers, employees, contractors, subcontractors, consultants, advisors or agents.

## 12.4. [\*\*\*] Covenant.

(a) Each Party hereby covenants not to [\*\*\*] the other Party regarding the [\*\*\*] which such Party may [\*\*\*] hereunder, for the other Party's [\*\*\*] through contract research organizations or "bona fide Third Party collaborators"; provided that neither Party shall [\*\*\*] such contract research organizations or Third Party collaborators who have [\*\*\*] the Parties under this Agreement.

(b) The covenant in Section 12.4(a) shall not: (i) be construed to give either Party [\*\*\*] the other Party, with any [\*\*\*]; or (ii) restrict any rights that either Party may have under applicable [\*\*\*] law, for example, but without limitation, [\*\*\*].

(c) The term "bona fide Third Party collaborators" used in Section 12.4(a) means: (i) [\*\*\*] Third Party who enters into a written agreement with a Party to conduct collaborative research [\*\*\*]; or (ii) [\*\*\*] Third Party who enters into a written agreement with a Party to conduct collaborative research.

- 26 -

# 13. PUBLICATION

13.1. In case a Party desires to publish or otherwise disclose in public any Work Results, such Party shall furnish the other Party with a copy of any proposed written or oral publication or presentation (including manuscripts, abstracts, and oral presentations) at least [\*\*\*] days prior to submission for publication or presentation. The other Party shall promptly notify in writing the Party desiring to publish or present if any action is necessary to delete or redact any Confidential Information of the other Party or to file for patent protection of any Work Results proposed to be disclosed in the written or oral publication or presentation. The Party desiring the publication shall: (i) delete or redact any Confidential Information identified in a notice(s) by such other Party, and/or (ii) delay publishing such proposed publication for a maximum of [\*\*\*] days in order to allow for patent protection of the Work Results to be secured.

13.2. Each Party recognizes the need to secure patent applications to protect the value of inventions made in the Initial Research. Therefore, in case of Section 13.1(ii), the Parties shall work in good faith to properly secure patent applications in a timely manner and establish a publication process that preserves the ability of the Parties to maximize patent protection while publishing results in a reasonable timeframe. Each Party shall have the right to participate in publications as authors when appropriate.

## 14. REPRESENTATIONS AND WARRANTIES

14.1. Mutual Representations and Warranties. Each Party warrants and represents to the other Party as of the Effective Date that:

(i) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation, and it has full corporate power and authority to execute, deliver, and perform this Agreement and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(ii) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity); and

(iii) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not (a) conflict with or result in a breach of any provision of its organizational documents, (b) result in a breach of any agreement to which it is a party; or (c) violate any Applicable Laws.

14.2. Representations and Warranties by Noile. Additionally, Noile represents and warrants that:

(i) it solely and exclusively owns or Controls all rights, title and interest in and to the Licensed Patents and the Licensed Know-How free and clear of any liens, charges and encumbrances;

- 27 -

- (ii) as of the Effective Date, no other person, corporate or other private entity, or government entity or subdivision thereof, has any claim of ownership whatsoever with respect to the rights under the Licensed Patents and Licensed Know-How;
- (iii) it has the right to enter into this Agreement and to grant the licenses to Legend hereunder;
- (iv) as of the Effective Date, other than the Licensed Patents and Licensed Know-How, neither Noile nor its Affiliates owns or controls any patents or know-how that would be necessary or useful for Legend's performance as contemplated in this Agreement;
- (v) all maintenance fees and annual payments due for the Licensed Patents in the Territory have been paid when due;
- (vi) as of the Effective Date it has not received any notice of infringement or any written communication relating in any way to the possible infringement of any Third Party Intellectual Property by the activities of Noile prior to the Effective Date or by the activities of Legend contemplated by this Agreement;
- (vii) it shall not knowingly enter into any agreement after the Effective Date which would be inconsistent with its obligations under this Agreement or deprive Legend of its rights or licenses granted under this Agreement;
- (viii) as of the Effective Date it has not knowingly granted any licenses to Third Parties or filed any patent applications inconsistent with the licenses granted to Legend hereunder;
- (ix) it has provided to Legend, prior to the Effective Date, any and all Clinical Trial data related to the Noile Platform owned or Controlled by or otherwise known to it or its Affiliates as of the Effective Date; provided, however, that nothing under this Section 14.2(xii) shall require Noile to breach its obligations to any Regulatory Authority under Applicable Law and/or its confidentiality obligations to any third party under non-disclosure agreements or other similar agreements; and
- (x) except for [\*\*\*], it has not been aware of, prior to the Effective Date, any and all passive information or result concerning [\*\*\*].
- 14.3. Nothing in this Agreement shall be construed as:

(a) a warranty or representation by Noile as to the validity, patentability, scope and/or enforceability of any of the Licensed Patents, subject to Section 14.2;

- 28 -

(b) a warranty or representation by Noile that any Products made, used, sold, or otherwise disposed of under any Licensed Patents and Licensed Know-How are or shall be free from infringement of patents or other Intellectual Property rights not licensed hereunder or of Third Parties, subject to Section 14.2;

(c) a warranty or representation by Noile that Intellectual Property rights owned by Third Parties, other than the Licensed Patents and Licensed Know-How, are not required to formulate, manufacture, sell, or use the Licensed Products, subject to Section 14.2; or

(d) an obligation of Noile to defend any suit or action brought by a Third Party which challenges or concerns any of the Licensed Patents.

14.4. <u>Representations and Warranties by Legend</u>. Legend warrants that its Affiliates and Sublicensees shall observe the substance of the terms and conditions of this Agreement. [\*\*\*]

## 15. DISCLAIMER AND LIMITATION OF LIABILITY

15.1. EXCEPT AS EXPRESSLY SET FORTH UNDER SECTIONS 14.1 AND 14.2, NOILE HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND OR NATURE, WHETHER EXPRESS OR IMPLIED, RELATING TO LICENSED PATENTS, LICENSED KNOW-HOW, LICENSED COMPOUNDS, AND LICENSED PRODUCTS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, VALIDITY, PATENTABILITY, OR ENFORCEABILITY OF LICENSED PATENTS.

15.2. OTHER THAN AS EXPRESSLY PROVIDED IN SECTION 16, NOILE SHALL NOT BE LIABLE TO LEGEND, INCLUDING ITS AFFILIATES AND SUBLICENSEES, FOR THIRD PARTY CLAIMS, ACTIONS, AND DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE LICENSED COMPOUNDS AND LICENSED PRODUCTS.

15.3. EXCEPT FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 7.5 OR SECTION 12, NEITHER PARTY SHALL BE ENTITLED TO CLAIM FROM, OR RECOVER FROM, THE OTHER PARTY, ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

- 29 -

# 16. INDEMNIFICATION

16.1. <u>Indemnification by Legend</u>. Subject to Section 16.3, Legend shall indemnify, defend and hold Noile, its Affiliates and their respective directors, officers, and employees and the successors and assigns of any of the foregoing harmless from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees and other reasonable expenses of litigation) (collectively, "<u>Loss</u>" or "<u>Losses</u>") to the extent arising out of or in connection with any Third Party claims, suits, actions, demands or judgments ("<u>Third Party Claims</u>") relating to (a) the negligence or willful misconduct of Legend or its Affiliates or any of its or their sub-contractors; and (b) any breach of Applicable Laws by Legend or its Affiliates, Sublicensees or any of its or their sub-contractors; and (c) any breach of the warranties under Section 14 by Legend or its Affiliates; and (d) infringement of a patent owned by a Third Party by Legend's activities under this Agreement ([\*\*\*]); except, in each case, to the extent caused by the negligence or willful misconduct of Noile or its Affiliates or any of its or their sub-contractors or breach of this Agreement by Noile or its Affiliates.

16.2. <u>Indemnification by Noile</u>. Subject to Section 16.3, Noile shall indemnify, defend and hold Legend, its Affiliates and their respective directors, officers, and employees and the successors and assigns of any of the foregoing harmless from and against any and all Losses to the extent arising out of or in connection with any Third Party Claims relating to (a) the negligence or willful misconduct of Noile, its Affiliates or any of its or their sub-contractor; and (b) any breach of Applicable Laws by Noile, its Affiliates, or any of its or their sub-contractors; and (c) any breach of the warranties under Section 14 by Noile or its Affiliates; except, in each case, to the extent caused by the negligence or willful misconduct of Legend or its Affiliates or any of its or their sub-contractors or breach of this Agreement by Legend or its Affiliates.

16.3. <u>Indemnification Procedures</u>. If a Party intends to claim indemnification under this Agreement (the "<u>Indemnitee</u>"), it shall promptly notify the other Party (the "<u>Indemnitor</u>") in writing of such alleged Loss and the Third Party Claim. The Indemnitor shall have the right to control the defense thereof with counsel of its choice as long as such counsel is reasonably acceptable to the Indemnitee. The Indemnitee shall have the right to retain its own counsel at its own expense for any reason in connection with such Third Party Claim, [\*\*\*]. The Indemnitee and its employees and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Third Party Claim covered by this Agreement. The obligations of this Section 16 shall not apply to any settlement of any Third Party Claim if such settlement is effected without the consent of both Parties, which shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Section 16.3. It is understood that only Noile and Legend may claim indemnity under this Agreement (on their own behalf or on behalf of their respective directors, officers, and employees and the successors and assigns of any of the foregoing), and no other party may directly claim indemnity hereunder.

16.4. <u>Other Infringement</u>. In the event of any patent infringement, misappropriation claim, or suit against either Legend or Noile with respect to Legend's activities under this Agreement, including any claim made as part of an arbitration, which is not indemnifiable

- 30 -

pursuant to this Agreement, each Party shall nevertheless immediately notify the other Party in writing and such other Party shall give the notifying Party reasonable assistance to defend the said claim or suit and any appeal arising therefrom; provided, however that the notifying Party shall continue, at its own cost and expense, to take all necessary measures and actions to defend the said claim or suit and shall continue to control such claim, suit and appeal.

16.5. <u>Insurance</u>. Each Party shall obtain and maintain comprehensive general liability insurance customary in the industry for companies of similar size conducting similar business. [\*\*\*] days after signing this Agreement, each Party shall provide, upon request therefor, the other Party with its certificate of insurance evidencing such insurance coverage.

## 17. TERM AND TERMINATION

17.1. This Agreement shall become effective as of the Effective Date and shall, unless terminated sooner as set forth herein, remain in effect on a country-by-country, Licensed Target-by-Licensed Target, and Licensed Product-by-Licensed Product basis as long as Legend has an obligation to pay the Initial Payments pursuant to Section 9.1, the Milestone Payments pursuant to Section 9.2, or royalties to Noile pursuant to Section 9.3. After the expiration of this Agreement under this Section 17.1, the exclusive license granted by Noile to Legend under Section 7.3 shall be converted into [\*\*\*], fully paid-up, irrevocable, royalty-free, and perpetual license.

17.2. Legend may terminate this Agreement, either as a whole, on a country-by country basis, on a Licensed Target-by-Licensed Target basis, or on a Licensed Product-by-Licensed Product basis at any time by giving [\*\*\*] days' prior written notice, if in its reasonable judgment, such termination is justified for any reason including but not limited to commercial, scientific, or medical reasons.

17.3. This Agreement may be terminated by either Party at any time during the life of this Agreement:

(a) if it is proven by reasonable evidence that the other Party is in breach of its essential obligations hereunder by causes and reasons within its control and responsibility and has not cured such default within [\*\*\*] days after the receipt of written notice identifying the default and requesting its correction; or

(b) upon filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings against the other Party.

17.4. If this Agreement is terminated pursuant to Section 17.2 by Legend or pursuant to Section 17.3 by Noile, then Legend shall take and/or cause the relevant Affiliates or Sublicensees, unless otherwise agreed upon between the Parties in writing, to take the following measures solely with respect to the relevant countries, relevant Licensed Targets, relevant Licensed Compounds and relevant Licensed Products, as reasonably applicable:

(a) cease to use the Licensed Patents and the non-public, confidential Licensed Know-How, subject to an orderly wind-down, close out of any activity of relevant Licensed Targets and close out of any Clinical Trials of the Licensed Compounds or the Licensed Products that Legend may have on-going; and

- 31 -

(b) return all the relevant Licensed Know-How (including remaining materials) supplied by Noile.

17.5. If this Agreement is terminated by Legend pursuant to Section 17.3, then Legend shall take and/or cause its Affiliates or Sublicensees to take the following measures:

(a) cease to use the Licensed Patents and the non-public, confidential Licensed Know-How, subject to an orderly wind-down, close out of any activity of relevant Licensed Targets and close out of any Clinical Trials of the Licensed Compounds or the Licensed Products that Legend may have on-going;

(b) cease to discover, Develop, make, have made, use, import, export, sell and offer to sell Licensed Products (including Licensed Compounds as applicable); and

(c) return all the Licensed Know-How supplied by Noile.

17.6. Any expiration and/or termination of this Agreement for any reason shall be without prejudice to:

- (a) Noile's right to receive all payments of the Initial Payments, the Milestone Payments, the royalty payments, and any other payments accrued before the effective date of the expiration or termination of this Agreement; and
- (b) the obligation of Legend to keep records provided for in Section 10 above, Noile's right to examine records provided for in Section 10.4 above, and Legend's obligation to furnish tax receipts provided for in Section 10.7 above.

17.7. In addition to the rights/obligations of the Parties as provided for in Section 17.6 above, termination or expiration of this Agreement shall not relieve the Parties of any remaining liability, obligations (including indemnification), or rights as shall appropriately survive termination of this Agreement (as specified in the following sentence), nor shall it preclude either Party from pursuing all rights and remedies it may have hereunder or under Applicable Laws with respect to any breach of this Agreement, nor shall it prejudice any Party's right to obtain performance of any obligation. The provisions of Sections 1, 8.2(a), 8.2(b), 10.4, 10.6, 10.7, 11, 12, 13, 14, 15, 16, second sentence of 17.1, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9 and 18 shall survive the expiration or termination of this Agreement; provided however that Sections 8.2(a), 8.2(b) and second sentence of 17.1 shall not survive in the case where this Agreement was terminated for causes attributable to Legend, including without limitation termination by Legend pursuant to Section 17.2 and termination by Noile pursuant to Section 17.3.

17.8. The license as granted under Section 7 shall forthwith terminate, upon any termination of this Agreement, except for expiration of the term of this Agreement as provided for in Section 17.1 above.

17.9. Notwithstanding anything in this Section 17 to the contrary, Legend shall have the right to sell and otherwise dispose of the Licensed Products in stock and in the process of being made at the time of early termination of this Agreement for [\*\*\*] following such termination, subject to Legend's compliance with the terms and conditions of this Agreement, specifically including, without limitation, the payment of royalties and the submission of royalty reports with respect to such sale of Licensed Products.

- 32 -

# 18. MISCELLANEOUS PROVISIONS

18.1. Amendment. Any amendment or modification of any provision of this Agreement shall be in writing, dated, and signed by each Party.

# 18.2. Arbitration.

(a) Any dispute, controversy, or claim arising under, out of, or relating to this Agreement or any subsequent amendments of this Agreement, including without limitation its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as non-contractual claims (collectively referred to as "<u>Disputes</u>") first shall be attempted to be resolved by discussions between the senior management of the Parties, [\*\*\*] days following the date on which the Dispute was submitted to them. All negotiations pursuant to this Section 18.2(a) shall be deemed each Party's Confidential Information, and shall be treated as settlement negotiations for purposes of any applicable rules of evidence in any subsequent litigation between the Parties relating to such Dispute. If the Parties' senior management are unable to resolve such Dispute within [\*\*\*] period, then either Party may initiate arbitration proceedings in accordance with the provisions of Section 18.2(b) below.

(b) If a Dispute is not resolved within [\*\*\*] (or such other period of time mutually agreed upon by the Parties) after the senior management of the Parties have met as required by Section 18.2(a) above, then it shall be finally resolved by arbitration initiated by either Party and conducted by a [\*\*\*] under the Rules of Conciliation and Arbitration of the ICC (International Chamber of Commerce) then in force. The arbitration shall take place [\*\*\*]. The Parties shall [\*\*\*]. Failing such agreement, any Party may apply under the applicable rules of the ICC for the appointment of arbitrator(s) and the selection of arbitrator(s) under such rules of the ICC shall be final and binding on the Parties. All such arbitrator(s) shall have appropriate experience in the pharmaceutical industry and be independent of all the Parties. The Parties shall [\*\*\*] after the arbitrator(s) have been appointed. The award shall be final and binding upon the Parties, and judgment upon the award may be entered in any court having jurisdiction thereof. [\*\*\*] The arbitrators shall examine arguments and evidence by each Party and resolve each of the issues identified by the Parties. The panel of arbitrators shall render a formal, binding non-appealable resolution and award on each issue as expeditiously as possible. In any arbitration, discovery shall be permitted subject to the arbitrators' reasonable judgment, and each Party shall voluntarily produce to the other all documents such Party shall use in its portion of the arbitration. The arbitrators shall have no power to include an award of attorneys' fees and costs to the prevailing Party, or to award punitive, special, incidental or consequential damages. All rulings of the panel of arbitrators

- 33 -

shall be in writing and shall be delivered to the Parties. Each Party shall bear its own costs for its counsel and other expenses, and the Parties shall equally share the costs of the arbitration. Judgment upon the award may be entered in any court having jurisdiction, or application may be made to such court for judicial acceptance of the award and/or an order of enforcement as the case may be. Notwithstanding the foregoing, this Section 18.2 shall not apply to any disputes relating to a Party's patent rights (including the validity or infringement of patents or scope of patent claims), which instead shall be resolved by a court or the patent office (or its equivalent) of competent jurisdiction.

18.3. <u>Assignment</u>. Neither Party may assign or transfer this Agreement or any right or obligation hereunder to any Third Party without the prior written consent of the other Party, except that either Party may assign this Agreement to an Affiliate or to an assignee or successor to all or substantially all of its business or assets without the consent of the other Party. This Agreement is binding upon and shall inure to the benefit of the Parties, their representatives, and permitted assigns.

18.4. <u>Captions</u>. The captions and section headings used in this Agreement are for convenience only and are not intended to have, nor shall they be interpreted as having, any substantive effect whatsoever.

18.5. <u>Entire Agreement</u>. This Agreement embodies the entire understanding between the Parties relating to the subject matter hereof, and there are no prior representations, warranties, or agreements, whether written or oral, between the Parties, not contained in this Agreement.

18.6. Force Majeure. Neither of the Parties shall be liable for any default in performance of this Agreement due to the occurrence of any event beyond the reasonable control of the affected Party, including, but not limited to, enactment or change of government laws, regulations, or orders, an act of God, fire, storm, earthquake, act of terrorism, labor disturbances, war, and riot (defined as "<u>Force Majeure</u>" herein). On the occurrence of any event of Force Majeure, the affected Party shall give notice and full particulars of such event of Force Majeure to the other Party as soon as practicable and shall exert [\*\*\*] to remedy the situation. In the meantime, the Parties hereto shall consult with each other [\*\*\*].

18.7. <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of [\*\*\*] without reference to any rules of conflict of laws. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

18.8. <u>Notice</u>. Any notice or communication in connection with this Agreement shall be made in the English language and considered sufficient if in writing and personally delivered to an officer of the Party for which it is intended, or if sent first by facsimile or email and confirmed by registered air mail or special courier at the address specified below or such other address as the Party has given notice of in writing. It shall (except as otherwise provided in this Agreement) be deemed to have been received (a) when delivered, if personally delivered and (b) on the [\*\*\*] day after dispatch, if sent

- 34 -

by facsimile or nationally-recognized express delivery service; provided that any legal process served in such manner pursuant to this Section shall be deemed to have been received only when actually delivered, unless otherwise provided by Applicable Law. All notices shall be deemed effective upon actual receipt by a Party to whom such notices are given.

```
If to Noile:

[***]

With required copy to:

[***]

If to Legend:

[***]

With required copies to:

[***]

and

[***]
```

Either Party may change its address or facsimile number by notice to the other Party pursuant to this Section 18.8.

18.9. <u>Severability</u>. If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall endure except for the part declared invalid or unenforceable by orders of such a court. The Parties shall consult and make their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such invalid or unenforceable provision in light of the intent of this Agreement.

18.10. <u>Waivers</u>. A waiver by either Party of any term or condition of this Agreement in any one instance shall not be deemed to continue to be a waiver of such a term or condition for any similar instance in the future or of any subsequent breach thereof or of any other term or condition of this Agreement.

- 35 -

18.11. Counterparts. This Agreement may be executed in any number of counterparts and each such counterpart shall be deemed to be an original.

**IN WITNESS WHEREOF,** the Parties have caused this Agreement to be executed and delivered by their respective duly authorized representatives as of the date first above written.

# Noile-Immune Biotech, Inc.

By: /s/ Hidenobu Ishizaki Hidenobu Ishizaki, President & CEO

Date: April 27, 2020

## Legend Biotech USA, Inc.

By: /s/ Meeta Chatterjee

Meeta Chatterjee Senior Vice President, Global Business Development

Date: April 27, 2020

- 36 -

# EXHIBIT A

Noile Patents

[\*\*\*]

- i -

# <u>EXHIBIT B</u>

# Noile's Bank Account

[\*\*\*]

- iv -

# Subsidiaries

# Name of Subsidiary

Legend Biotech Limited Legend Biotech HK Limited Nanjing Legend Biotech Co., Ltd. Legend Biotech Ireland Limited Legend Biotech (Netherlands) BV Legend Biotech USA Inc.

## State or Other Jurisdiction of Incorporation

British Virgin Islands Hong Kong People's Republic of China Ireland Netherlands New York

# **Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated April 20, 2020, in the Registration Statement (Form F-1) and related Prospectus of Legend Biotech Corporation dated May 13, 2020.

/s/Ernst & Young Hua Ming LLP Shanghai, the People's Republic of China May 13, 2020