As confidentially submitted to the Securities and Exchange Commission on May 8, 2020
This draft registration statement has not been filed publicly with the Securities and Exchange Commission, and all information herein remains strictly confidential.

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	2834	Not Applicable
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Legend Biotech Corporation
2101 Cottontail Lane
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)

	Copies to:	
Divakar Gupta, Esq. **Richard C. Segal, Esq.** **Mark Ballantyne, Esq.** **Cooley LLP** **55 Hudson Yards** **New York, NY 10001** **(212) 479-6000**	**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† 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)	$	$

(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 one ordinary share.
(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 on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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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 , 2020

American Depositary Shares

Representing ordinary shares

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

We are offering ADSs. Each ADS represents one ordinary share, $0.0001 par value per share. We anticipate the initial public offering price per ADS will be between $ and $.

Prior to this offering, there has been no public market for the ADSs or our ordinary shares. We will apply 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.

PRICE $ PER ADS

	Price to Public	*Underwriting Discounts and Commissions(1)*	*Proceeds to us*
Per ADS	*$*	*$*	*$*
Total	*$*	*$*	*$*

(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 ADSs to cover over-allotments at the initial public offering price, less underwriting discounts and commissions.

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

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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.

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 and 76 percent achieving a CR or better. As of January 17, 2020, 26 of the 29 patients were progression free with a median follow-up time of nine months. 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 January 17, 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 and one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator. 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

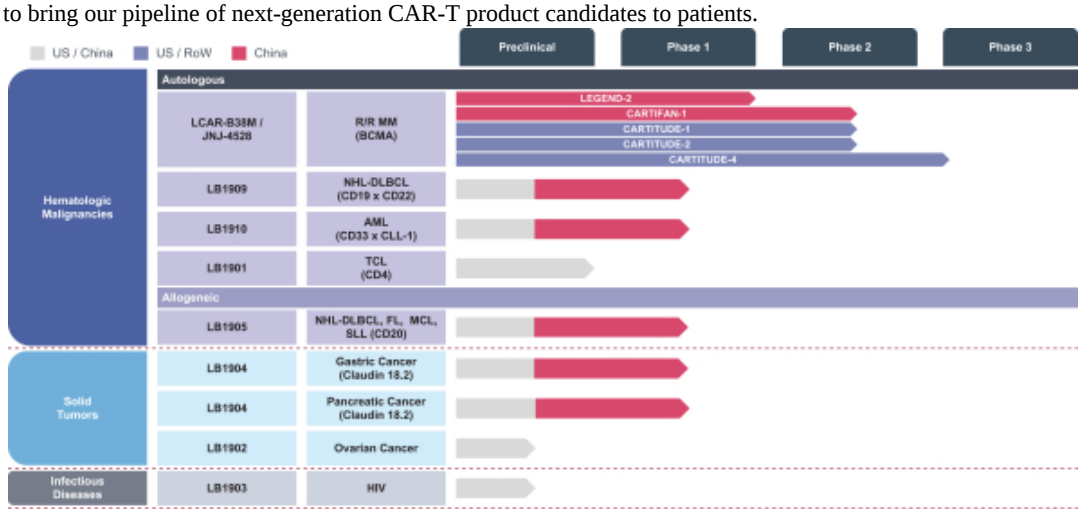
half of 2020. JNJ-4528 has been granted breakthrough therapy designation and orphan drug designation by the U.S. Food and Drug Administration, or FDA, and Priority Medicines, or PRIME, designation, enabling accelerated assessment, by the European Medicines Agency, or EMA. We anticipate that a biologics 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 fully-integrated, 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 one 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 one ordinary share. 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 intend to apply 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;

- the ADSs (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) that GenScript must make available to its shareholders pursuant to the rules of the Hong Kong Stock Exchange; and
- 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

	Year Ended December 31,	
	2018	2019
	(in thousands, except per share 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	$ (0.01)	$ (0.66)
Diluted	$ (0.01)	$ (0.66)

Summary consolidated statement of financial position data

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

(1) 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 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.

(2) 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 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.

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

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 months. However, we will need to raise additional capital to complete the 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, in the first half of 2020, we expect to begin enrolling approximately 400 patients in a Phase 3 trial in the United States, Europe and Japan (CARTITUDE-4) to compare 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, we will not be permitted to conduct clinical trials in the United States.

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 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 EMA, 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 with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to 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 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 toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three weeks, but several patients died in clinical trials involving CAR-T cells, including 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 January 17, 2020, CRS was reported in 93 percent of patients. One patient died as a result of CRS and one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator.

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;

- 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 third-party 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 measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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, third-party 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 patents or 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 incorrectly 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 in issued patents that any of our product candidates may infringe, or which such third parties claim to be infringed by our technologies.

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 has 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 or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

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" 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 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 incentive plan and obtain approval for an annual allowance with respect to the purchase of 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 firms depending on the nature of the failure. Remedies for any future noncompliance could include, as appropriate, an automatic six-month bar on a single 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 diagnosis 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 intend to apply 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, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our 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 and the initial public offering price 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 freely tradable, and the remaining 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 loses 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, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board 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. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

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 cease 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 would increase or decrease, as applicable, the net proceeds to us from this offering by $, 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.

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. While we have no current agreements, commitments or understandings for any specific licenses, acquisitions or investments at this time, 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 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; 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.

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	Pro Forma As Adjusted(1)
		(in thousands)	
Cash and cash equivalents	$ 83,364		$
Equity			
Share capital	20		
Reserves	(122,889)		
Total ordinary shareholders’ equity (deficit)	(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’ equity (deficit) 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’ equity (deficit) and total capitalization by $ million, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions 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 approximately $, 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 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. 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, 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 to investors purchasing ADSs 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 forma as adjusted net tangible book value after giving effect to this offering by $, the pro forma as adjusted net tangible book value per ordinary share 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 ordinary share, and would decrease dilution to investors in 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 by $ per ordinary share, and would increase dilution to investors in 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.

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 over-allotment option granted to the underwriters.

	Ordinary Shares Purchased(1)		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
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 federal securities laws of 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

	Year Ended December 31,	
	2018	2019
	(in thousands, except per share 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	$ (0.01)	$ (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(1)	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 approximately $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 (Decrease)
	2018	2019	
	(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 thousands)	
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	More than 5 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.

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.

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.

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 and restricted stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

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 *Share-based 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. As a result, its market multiples are not comparable to those publicly traded guideline companies.

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	Per Share Exercise Price of Options	Fair Value of Common Stock per Share on Option Grant Date	Per Share Estimated Fair Value 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 completed 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 and 76 percent achieving a CR or better. As of January 17, 2020, 26 of the 29 patients were progression free with a median follow-up time of nine months. 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 fully-integrated, 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.

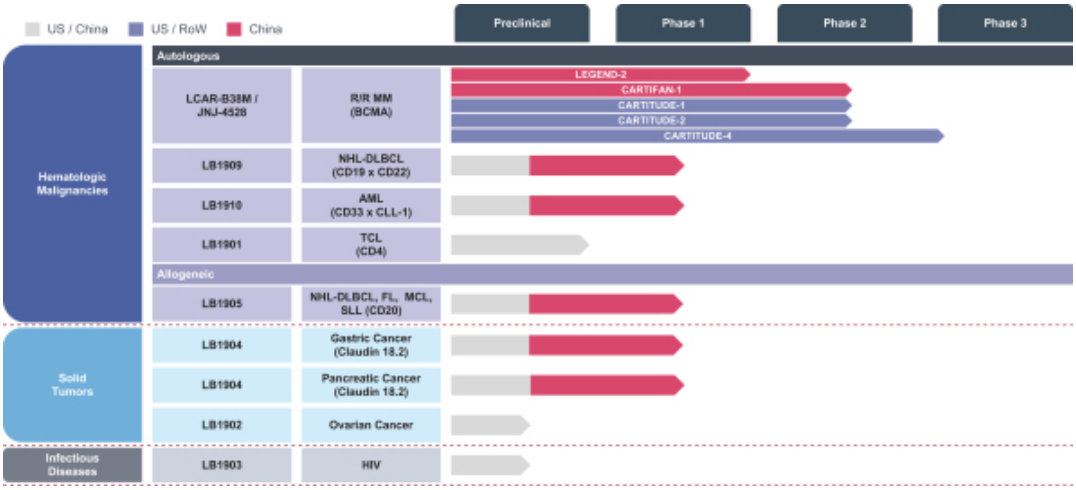
Our lead product candidate, LCAR-B38M/JNJ-4528, is an autologous CAR-T cell therapy that targets the B-cell maturation antigen, or BCMA, which is a highly expressed protein in a number of hematologic malignancies including MM. Autologous cells refer to the patient's own cells. We are developing LCAR-B38M/JNJ-4528 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, in the first half of 2020, we expect to begin enrolling approximately 400 patients in a Phase 3 trial in the United States, Europe and Japan, which we refer to CARTITUDE-4, to compare 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 fully-integrated, 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 investigator-initiated 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 China and JNJ-4528 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
VGPR	• Serum and urine monoclonal protein, or M-protein, detectable by immunofixation but not on electrophoresis or • ³90% reduction in serum M-protein plus urine M-protein level <100 mg/24 h
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 ³50% 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, ³50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma-cell percentage was ³30% • 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 and 76 percent achieving a CR or better. As of January 17, 2020, 26 of the 29 patients were progression free with a median follow-up time of nine months. 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 January 17, 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 and one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator. 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 antibody-producing 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.

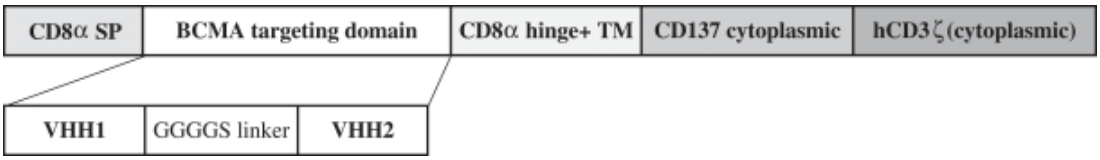
Tissue distribution of BCMA, as determined using quantitative analysis of transcription levels, show that BCMA is generally expressed only in lymphoid cells and not in other tissues in the body. The expression level of BCMA in plasmacytomas, or MM tumors, is hundreds to thousands of times higher than 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 10^6 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.

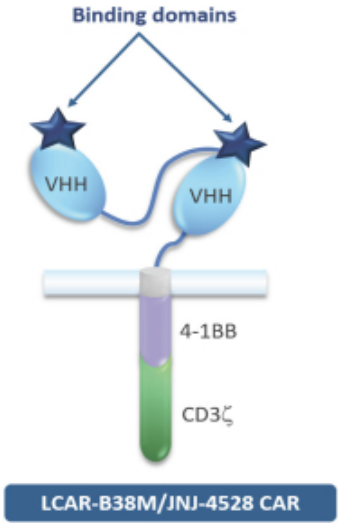
Our Solution, LCAR-B38M/JNJ-4528

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



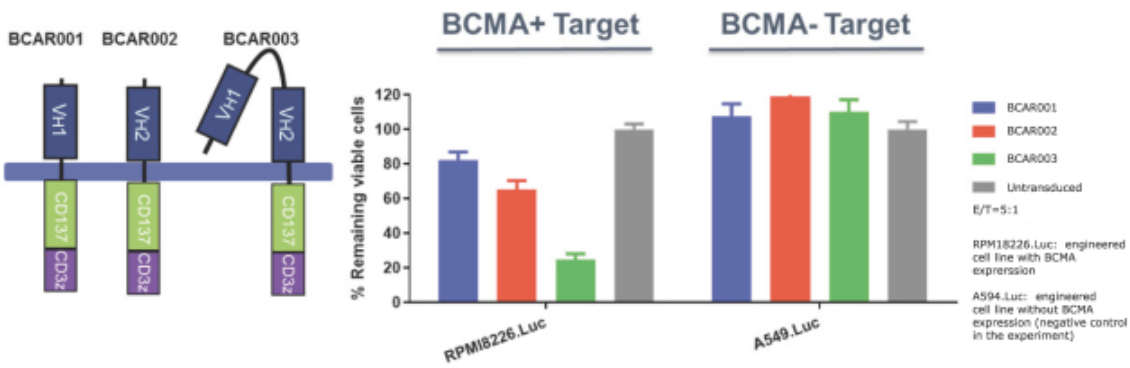
Same antigen dual binding domain CAR

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), anti-tumor 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)

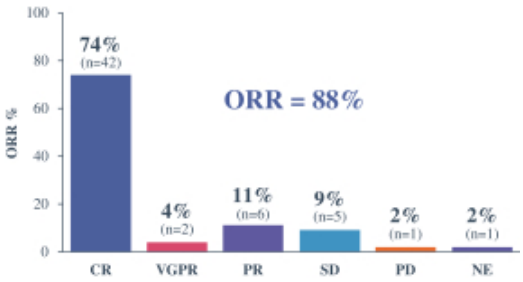
In October 2015, an investigator-initiated Phase 1 trial of LCAR-B38M was initiated at four independent sites in China, enrolling a total of 74 patients with RRMM. We reported updated data from the trial in December 2019 at the American Society of Hematology conference. The primary endpoint of the trial 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

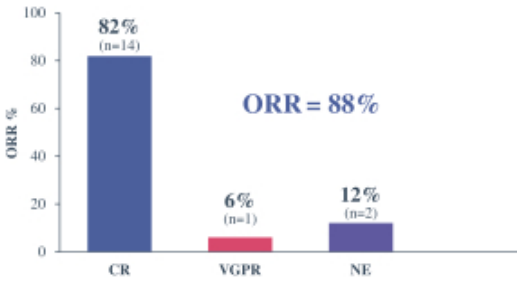
Investigators have publicly presented the results of the LEGEND-2 trial as a set of two independent analyses. The Xi'an site enrolled the largest number of patients, 57, and published additional molecular and cellular profiling data on responses. The Ruijin, Jiangsu and Changzheng sites, which enrolled 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

Xi'an: Best overall response (n=57)



Ruijin (RJ), Jiangsu (JS), Changzheng (CZ): Best overall response (n=17)

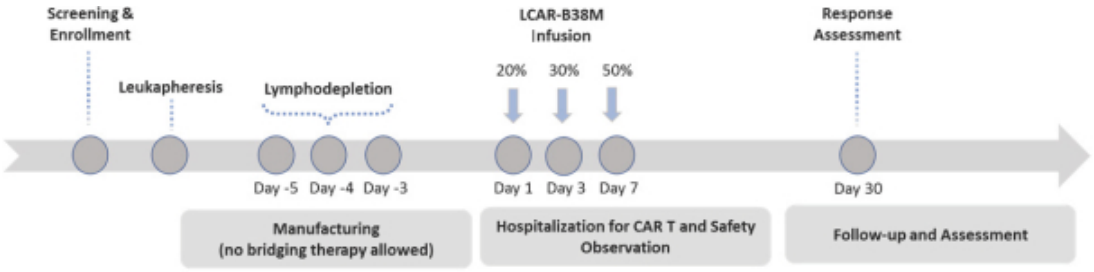


SD = stable disease
PD = progressive disease
NE = not evaluable

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.

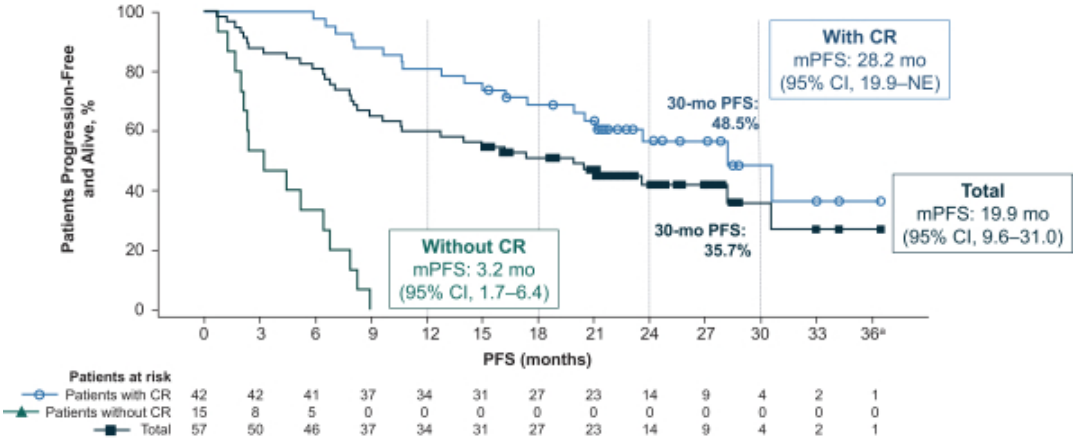
At the Xi'an site, all 57 patients treated had lymphodepletion three to five days before receiving LCAR-B38M using cyclophosphamide alone. LCAR-B38M was administered as three split infusions, as shown below, with the total number of CAR-T cells delivered to patients averaging 0.5 x 10^6 cells/kg. Patients were assessed for response to treatment beginning 30 days after the first LCAR-B38M infusion.

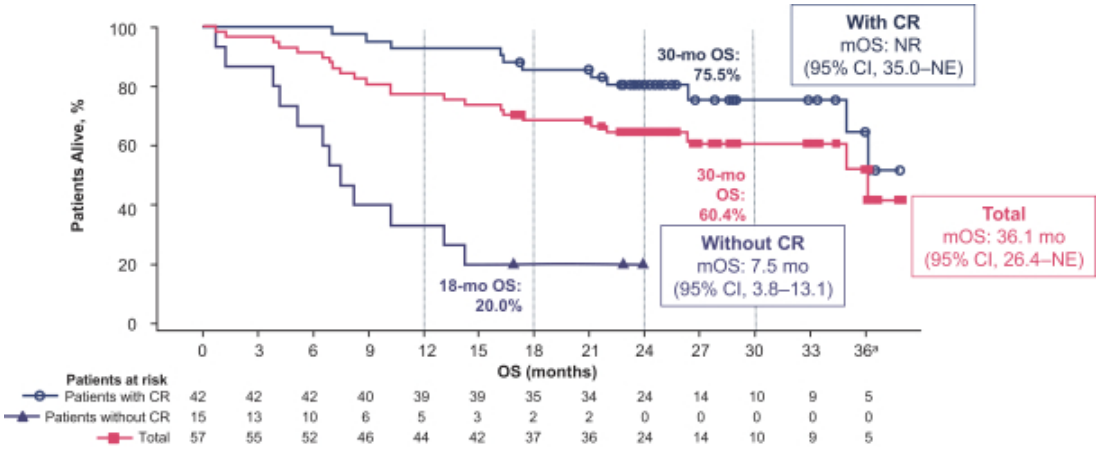
Dosing regimen in the LEGEND-2 patients at the Xi'an site



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 duration of 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.

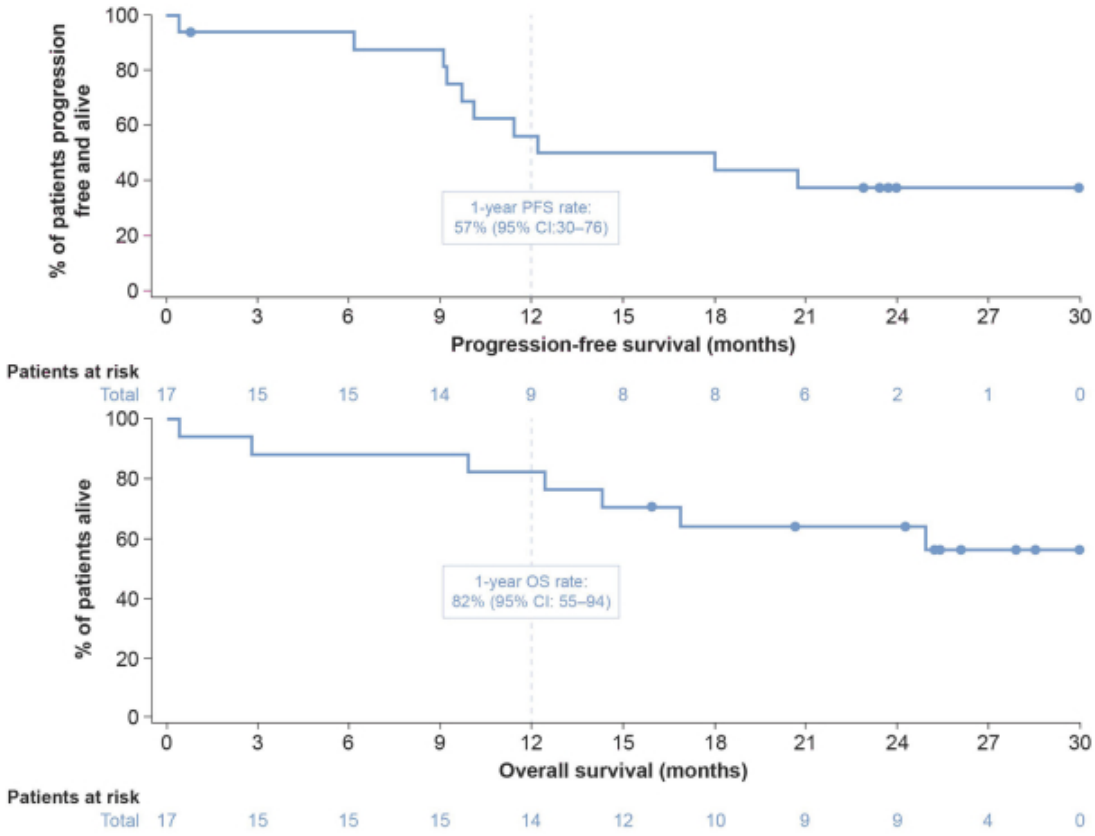
PFS and overall survival of patients enrolled at the Xi'an site in the LEGEND-2 trial





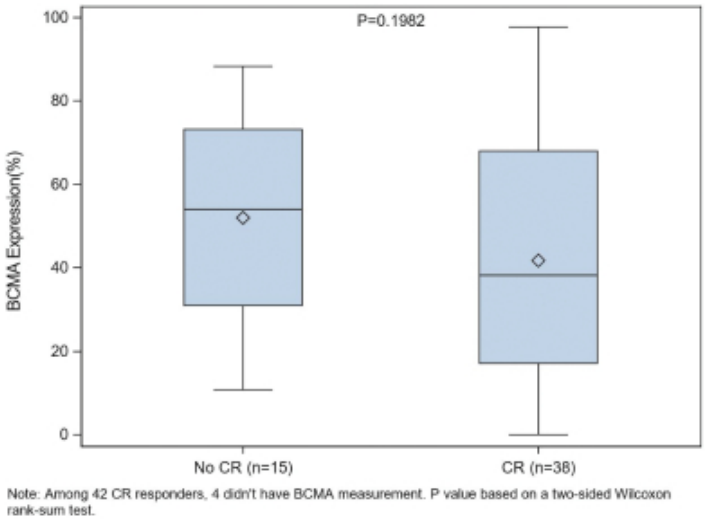
The 17 patients treated at the other three sites had similar outcomes, achieving an ORR of 88 percent and a CR rate of 82 percent as of October 31, 2019. The median progression free survival was 18 months and overall survival was 82 percent at 12 months and 64 percent at 24 months as of October 31, 2019.

PFS and overall survival in the LEGEND-2 patients enrolled at the Ruijin, Changzheng and Jiangsu sites



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

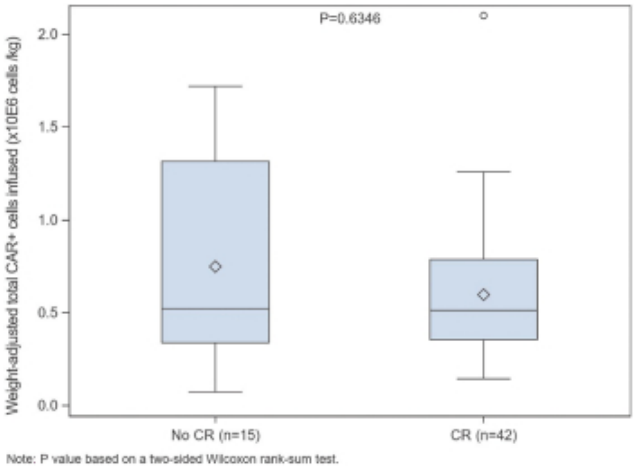


Note: Among 42 CR responders, 4 didn't have BCMA measurement. P value based on a two-sided Wilcoxon rank-sum test.

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 10^6 CAR+ viable T cells/kg (range 0.07 x 10^6 to 2.1 x 10^6). In the other three sites combined, patients received a mean of 0.70 x 10^6 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.

Adverse Events Reported: Xi'an site (n=57) and RJ, JS, and CZ sites (n=17)

	All grade		Grade ≥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)

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 Phase1b/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. As of January 17, 2020, 29 patients had been dosed in the Phase 1b portion of the trial. These patients had failed a median of five prior therapies. All patients were exposed to immunomodulatory drugs, proteasome inhibitors and anti-CD38 therapies. 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, CARTITUDE-2 and CARTITUDE-4 trials, patients receive JNJ-4528 infusion following apheresis and lymphodepletion with cyclophosphamide and fludarabine daily for three days. The median administered dose of JNJ-4528 was 0.73 x 10^6 CAR+ viable T cells/kg (range 0.52 – 0.89 x 10^6). All 29 patients in the Phase 1b portion achieved response with 76 percent having a stringent CR, 21 percent having a VGPR, and three percent having a PR with a median follow-up time of nine months. With a median follow-up of nine months, 26 of 29 patients remained progression-free, with 6-month progression free survival rate of 93 percent and the longest response ongoing at 15 months.

The median time to achieving an initial response and the median time to achieving CR were each one month.

All 16 patients evaluable at six months were minimal residual disease, or MRD, negative. 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 January 17, 2020, 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. Neurotoxicity was observed in 4 patients (Grade 1-2, n=3; Grade 3, n=1). Other adverse events included neutropenia (100 percent), thrombocytopenia (93 percent); grade ^{3}3 hematologic adverse events were neutropenia (100 percent), thrombocytopenia (69 percent), and leukopenia (59 percent). One patient died as a result of CRS and one patient died due to acute myeloid leukemia that occurred during the trial, which was considered unrelated to treatment by the investigator.

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, including MRD negativity.

We have completed enrolling patients with the Phase 2 portion of the 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. We anticipate beginning to enroll patients in this trial in the first half of 2020.

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.

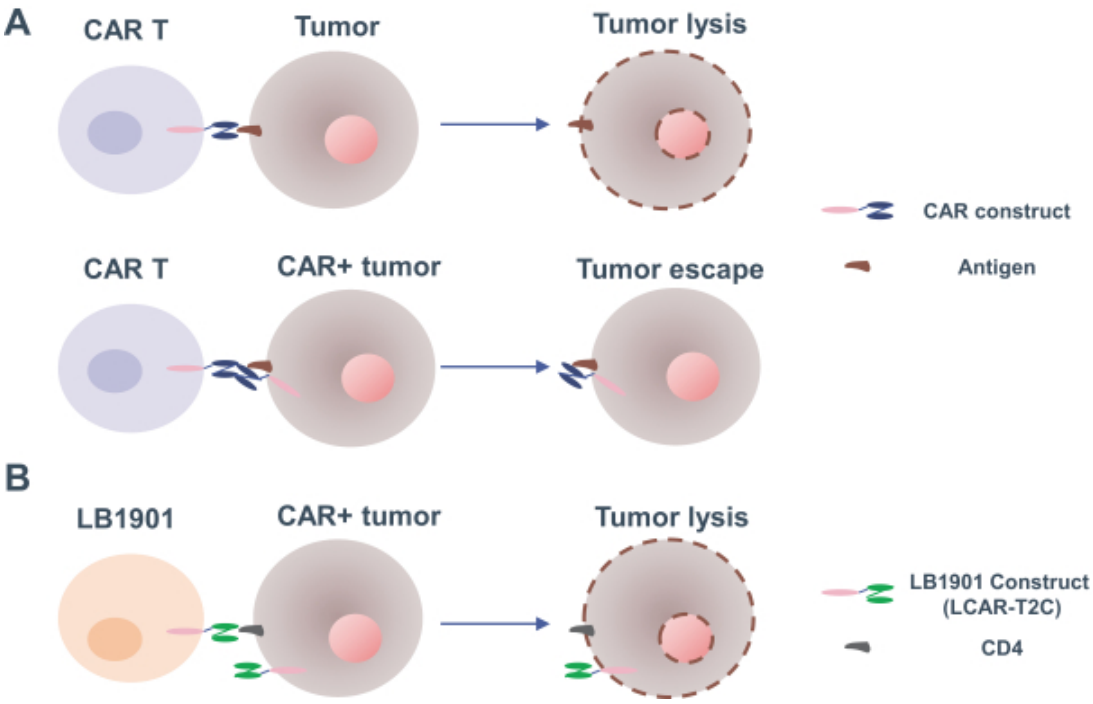
Our Solution: LB1901

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

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.

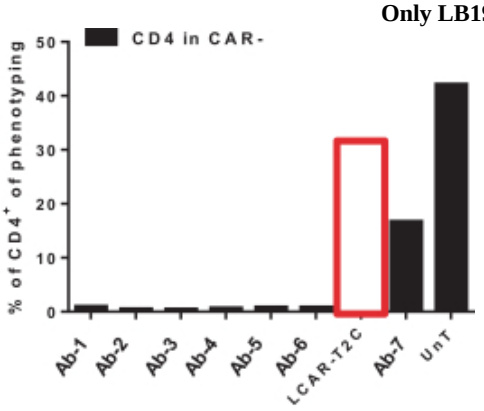
LB1901 was selected to avoid resistance due to inadvertent transduction of the CAR construct into tumor cells

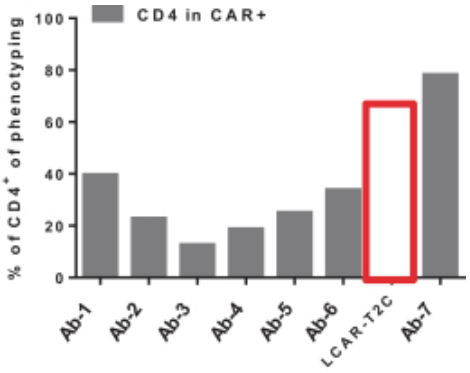


Preclinical Data

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.

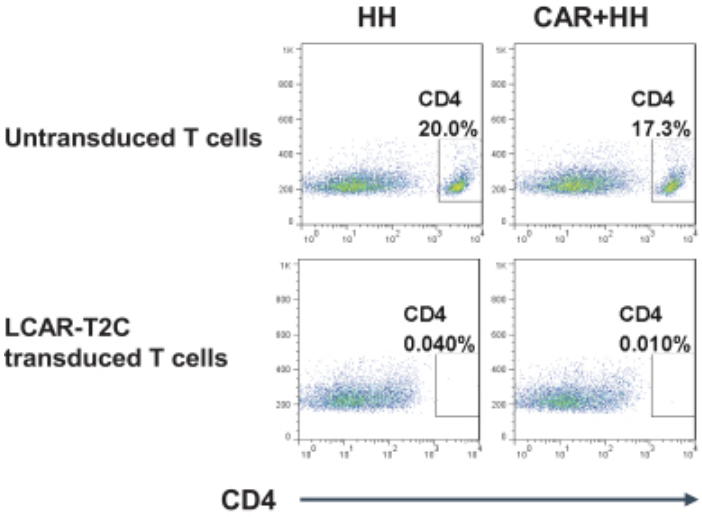
Only LB1901 was able to kill T cells transduced with the CAR construct





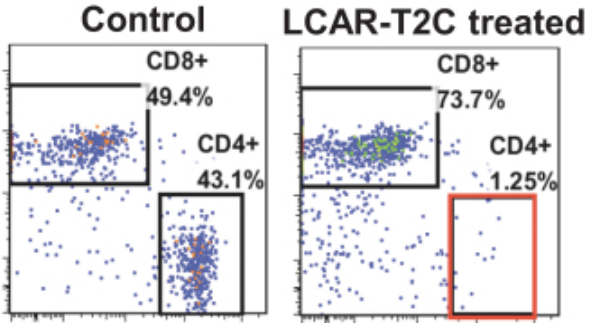
To confirm the ability of LB1901 to effectively target CD4 tumor cells that also express the CAR construct, we deliberately transduced HH, a CD4+ human tumor cell line derived from a patient with CTCL, with the LB1901 CAR construct. The preclinical results showed that LB1901 has the ability to eliminate 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.

LB1901 killed CAR-expressing CD4+ tumor cells



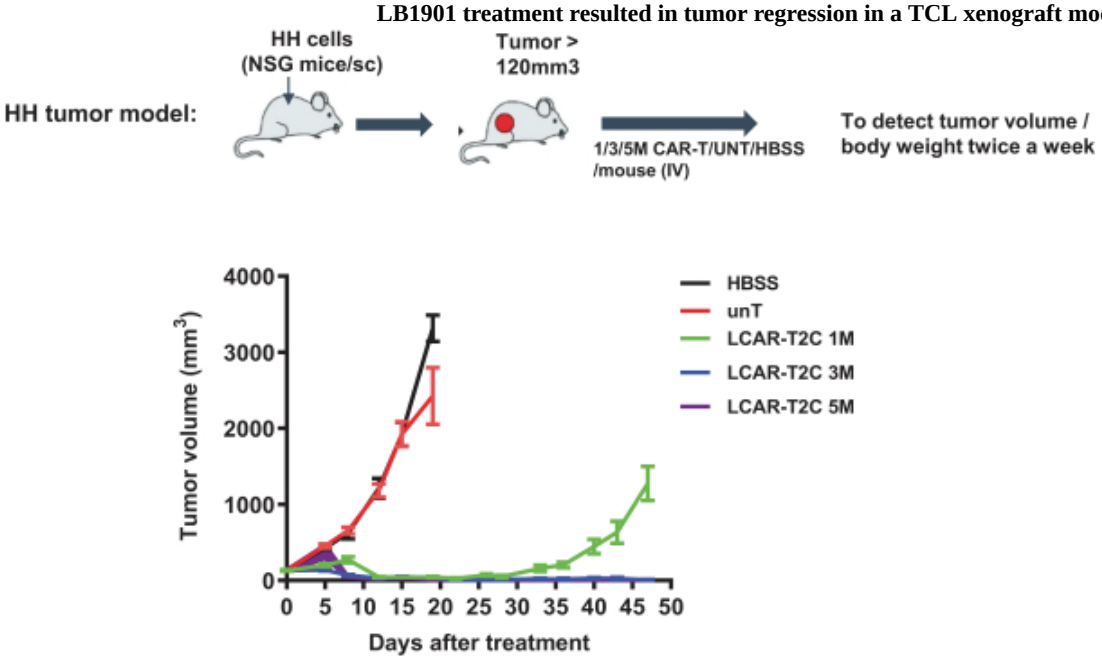
We have observed that LB1901 leads to selective killing of multiple CD4+ T cell lines. We have also observed that CD4+ T cell killing occurs in humanized mice treated with LB1901. In untreated mice, the CD4+ cells represented 43.1 percent of T cells. After treatment with LB1901, the percentage of CD4+ 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.

LB1901 treatment resulted in tumor regression in a TCL xenograft 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 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.

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.

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 that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the 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 that covers an approved drug. In the future, if and when our products receive FDA approval, 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, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, 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 competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may 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, see "Risk Factors—Risks Related to 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 facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and 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 will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and 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 replace the ACA will impact the ACA.

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 marked in China, and Category 5 refers to an application to import into 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 foreign-invested 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 subsidiary (or between the 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 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 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.

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, enterprises 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, or does not have 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.

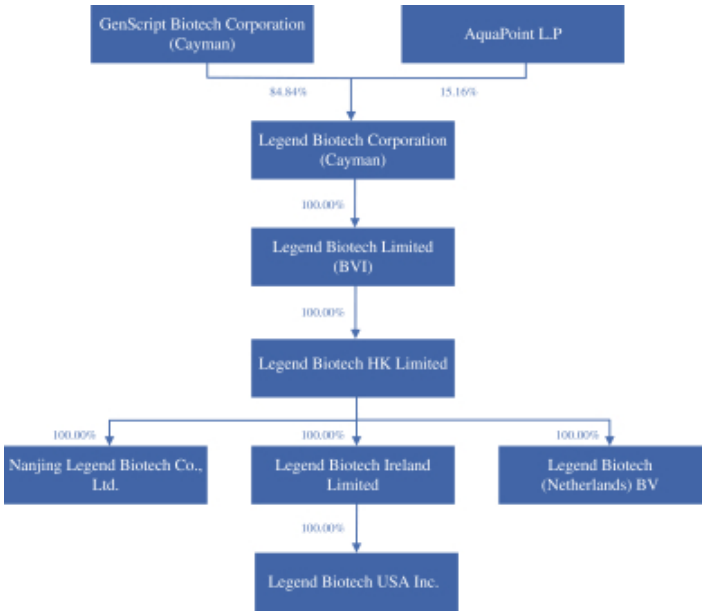
	As of December 31,	
	2018	2019
Function:		
General and administrative	13	41
Research and development	179	336
Sales and marketing	7	17
Others	95	251
Total	294	645
Geography:		
United States	37	158
Asia-Pacific	255	479
Ireland	2	8
Total	294	645

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

Our board of directors will consist of directors upon the effectiveness of our registration statement on Form F-1, of which this prospectus is 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 senior management such as managing directors and executive directors;
- providing employee benefits and pensions;
- managing our company's finance and bank accounts;
- 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 , and . will be the chairperson of our audit committee. satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC. Each of , and satisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq and 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;
- setting clear hiring policies for employees and former employees of the independent auditors;
- 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, internal auditors and the independent auditor;
- 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 , and . will be the chairperson of our compensation committee. Each of and satisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq.

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 senior officers and determining the compensation of our senior officers;
- reviewing and approving our senior officers' employment agreements with us;

- setting performance targets for our 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 , and . will be the chairperson of our nominating and corporate governance committee. satisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq.

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 is B (Meet Expectations), 720,000 shares will vest for that 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

Prior to the completion of this offering, we intend to adopt a Restricted Share Unit Incentive Plan under which we would have the discretion to grant restricted share units to eligible participants.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2019:

- 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 Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Shareholders:			
GenScript Biotech Corporation(1)	169,680,000	76.9%	
AquaPoint L.P.(2)	30,320,000	13.7	
Executive Officers and Directors:			
Yuan Xu, Ph.D.			
Ying Huang, Ph.D.			
Fangliang Zhang, Ph.D.			
Ye Wang, M.S.			
All Current Executive Officers and Directors as a Group (4 persons)			

* Represents beneficial ownership of less than 1% of our total outstanding shares.

(1) 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 Cayman KY1-1002, Cayman Islands.

(2) 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.

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) (value-added 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 and the automatic conversion of all of our outstanding Series A Preference Shares into ordinary shares, our authorized share capital will consist of shares of a par value of $ per share, all of which are designated as ordinary shares of a par value of $0.0001 each (the "Ordinary Shares"). 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.

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. However, our amended and restated memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

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; and
- the rights and terms of redemption and liquidation preferences.

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 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 must approve a written plan of merger or consolidation, which must then be authorized by (a) a special resolution of the shareholders 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 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 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. Cayman Islands law and our amended and restated articles of association provide that our shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

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, 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 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. Other than this right to requisition a shareholders' meeting, our amended and restated articles of association do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As an exempted Cayman Islands company, we may but are not obliged by law to call shareholders' annual general meetings.

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 with or without 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 ordinary shares to employees with an exercise price of $.
- From January 1, 2018 to December 31, 2018, we issued options to purchase an aggregate of ordinary shares to employees with an exercise price of $.
- From January 1, 2019 to December 31, 2019, we issued options to purchase an aggregate of ordinary shares to employees with an exercise price of $.
- 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 ordinary shares outstanding with a weighted average exercise price of $ 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 intend to apply 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 deposit agreement solely through 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 deposit agreement. 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 proxy will not result in a violation of the laws, rules, regulations or permits of the Cayman Islands, (iii) the voting arrangement and deemed instruction as contemplated herein will be given effect under the laws, rules and regulations 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 of 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.

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 transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of an 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, 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 60th 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 and (b) provide us with a copy of the ADR register maintained by the depositary. Upon receipt of such shares and 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 ADSs or 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 and 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, 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 intend 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 , 2020, options and instruments exercisable for 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 Act, subject only to the availability of current public information about us, and will be entitled to sell 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 United States for so long as they are listed on 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.

	Per ADS	Total	
		No Exercise	Full 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 intend to apply 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 must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if 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, 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's province or territory for particulars 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 except pursuant to the applicable laws and regulations 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 Cayman Islands law and JunHe LLP 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 summaries 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 and, if we so request, will mail to all record 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

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

	Notes	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	(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 capital	Share premium*	Share option reserves*	Foreign currency translation reserve*	Retained earnings/ (accumulated losses)*	Total (deficit)/ equity
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'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	2019
		US$'000	US$'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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 of equity interest attributable to the Company		Principal activities
			Direct %	Indirect %	
Legend Biotech Limited ("Legend BVI")	The British Virgin Islands June 2, 2015	—	100	—	Investment holding
Legend Biotech HK Limited ("Legend HK")	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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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	*Definition of a Business*[1]
Amendments to IFRS 9 IAS 39 and IFRS 7	*Interest Rate Benchmark Reform*[1]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[4]
IFRS 17	*Insurance Contracts*[2]
Amendments to IAS 1 and IAS 8	*Definition of Material*[1]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[3]

1 Effective for annual periods beginning on or after January 1, 2020
2 Effective for annual periods beginning on or after January 1, 2021
3 Effective for annual periods beginning on or after January 1, 2022
4 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

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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,

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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

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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 33⅓%
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	3 years

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.

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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.

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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.

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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.

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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.

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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.

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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.

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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 stand-alone 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 regulatory milestones and $210 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.

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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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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.

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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 interdependent or 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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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

LEGEND BIOTECH CORPORATION
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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 US$'000	2019 US$'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.

LEGEND BIOTECH CORPORATION
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5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2018 US$'000	2019 US$'000
Revenue from contracts with customers*		
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 US$'000	2019 US$'000
Revenue recognized that was included in contract liabilities at the beginning of the reporting period:		
License and collaboration revenue		
- JSC service	30,212	40,324

	2018 US$'000	2019 US$'000
Revenue recognized from performance obligation satisfied in previous periods:		
License and collaboration revenue		
- Licensing of intellectual property	—	4,523
- JSC service	—	6,334
	—	10,857

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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		
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.

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6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	Notes	2018 US$'000	2019 US$'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

	2018 US$'000	2019 US$'000
Interest on lease liabilities	82	199
Interest on an entrusted loan from a related party	—	24
Total	82	223

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.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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 US$'000	2019 US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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	2019
	US$'000	US$'000
Earnings		
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(2,784)	(132,972)

	Number of shares	
	2018	2019
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	200,000,000	200,000,000

LEGEND BIOTECH CORPORATION
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10. PROPERTY, PLANT AND EQUIPMENT

	Buildings US$'000	Machinery and equipment US$'000	Computer and office equipment US$'000	Transportation equipment US$'000	Construction in progress US$'000	Total US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

10. PROPERTY, PLANT AND EQUIPMENT (Continued)

	Freehold land US'000	Buildings US$'000	Machinery and equipment US$'000	Computer and office equipment US$'000	Transportation equipment US$'000	Construction in progress US$'000	Total US$'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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 payments US$'000	Buildings US$'000	Total 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 US$'000	2019 US$'000
Carrying amount at January 1	269	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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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:

	2018 US$'000	2019 US$'000
Within one year	—	16

13. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	December 31, 2018 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 US$'000	December 31, 2019 US$'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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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	Expected loss rate	Expected credit loss
	USD'000		USD'000
Within 3 months	26,229	0.03%	8

	As at December 31, 2019		
	Gross carrying amount	Expected loss rate	Expected credit loss
	USD'000		USD'000
Within 3 months	30,000	0.03%	9

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.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

17. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

	December 31, 2018 US$'000	December 31, 2019 US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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$'000	December 31, 2019 US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 and accrued US$'000	Expense of share Options US$'000	Unrealised profit from intercompany US$'000	Contract liabilities US$'000	Losses available for offsetting against future taxable profits US$'000	Total US$'000
At January 1, 2018	540	—	4,282	—	38	4,860
Deferred tax credited/(charged) to the statement of profit or 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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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 US$'000	2019 US$'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.

LEGEND BIOTECH CORPORATION
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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:

	Number of shares in issue	Share capital US$'000	Share premium US$'000	Total 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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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 exercise price US$ per share	Number of options '000	Weighted average exercise price US$ per share	Number of options '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
6,347	0.5	2019/12/25 - 2027/12/25
7,283	1.0	2019/07/01 - 2028/08/29
656	1.0	2019/12/31 - 2028/12/30
3,225	1.5	2020/07/02 - 2029/07/01
502	1.5	2020/11/29 - 2029/11/28
18,013		

* 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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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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$'000	Lease liabilities US$'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 US$'000	2019 US$'000
Construction in progress	2,628	2,844

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 US$'000	2019 US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 US$'000	2019 US$'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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

27. RELATED PARTY TRANSACTIONS (Continued)

(viii) Repayment of cash advances from related parties:

	2018 US$'000	2019 US$'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 US$'000	2019 US$'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 US$'000	2019 US$'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.	—	2,867

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

27. RELATED PARTY TRANSACTIONS (Continued)

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.

(xiii) Purchase of equipment

	2018 US$'000	2019 US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	14	7

(xiv) Sale of equipment

	2018 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 US$'000	December 31, 2019 US$'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	-	4
	5,667	5,225

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

28. FINANCIAL INSTRUMENTS BY CATEGORY (Continued)

Financial liabilities

	Financial liabilities at amortised cost 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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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 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 (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	US$'000	US$'000	US$'000	US$'000
Financial assets at fair value through profit or loss:	—	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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (Continued)

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.

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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (Continued)

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.

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	9,586	—	9,586
Other payables and accruals	64,221	—	64,221
Lease liabilities	1,027	5,860	6,887
	74,834	5,860	80,694

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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (Continued)

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.

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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	—	—

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

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.

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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	Date of Issuance	Number of Shares		Consideration/ Exercise Price
Ordinary Shares				
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

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.

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 Number	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)
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)

Exhibit Number	Description of Document
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)
99.1*	Code of Business Conduct and Ethics of the Registrant

Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.
+ 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 , 2020.

Legend Biotech Corporation

By: _____
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
Yuan Xu, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	, 2020
Ying Huang, Ph.D.	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2020
Fangliang Zhang, Ph.D.	Chairman of the Board of Directors	, 2020
Ye Wang, M.S.	Director	, 2020

Exhibit 10.1

CONFIDENTIAL – EXECUTION VERSION

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.

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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 Exhibit A).

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 Exhibit A).

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

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.

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 are packaged and sold separately. For clarity, 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.

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:

(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; provided, however, 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.

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.

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 Exhibit C.

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.

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.

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 Schedule 1.77. [***]

1.78 "**Licensed CAR**" means (a) LCAR-B38M and its Equivalents, [***].

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.

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)):

(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, or (ii) other guidance or minutes issued by 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^{th}) 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.

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 [***].

1.112 **Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	Section
1974 Convention	14.4
Acquiring Party	3.6.4
[***]	
Additional Development Events	7.2.2
Additional Milestone Events	7.2.2
Agreement	Preamble
Agreement Wind-Down Period	12.4.2(b)
Alliance Manager	2.11
Allowable Expenses	Financial Exhibit
Anti-Corruption Laws	10.8.1(a)
Assigning Party	4.6.3(e)
Bankruptcy Code	3.8
Biosimilar Application	8.3.2
BLA	1.33
Breaching Party	12.2
Charitable Contribution Costs	Financial Exhibit
[***]	
China Manufacturing Facilities	6.3.1(a)
[***]	
[***] Plan	5.4.3(b)
China Product Quality Agreement	6.3.4
China Product Supply Agreement	6.3.4
Claim	11.4.1
Claim Amount	11.4.1
Claim Basis	11.4.1
Clinical Supply Costs	6.1.3(e)
CMC Development Costs	6.1.3(a)
CMC Development Plan	6.1.3(a)
CMO	6.2.3(c)
COGS	7.2.2
Collaboration Activities	3.5.4
[***]	
Collaboration Intellectual Property	3.5.4
Collaboration Losses	Financial Exhibit
Commercialization Approval Events	7.2.2
Commercial Supply Costs	6.2.3(c)(ii)
Committee Matters	2.8.2(a)
Committees	2.5
Comparator	6.1.3(e)
Competing BCMA CAR-T	3.6.5
Confidential Information	9.1
Cooperative Group Study	1.85
Cost Report	7.3.3
CPR	13.3.1
Designated China Equipment	6.3.1(c)
Designated Equipment	6.2.2(b)(v)
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)

Definition	Section
Development Reconciliation Procedures	7.3.3
Disbandment Notice	2.10
Disclosing Party	9.1
Dispute	13.1
Distribution Costs	Financial Exhibit
[***]	
Effective Date	Preamble
[***]	
[***]	
[***]	
EU Commercialization Approval Event	7.2.1
EU Regulatory Filing Event	7.2.1
[***]	
[***]	
Exclusivity Period	3.6.5
[***]	
[***]	
[***]	
Ex-U.S. Territory Activities	7.8.2
Facilities	6.1.3(b)
Facilities Use Agreement	6.2.2(b)(vii)(1)
[***]	
Filing Party	4.10.6
Finance Working Group	2.6.2
[***]	
[***]	
First Position Detail	Financial Exhibit
[***]	
[***]	
[***]	
[***]	
GCCC	2.4
Global Commercialization Strategy Budget	5.1.2
Global Commercialization Strategy Costs	Financial Exhibit
Global Commercialization Strategy Plan	5.1.1
Global CQAs	6.1.4
Global Publication Strategy	9.8.1
Global Product Specifications	6.1.4
Greater China Commercialization Budget	5.4.2
Greater China Commercialization Plan	5.4.2(a)
Greater China Pricing and Discounting Plan	5.4.6
Greater China Reconciliation Procedures	7.4.2
Greater China Regulatory Submissions	4.6.4
Group	1.14(a)
Health Care Reform Fees	Financial Exhibit
Incumbent Board	1.14(c)

Reverted Know-How	12.4.1(d)
Reverted Products	12.4.1(e)
Reviewing Party	9.8.2
[***]	
[***]	
[***]	
[***]	
Second Position Detail	Financial Exhibit
Securities Authority	9.4.1
Securities Disclosure Obligations	9.4.1
Selling Costs	Financial Exhibit
Shared Patent Costs	8.2.3
Shared Product Liability Costs	11.3
Sole Inventions	8.1.1
Specified Change of Control	14.2.1
[***]	
Subcommittee	2.6.1
Subcontract	4.2.5
Subcontractor	4.2.5
Subject CAR	1.86
[***]	
Successful Technology Transfer	6.2.4(b)(i)
Supplemental Application	1.33
Supply Cost	Financial Exhibit
[***]	
Target Bonus Compensation	Financial Exhibit
Tax or Taxes	7.7.5
Tax Representative	7.8.6(b)
Tax Return	7.7.5
Technology Transfer Plan	3.11
Term	12.1
[***]	
[***]	
Third Party Expenditures	6.1.3(e)
Third Party Intellectual Property	7.5
Third Party IP Costs	7.5.3
Third Party Products Liability Action	11.5.1
[***]	
Unprocessed Cells Supply Price	6.2.3(d)
USCC	2.3
U.S. Commercialization Approval Event	7.2.1
U.S. Commercialization Budget	5.2.2(c)
U.S. Commercialization Plan	5.2.2(a)
[***]	
U.S. Pricing and Discounting Plan	5.2.6
U.S. Reconciliation Procedures	7.4.1
U.S. Regulatory Filing Event	7.2.1
U.S. Territory Partnership	7.8.1
U.S. Upfront Payment	7.1
Upfront Payment	7.1
Working Group	2.6.1
[***]	
[***]	

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.

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 Formation. 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 Finance Working Group. 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.

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 this Section 2.8.1, the matter shall be determined by [***].

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,

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, [***].

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, [***].

(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 Other Matters. 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) [***].

(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, provided 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 upon thirty (30) days prior notice, and neither Party shall unreasonably withhold attendance of at least one representative of such Party at any meeting of a Committee, Subcommittee 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.

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 Commercialize the Products outside or in a manner inconsistent with the GDP, CMC Development Plan, Manufacturing Plan or an applicable 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's 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 Subcommittees and Working Groups shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Committee, Subcommittee and 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.

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 To Janssen. 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 To Janssen. 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; provided, however, 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.

3.5.3 Sublicenses. 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 Definition. 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.

3.6.4 Acquisition of Certain Agents or Products(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^{th}) 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, (ix) pre-clinical research data and results, and (x) marketing, advertising 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 obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary for 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

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

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 Exhibit C ("**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 [***]. [***]

(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 Updates and Amendments to the GDP.

(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; provided, however, 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 Clinical Studies with other Product. 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 [***].

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 providing funding or clinical supplies of Product for IIS or Cooperative Group Studies and the portion of such budget that will be allocated to conduct of Post-Approval Commercialization Studies by or on behalf of the Parties, 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.

4.2.3 Standards of Conduct. 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 Clinical Study Protocols. 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 Subcontracting. 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**"), provided 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, and each Party shall have the right from time to time, but not more than once per Calendar Year, to audit the performance of the other Party's 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 Clinical Quality Agreement. 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.

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.

(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 Development Reports. 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 Conduct of Independent Development Activities. 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; provided 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 Costs of Independent Development Activities. 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 Right to Opt-In to Independent Development Activities. 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

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 Right to Object to Independent Development Activities. 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 that requires a regulatory filing to conduct such activity 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 [***].

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.

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).

(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

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 pricing or reimbursement approval proceedings 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

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 Patent Rights in 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:

(a) all terms of this Agreement that apply to Products shall apply to such Second Generation Product, including Sections 3.6.2 and 3.6.3;

(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.

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 [***].

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 Global Commercialization Strategy Plan. [***] 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 Global Commercialization Strategy Budget. 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 Annual Updates. [***] 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.

5.1.4 Other Updates. 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 General. 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.

(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 commence such U.S. Commercialization activities, and Legend shall [***] to perform such U.S. Commercialization activities. Such allocation of 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 Plan and shall otherwise be allocated responsibility for 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."

5.2.4 U.S. Commercialization Reports. 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 Booking Sales in U.S. 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.S. Pricing Matters. [***] 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.S. Recalls. [***] 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 Product Packaging; Promotional Materials. 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 Day-to-Day Responsibility. 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.S. Medical Inquiries5.2.11 . 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.

5.3 **Commercialization in Janssen Territory**.

5.3.1 General. 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 [***].

(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 Janssen Territory Commercialization Reports. 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 Right to Discuss Janssen Territory Activities. 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 Booking Sales in Janssen Territory. 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 consistent with such guidance and 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.

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 Product Packaging; Promotional Materials. 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 General. 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.

(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 have the right to participate in all such interactions 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, [***].

(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 Greater China Commercialization Reports. 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 Booking Sales in Greater China. 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 Greater China Pricing Matters. [***] 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 Greater China Recalls. [***] 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 Product Packaging; Promotional Materials. 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 Greater China Medical Inquiries. 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 [***].

5.4.10 Day-to-Day Responsibility. 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 Diligence. 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 Delays in Approving Plans and Budgets. 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 Commercialization Subcontracting. 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.

(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 Parallel Imports. 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 Sharing of Commercial Information. 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 China. 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 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.

6.1.3 Plans and Budgets.

(a) CMC Development Plan. 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) Manufacturing Plan. 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 in accordance with the Manufacturing Plan: (a) with respect to the United States and the Janssen Territory shall be shared equally 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) Initial Plans; Updates and Changes. 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 Schedule 6.1.3A. The initial Manufacturing Plan shall be consistent with the CMC Development and Manufacturing roles and responsibilities chart attached hereto as Schedule 6.1.3A and shall include the initial site selection, design plan and budget for the China Manufacturing Facilities attached hereto as Schedule 6.1.3B. Thereafter, the JMC shall provide to the JSC at least annually for its review and approval an updated version

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) Supply Costs. [***] 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 Global Product Specifications and CQAs. 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 Schedule 6.1.4. 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.

(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) Cell Collection. [***] 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) General. [***] 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.

(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 [***]. 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 Schedule 6.2.2B 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 Schedule 6.2.2B, 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 in clause (i) and the arrangement between the Parties as contemplated 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) Key Terms of Manufacturing Operations. 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;

(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) Supply Costs prior to [***]. 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 Commercial Supply and Clinical Supply after [***]. [***] 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) Timing of [***] Manufacturing Facilities. 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) Manufacturing Responsibilities following [***]. 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) Product Supply Agreements for [***]. [***] 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.

(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 [***].

(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) Unprocessed Cells Supply Agreements for [***]. [***] 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

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) Supply Costs after [***]. 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 [***]; provided, however, 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.

6.2.4 Rights on Termination of this Agreement. 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) Term of Facilities Use Agreement. 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 then-current term without causing [***], provided that, in each case (x) and (y), [***] 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 [***].

(c) Allocation of Designated Equipment. 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) Reimbursement of [***]. 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) Operation of Facility after Termination. 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) Costs Incurred after Termination. 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) Termination Prior to [***]. 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

(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) Termination for Cause. In the event of a termination of this Agreement under Section 12.2 of this Agreement, [***].

(i) Transition. 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) Supply Agreements. 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) China Manufacturing Facilities. [***] 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) Construction. 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) Costs. 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.

(a) General. [***] 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) Key Terms of Manufacturing Operations. 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) Product Release. 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.

6.3.3 Supply for [***]. 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 China Product Supply Agreement. 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 Costs of China Product Supplies. 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 Other Products. 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.

6.3.7 Rights upon Termination of this Agreement. 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 Milestone Events. 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. 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

4.		
5.		
6.		
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 at least 50% ORR (the "**Initial ORR Milestone**")	US$25 million

Additional Development Events

		First Original GDP Indication	*Second Original GDP Indication*	*[***]*	*[***]*	*[***]*
8.	Dosing of the fifth (5th) patient in a Registration Study of a Product in the United States, EU or Japan	US$30 million	US$30 million	[***]	[***]	[***]

Regulatory Filing Events

		[***]	*[***]*	*[***]*	*[***]*	*[***]*
9.	[***]	[***]	[***]	[***]	[***]	[***]
10.	[***]	[***]	[***]	[***]	[***]	[***]
11.	[***]	[***]	[***]	[***]	[***]	[***]

Commercialization Approval Events

		[***]	*[***]*	*[***]*	*[***]*	*[***]*
12.	[***]	[***]	[***]	[***]	[***]	[***]
13.	[***]	[***]	[***]	[***]	[***]	[***]
14.	[***]	[***]	[***]	[***]	[***]	[***]

Additional Milestone Events

15.	[***]			[***]		
16.	[***]			[***]		

7.2.2 Definitions. 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 [***].

(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 Milestone Payments for Additional Development Events. 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 (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 Milestone Payments for Regulatory Filing Events. 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 Milestone Payments for Commercialization Approval Events. 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 Skipped Milestones. 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.[***]

7.2.8 Independent Development Activities. 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 Allocation of Certain Milestone Payments. Milestone Payments for Milestone Events 1, 2, 5, 12 and 13 will be allocated [***] and payable to [***] 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 Cost Sharing. 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 Clinical Studies Involving Other Products of a Party. 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 Costs Reports. 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 prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes.

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 Schedule 7.3.5.

(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 United States Pre-Tax Profit or Loss. 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.

7.4.2 Greater China Pre-Tax Profit or Loss. 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, and Development Costs, shall be paid [***] after the end of each Calendar Quarter.

7.4.5 Pre-Tax Profit or Loss Adjustment Example. 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.

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.

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.

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.

(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 Currency of Payments. 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 Currency Conversion(a) . 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 Sole Inventions. 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 Inventorship. 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.

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 under this Section 8.2.1. If Legend or its Affiliate, prior or subsequent to filing patent applications that would constitute any Legend 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 maintain 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 Maintenance and Prosecution Costs. 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)

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 Cooperation. 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 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. 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 [***].

(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 Conduct of Patent Litigation Under the Biologics Price Competition and Innovation Act. 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(l)(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(l)(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, including whether or not to utilize, in whole or in part, the procedures provided in Section 351 of the PHSA or equivalent in any other jurisdiction in [***] and (b) with respect to [***] an Infringement Action against the filer of the Biosimilar Application, including whether or not to utilize, in whole or in part, the procedures equivalent to those 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.

(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 Cooperation. 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 Conduct of Certain Actions; Costs. 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 Recoveries(a) . 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 Right to Respond. 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.

8.4.2 Conduct of Certain Actions; Costs. 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.

8.7.2 Ownership of Product Trademarks. 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 Trademark License. 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 Product Trademarks and Co-Branding. 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 Enforcement. 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.

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 Agreement;

(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;

(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;

(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, provided 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 and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own 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

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 Initial Press Releases. Each Party may, but is not obligated to, make a public announcement of the execution of this Agreement in the forms attached as Schedule 9.5.1A and Schedule 9.5.1B 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 Further Publicity. 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.

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 Global Publication Strategy. 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 Approval of Publications. 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.

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.

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 Schedule 1.77 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 Schedule 1.77. 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 Schedule 1.77 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

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).

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;

(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's agreement to receive such training or materials, Legend will use reasonable efforts to facilitate an introduction of Janssen to such 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

(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.

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 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 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.

11.4 **Claims for General Indemnification**.

11.4.1 Notice. 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; provided, however, 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 Defense. 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 Cooperation. 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 Settlement. 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

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 (including those of the non-controlling 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, provided 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, provided that no such extension shall exceed 90 days without the consent of the Non-Breaching Party.

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 Termination for Any Reason. In the event of expiration or any termination of this Agreement, the provisions of this Section 12.4.1 shall apply.

(a) Accrued Obligations. 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) Non-Exclusive Remedy. 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.

(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 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) Regulatory Documentation and Data. 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

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) Marks and Domains. 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) Governance During Wind-Down. 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. [***]

(h) Return of Materials. [***] 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, provided 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) Post-Termination Shared Product Liability Costs. 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) On-Going Trials. 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

(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) Commercialization Wind-Down. 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**"), provided 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) Transition; Manufacturing; Inventory. 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,

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) On-Going Trials. 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) Transition; Manufacturing; Inventory. 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 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.

(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 Arbitration. 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 Panel. 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 http://www.adr.org/EthicsAndStandards).

13.3.3 Procedures if Arbitrator(s) Not Agreed. 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 Timing. 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 Discovery. 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, provided 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 Motions; Independent Expert. 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).

13.3.7 Decision of the Arbitrator(s). 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 Courts. 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; provided, however, 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, provided 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), provided, 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.

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 Reimbursement of Excess Amounts. 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

(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):

If to Legend:

[***]

with a copy to:

[***]

If to Janssen:

[***]

with copies to:

[***]

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; provided, 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.

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,

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

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

EXHIBIT A

[***]

EXHIBIT B

FINANCIAL EXHIBIT

[***]

EXHIBIT C

INITIAL GDP[1]

[***]

1 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. Definitions. 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. Amendments.

   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 Allocation of Certain Milestone Payments. Milestone Payments for Milestone Events 1, 2, 5, 12 and 13 will be allocated [***] and payable to [***] 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. Effect. The amendments to the Agreement set forth in Section 2 of this First Amendment shall take effect on the First Amendment Effective Date.

4. No Other Amendments. 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.

5. Counterparts. 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:

7.2.1 Milestone Events. 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. 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				
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 "**Initial ORR Milestone**")	a. US$25 million b. [***]				
b. [***]					
Additional Development Events					
	First Original GDP Indication	*Second Original GDP Indication*	*[***]*	*[***]*	*[***]*
5. Dosing of the fifth (5th) patient in a Registration Study of a Product in the United States, EU or Japan	US$30 million	US$30 million	[***]	[***]	[***]
Regulatory Filing Events	*[***]*	*[***]*	*[***]*	*[***]*	*[***]*
6. [***]	[***]	[***]	[***]	[***]	[***]
7. [***]	[***]	[***]	[***]	[***]	[***]
8. [***]	[***]	[***]	[***]	[***]	[***]

	Commercialization Approval Events					
	[***]	*[***]*		*[***]*	*[***]*	*[***]*
9. [***]	[***]	[***]		[***]	[***]	[***]
10. [***]	[***]	[***]		[***]	[***]	[***]
11. [***]	[***]	[***]		[***]	[***]	[***]
	Additional Milestone Events					
12. [***]		[***]				
13. [***]		[***]				

2.2 Section 7.2.4 is hereby deleted and replaced with the following text:

7.2.4 Milestone Payments for Additional Development Events. 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 (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) [***]; 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

LEGEND BIOTECH IRELAND LIMITED

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