UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Amendment No. 1)

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 001-39307

LEGEND BIOTECH CORPORATION

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Cayman Islands
(Jurisdiction of incorporation or organization)

Legend Biotech Corporation
2101 Cottontail Lane
Somerset, NJ 08873
(Address of principal executive offices)

Ying Huang, Ph.D.
Chief Executive Officer
Legend Biotech Corporation
2101 Cottontail Lane
Somerset, NJ 08873
Telephone: (737) 317-5050
(Name, telephone, email and/or facsimile number and address of Company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares, each representing two ordinary shares, par value $0.0001 per share	LEGN	Nasdaq Global Select Market
Ordinary shares, par value $0.0001 per share*		Nasdaq Global Select Market

* Not for trading, but only in connection with the registration of the American depositary shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:
None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the Annual Report:
308,456,852 ordinary shares, par value $0.0001 per share, were issued and outstanding as of December 31, 2021

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒ Yes ☐ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Note-checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "accelerated filer and large accelerated filer" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-Accelerated Filer	☐	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† pursuant to Section 13(a) of the Exchange 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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP	☐	International Financial Reporting Standards as issued by the International Accounting Standards Board	☒	Other	☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an Annual Report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

EXPLANATORY NOTE

Legend Biotech Corporation ("Legend Biotech", "Legend", "we", "our", "ours", "us", or the "Company") is filing this Amendment No. 1 on Form 20-F/A (the "Form 20-F/A", "Amendment No. 1", or "Amended Annual Report") to the Annual Report on Form 20-F for the fiscal year ended December 31, 2021, which was originally filed with the U.S. Securities and Exchange Commission (the "SEC") on March 31, 2022 (the "Original 20-F") to (i) address comments from the staff of the Division of Corporation Finance of the SEC on the Original 20-F and (ii) to amend and restate (the "Restatement") its audited financial statements as at December 31, 2021 and 2020 and for the years ended December 31, 2021, December 31, 2020 and December 31, 2019 (the "Audited Affected Financials").

Background of the Restatement

As previously reported, on October 19, 2022, the audit committee (the "Audit Committee") of Legend Biotech, based on the recommendation of, and after consultation with, the Company's management, concluded that the Company's previously issued Audited Affected Financials and the Company's financial statements for the interim period ended March 31, 2022 should no longer be relied upon. The Company determined that the original valuation of the commercial license for cilta-cel (the "Commercial License") pursuant to its worldwide collaboration and license agreement with Janssen Biotech, Inc. ("Janssen") was understated and was a single performance obligation and, as a result, the accounting for revenue recognition in the Audited Affected Financials was materially incorrect.

As a result of the Restatement, the Company has concluded there was a material weakness in its internal control over financial reporting as of December 31, 2021, and its disclosure controls and procedures were not effective. See additional discussion included in Part II, Item 15 of this Amended Annual Report. The Restatement adjustments also affect periods prior to the Original 20-F and such adjustments have been reflected in the restated opening stockholders' equity balances as of January 1, 2019. Also, as previously disclosed, management determined that its report regarding the effectiveness of the Company's internal controls over financial reporting ("ICFR") contained in the Original 20-F, and Ernst & Young Hua Ming LLP ("EYHM"), the Company's independent registered accounting firm as of December 31, 2021, has determined its opinion relating to the effectiveness of the Company's ICFR as of December 31, 2021 included in the Original 20-F, should not be relied upon. The impact of the Restatement is more fully described in Note 2.2 to the Company's restated consolidated financial statements included in Part III, Item 18 of this Amended Annual Report.

Items Amended

This Form 20-F/A includes changes to: (1) Part I, Item 3 – Key Information, including Item 3D – Risk Factors, (2) Part I, Item 4 – Information on the Company, (3) Part I, Item 5 – Operating and Financial Review and Prospects, (4) Part II, Item 15 – Controls and Procedures, (5) Part III, Item 18 – Financial Statements and (6) Part III, Item 19 – Exhibits. See below and 2.2 Restatement of Previously Issued Consolidated Financial Statements of the Notes to Consolidated Financial Statements in Part III, Item 18 of this Form 20-F/A for a detailed discussion of the changes made as a result of the Restatement.

As required by Rule 12b-15 under the Securities and Exchange Act, as amended, Part III Item 19 of the Original 20-F has been amended to include updated certifications from Legend Biotech's principal executive officer and principal financial officer pursuant to Sections 906 and 302 of the Sarbanes-Oxley Act of 2002, which are attached to this Form 20-F/A as Exhibits 12.1, 12.2, 13.1 and 13.2, respectively.

Except as otherwise noted, this Amendment No. 1 does not amend, update or change any other disclosures in the Original 20-F and does not reflect events occurring after the filing of the Original 20-F. Among other things, forward-looking statements made in the Original 20-F have not been revised to reflect events, results or developments that occurred or facts that became known to us after the date of the Original 20-F, other than with respect to the Restatement, and such forward-looking statements should be read in conjunction with our filings with the SEC, including those subsequent to the filing of the Original 20-F.

Substantially concurrently with the filing of this Amendment No. 1, the Company is filing an amendment to its Form 6-K related to the Company's interim financial information for the three months ended March 31, 2022.

LEGEND BIOTECH CORPORATION
FORM 20-F ANNUAL REPORT
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CERTAIN INFORMATION

In this Annual Report on Form 20-F, unless otherwise indicated or the context otherwise requires, "Legend Biotech" refers to Legend Biotech Corporation, a Cayman Islands holding company, "PRC subsidiaries" refer to Legend Biotech's subsidiaries incorporated in the PRC (as defined below) and "we," "us," "our," and the "Company" refer to Legend Biotech and its consolidated subsidiaries. References to "GenScript" or "Genscript" refer to Genscript Biotech Corporation, our majority stockholder.

This Annual Report on Form 20-F contains translations of Renminbi amounts into U.S. dollars at specified rates solely for the convenience of the reader. We make no representation that the Renminbi or U.S. dollar amounts referred to in this Annual Report on Form 20-F could have been or could be converted into U.S. dollars or Renminbi, as the case may be, at any particular rate or at all. Unless otherwise noted, translations of Renminbi amounts into U.S. dollars in this Annual Report are made based on an exchange rate of RMB 6.38 to $1.00, which is the exchange rate as of December 31, 2021 as published by The People's Bank of China.

Various amounts and percentages set out in this document have been rounded and, accordingly, may account for apparent discrepancies in the tables appearing herein. Unless otherwise indicated or the context otherwise requires, references in this Annual Report to:

- "ADSs" are to the American depositary shares, each of which represents two 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, and solely in the context of describing PRC rules, laws, regulations and other legal and tax matters, excludes rules, laws, regulations and other legal and tax matters of the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan, however, the legal and operational risks discussed by the Company with respect to operating in the PRC throughout this filing also apply to Hong Kong and Macau; "Greater China" does not exclude the 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.

For our organization structure as of the date of this annual report, see "Item 4. Information on the Company—C. Organizational Structure."

MARKET, INDUSTRY AND OTHER DATA

This Annual Report 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 Annual Report 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.

TRADEMARKS AND SERVICE MARKS

"Legend Biotech," the Legend logo and other trademarks or service marks of the Company appearing in this Annual Report on Form 20-F are the property of the Company. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 20-F are the property of their respective holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of present and historical facts and conditions are forward-looking statements. Such forward-looking statements reflect our current expectations and views of future events, but are not assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our operational results and other future conditions. The forward-looking statements appear in a number of places throughout this Annual Report on Form 20-F and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth, strategies and the industry in which we operate.

Forward-looking statements can be identified 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, but are not limited to, statements relating to:

- the ability to effectively manufacture, market and sell CARVYKTI™;
- the market opportunity for and potential for commercial success of CARVYKTI™;
- potential effects of treatment with CARVYKTI™;
- 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 specified milestones under our collaboration with Janssen Biotech for cilta-cel;
- 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, retain and motivate 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 the product candidates we may develop, if approved;
- information about the prices and availability of labor, transportation and raw materials, including as a result of inflation, and our ability to obtain them in a timely manner;
- our exposure to and the potential impact of risks inherent in our foreign operations, including currency fluctuations, exchange controls and pricing restrictions;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- the effectiveness of our key information technology systems, networks, processes or related controls or those of our service providers;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our ability to consistently maintain effective internal control over financial reporting;
- changes in tax laws and the resolution of tax contingencies resulting in additional tax liabilities;
- 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 United States or foreign laws and regulations on the Company's operations, including the impact of tariffs;
- the effect of epidemics and pandemics, such as the COVID-19 pandemic, or other business disruptions on our business, including, without limitation, our ability to manage the demand, supply and operational challenges associated with the actual or perceived effects of such pandemics; and
- our anticipated use of our existing resources and the proceeds from our initial public 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. Many important factors, including those listed under "Risk Factors" as well as other known and unknown risks and uncertainties, may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. In addition, even if our results of operations, financial condition and liquidity are consistent with the forward-looking statements contained in this Annual Report on Form 20-F, those results or developments may not be indicative of results or developments in subsequent periods. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless specifically expressed as such, and should only be viewed as historical data. You should read thoroughly this Annual Report on Form 20-F 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 Annual Report on Form 20-F relate only to events or information as of the date on which the statements are made. 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 Annual Report on Form 20-F and the documents that we refer to and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. Given these risks and uncertainties, you are cautioned not to place undue reliance on these forward-looking statements.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

ITEM 3. KEY INFORMATION

Our Holding Company Structure and China Operations

Legend Biotech is a Cayman Islands holding company and not a Chinese operating company. We operate through our operating subsidiaries located primarily in the United States, PRC and European Union. Our operations in the PRC, in addition to our business presence elsewhere in the world, are enabled by our subsidiaries based therein. Investors in our ADSs do not hold equity securities of our operating subsidiaries but hold equity securities of a Cayman Islands holding company. See "Item 4—Information On The Company—C. Organizational Structure Chart" for an illustration of our corporate structure.

We face various legal and operational risks and uncertainties associated with having a portion of our operations in China and the complex and evolving PRC laws and regulations. For example, we face risks associated with regulatory approvals or filing requirements on offerings conducted outside of the PRC and investment by individuals or entities outside of the PRC ("non-PRC investors") in issuers with operations in China, anti-monopoly regulatory actions and oversight on cybersecurity, data privacy and genetic information, if we fail to comply with relevant regulatory requirements, which may negatively impact our ability to conduct certain businesses, access investments by non-PRC investors or list on stock exchanges outside of the PRC. If we fail to comply with these regulatory requirements on our offerings and investments outside the PRC, the PRC could take action against the assets of our PRC subsidiaries, which could materially and adversely affect our operations in the PRC. As a result, these risks could result in a material adverse change in our operations and the value of our ADSs, significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline.

Our operations in China are governed by PRC laws and regulations. The PRC governmental authorities have significant oversight and discretion over the conduct of our business in China, and it may intervene in or influence our operations at any time where we are not or might not be compliant with PRC laws or regulations, which could result in a material adverse change in our operation and/or the value of our ADSs. Also, the PRC governmental authorities have recently indicated an intent to exert more oversight and control over offerings that are conducted outside of the PRC and/or investment by non-PRC investors in issuers with operations in China. Any such action could result in actions taken against the assets of our PRC subsidiaries, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. In addition, the implementation of industry-wide regulations directly targeting our operations could cause the value of our securities to significantly decline. Therefore, our shareholders and our business face potential uncertainty from actions taken by the PRC governmental authorities affecting our business in the PRC.

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to a significant degree of interpretation by PRC regulatory agencies and courts. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of these decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. Therefore, it is possible that our existing operations may be found not to be in full compliance with relevant laws

and regulations in the future. In addition, the PRC legal system is based in part on governmental policies and internal rules, some of which are not published on a timely basis or at all, and which may be a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Recently, the PRC government has indicated an intent to exert more oversight and control over offerings that are conducted outside of the PRC and/or investment by non-PRC investors in issuers with operations in China, and initiated a series of regulatory actions and made a number of public statements, including cracking down on illegal activities in the securities market, enhancing supervision over companies with operations in China to be listed outside of the PRC, adopting new measures to extend the scope of cybersecurity reviews, and expanding efforts in anti-monopoly enforcement. As a result, risks to our business arise from, among other things, PRC governmental authorities' significant oversight and discretion over the business and financing activities of our PRC subsidiaries, the complex and evolving PRC legal system, frequent changes in laws, regulations and government policies, uncertainties and inconsistencies regarding the interpretation and enforcement of laws and regulations, uncertainties, difficulties or delays in obtaining regulatory approvals or completing filing procedures for listing on a non-PRC stock exchange or conducting certain business activities and increasing oversight on cybersecurity and data privacy related to the PRC government's recently issued statements and instituted regulatory actions and could result in actions taken against the assets of our PRC subsidiaries, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. Uncertainties in the PRC legal system and the interpretation and enforcement of PRC laws and regulations could limit the legal protection available to you and us, significantly limit, delay or hinder our ability to offer or continue to offer the ADSs, result in a material adverse effect on our business operations, and damage our reputation, which might further cause the ADSs to significantly decline in value.

For a detailed description of the risks associated with our operations in China, see "—D. Risk Factors—Risks Related to Doing Business in China."

The Holding Foreign Companies Accountable Act

On December 16, 2021, the Public Company Accounting Oversight Board (the "PCAOB") issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by local authorities. The Holding Foreign Companies Accountable Act (the "HFCA Act"), was signed into law on December 18, 2020. In accordance with the HFCA Act, trading in our ADSs on a national securities exchange or in the over-the-counter trading market in the United States may be prohibited if the PCAOB determines that it cannot inspect or fully investigate our auditor for three consecutive years beginning in 2021, and, as a result, an exchange may determine to delist our ADS.

On December 2, 2021, the SEC adopted final amendments implementing the disclosure and submission requirements under the HFCA Act, pursuant to which the SEC will (i) identify an issuer as a "Commission-Identified Issuer" if the issuer has filed an annual report containing an audit report issued by a registered public accounting firm that the PCAOB has determined it is unable to inspect or investigate completely because of the position taken by the authority in the foreign jurisdiction and (ii) impose a trading prohibition on the issuer after it is identified as a Commission-Identified Issuer for three consecutive years. In addition, on June 22, 2021, the U.S. Senate passed a bill on the Accelerating Holding Foreign Companies Accountable Act (the "AHFCAA"), which would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on a U.S. stock exchange if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. On February 4, 2022, the U.S. House of Representatives passed a bill which contained, among others, an identical provision. If this provision is enacted into law and the number of consecutive non-inspection years required for triggering the prohibitions is reduced from three to two, then the time period before the issuer's securities may be prohibited from trading or delisted could be reduced. On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission (the "CSRC") and the Ministry of Finance of the People's Republic of China, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. While significant, the Statement of Protocol is only a first step. Uncertainties still exist as to whether and how this new Statement of Protocol will be implemented. On December 29, 2022, President Biden signed the "Consolidated Appropriations Act, 2023" (the "Consolidated

Appropriations Act"), into law. The Consolidated Appropriations Act contained, among other things, an identical provision to AHFCAA, which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two.

Our auditor for the fiscal years ended December 31, 2021 and 2020, Ernst & Young Hua Ming LLP, is an independent registered public accounting firm that issues the audit reports included elsewhere in this annual report. The PCAOB previously identified Ernst & Young Hua Ming LLP as one of the registered public accounting firms that the PCAOB is unable to inspect or investigate completely and we were conclusively identified as a "Commission-Identified Issuer" on May 4, 2022. On December 15, 2022, the PCAOB announced that it was able to conduct inspections and investigations completely of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong in 2022. The PCAOB vacated its previous 2021 determinations accordingly. While vacating those determinations, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately reconsider the need to issue new determinations consistent with the HFCA Act and PCAOB's Rule 6100. On May 3, 2022, our Audit Committee (i) resolved that Ernst & Young Hua Ming LLP would resign as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to be filed with the SEC, effective on June 1, 2022 and (ii) approved the engagement of Ernst & Young LLP, located in the United States, as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting for the fiscal year ended December 31, 2022 to be filed with the SEC and the Company subsequently entered into an engagement letter with Ernst & Young LLP. However, there are no guarantees that engaging Ernst & Young LLP will remove us from being a "Commission-Identified Issuer". Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and make any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act.

The delisting of our securities, or the threat of such securities being delisted, may materially and adversely affect the value of your investment. For a detailed description of the related risks, see "—D. Risk Factors—Risks Related to Doing Business in China— The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for three consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022, or two consecutive years if the AHFCAA is enacted. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections.". See "—D. Risk Factors—Risks Related to Doing Business in China." Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and making any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act.

Permissions Required from the PRC Authorities for Our Operations

Each of our PRC subsidiaries is required to obtain, and has obtained, a business license issued by local counterparts of the State Administration for Market Regulation, or the SAMR. As of the date of this Amendment No. 1 and to our knowledge, our PRC subsidiaries have obtained the requisite licenses and permits from the PRC government authorities that are material for their business operations in China. However, given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by government authorities, we cannot assure you that we have obtained all the permits or licenses required for conducting our business in the PRC.

In connection with our previous issuance of securities to investors in stock markets outside the PRC, under current PRC laws, regulations and regulatory rules, as of the date of this Amendment No. 1, we and our PRC subsidiaries, (i) are not required to obtain permissions from the CSRC, (ii) are not required to go through cybersecurity review by the Cyberspace Administration of China, or the CAC, and (iii) to our knowledge, we have not received or were denied such requisite permissions by any PRC authority. However, the PRC government has recently indicated an intent to exert more oversight and control over offerings that are conducted outside the PRC and/or investment by non-PRC investors in issuers with operations in China.

We have been closely monitoring regulatory developments in China regarding any necessary permissions or approvals from the CSRC, the CAC or other PRC regulatory authorities for our operations in China. However, there are uncertainties as to the related interpretation and implementation of regulatory requirements, and the biopharmaceutical industry in the PRC is highly regulated and such regulations are subject to change. Therefore, it is uncertain whether we or our PRC subsidiaries will be required to obtain additional approvals, licenses, or permits, or complete additional filing procedures in connection with our business operations pursuant to the evolving PRC laws and regulations, and whether we would be able to obtain and renew such approvals, licenses, or permits, or complete such filing procedures in a timely manner or at all. Any failure by us or our PRC subsidiaries, even inadvertently, to maintain compliance with applicable PRC laws and regulations, or obtain and maintain required licenses and permits, in a timely manner or at all, may subject us or our PRC subsidiaries to administrative penalties, and the suspension or termination of our business activities in the PRC. See "—D. Risk Factors—Risks Related to Doing Business in China."

Dividends and other distributions

As of the date of this Amendment No. 1, we have not previously declared or paid any cash dividend or dividend in kind, and we have no plan to declare or pay any dividends in the near future on its ordinary shares or the ADSs. We currently intend to apply any future earnings to fund the clinical development of cilta-cel, fund the construction and expansion of our manufacturing facilities, fund the commercialization of CARVYKTI and fund the development of our pipeline programs, as well as for working capital and other general corporate purposes.

Legend Biotech is a holding company with no operations of its own. We conduct our operations through our subsidiaries, including our PRC subsidiaries. If the PRC government deems that any of our business operations carried out by our PRC subsidiaries were to be restricted or prohibited from non-PRC investment in the future, we may be required to stop our business operations in the PRC and we could be subject to material penalties or be forced to relinquish our interests in the affected operations. Such events could result in a material change in our operations and a material change in the value of our securities, including causing the value of such securities to significantly decline. As we have incurred net losses and negative cash flow from operations historically, none of our subsidiaries have declared or paid any dividends or distributions to Legend Biotech or any investors as of the date of this Amendment No. 1. Instead, we have primarily relied on upfront and milestone payments and interest-bearing borrowings from Janssen Biotech, Inc. under our collaboration and license agreement, proceeds from public offerings and private placements of equity securities, and capital contributions from GenScript to fund business operations of our operating subsidiaries. All the net cash proceeds we receive from financial activities are first deposited in the bank account of Legend Biotech. The funds deposited into Legend Biotech's accounts are then transferred through Legend Biotech's applicable subsidiaries to each operating subsidiary to meet its working capital needs primarily through capital contributions or intercompany loans. For the years ended December 31, 2020 and 2021, Legend Biotech transferred $61 million and $396.6 million, respectively, through such capital contributions or intercompany loans.

According to the Foreign Investment Law of the People's Republic of China and its implementing rules, which jointly established the legal framework for the administration of non-PRC-invested companies, a non-PRC investor may, in accordance with other applicable laws, freely transfer into or out of China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of China in Reiminbi ("RMB") or any non-PRC currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the People's Republic of China and other PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC

subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the PRC subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our PRC subsidiaries may allocate a portion of their after-tax profits based on PRC accounting standards to a discretionary reserve fund. See "—D. Risk Factors—Risks Related to Doing Business in China—Our business may be significantly affected by the newly enacted Foreign Investment Law and the "negative list."

RMB is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their potential future renminbi revenues to pay dividends to us. The PRC government imposes controls on the convertibility of RMB into non-PRC currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of non-PRC currency may then restrict the ability of our PRC subsidiaries to remit sufficient non-PRC currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our non-PRC-currency-denominated obligations. The renminbi is currently convertible under the "current account," which includes dividends, trade and service-related non-PRC exchange transactions, but not under the "capital account," which includes non-PRC direct investment and non-PRC currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase non-PRC currency for settlement of "current account transactions," including payment of dividends to us, without the approval of the State Administration of Foreign Exchange of China ("SAFE") by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase non-PRC currencies in the future for current account transactions. The PRC government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in renminbi to fund our business activities outside of China or pay dividends in non-PRC currencies to holders of our securities. Non-PRC exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain non-PRC currency through debt or equity financing for our subsidiaries. In addition, ADS holders may potentially be subject to PRC taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes. See "—D. Risk Factors—Risks Related to Doing Business in China—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" and "Item 10. Additional Information—E. Taxation—PRC Taxation" for further information.

A. [Reserved]

B. Capitalization and Indebtedness

Not Applicable.

C. Reasons for the Offer and Use of Proceeds

Not Applicable.

D. Risk Factors

Our business and *our industry are subject to significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, including the following risk factors, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results, and growth prospects would likely be materially and adversely affected. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements."*

Risk Factors Summary

The following summary description sets forth an overview of the material risks we are exposed to in the normal course of our business activities. The summary does not purport to be complete and is qualified in its entirety by reference to the full risk factor discussion immediately following this summary description. We encourage you to read the full risk factor discussion carefully.

Our revenue and expenses are difficult to predict, have varied significantly in the past and will continue to fluctuate significantly in the future due to numerous risks and uncertainties, many of which are beyond our control. As a result, we may not be profitable on a quarterly or annual basis. Our business, results of operations and financial condition could be materially and adversely affected by any of the following material risks:

Risks Related to the Commercialization of CARVYKTI™ and Our Other Product Candidates

- We have limited experience as a commercial company and the marketing and sale of CARVYKTI™ or future products may be unsuccessful or have less success than anticipated.
- The commercial success of CARVYKTI™, and of any future products, will depend upon the degree of market acceptance by physicians, third-party payors and others in the medical community.
- If the market opportunities for our product or any future products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.
- We may not be able to successfully create our own manufacturing infrastructure for supply of our requirements of products for use in clinical trials and for commercial sale.
- We have no prior sales experience and limited capabilities for marketing and market access. We expect to continue to invest significant financial and management resources to establish necessary capabilities and infrastructure to support our commercial needs. If we are unable to establish these commercial capabilities, we may be unable to generate sufficient revenue to sustain our business.
- We operate in a rapidly changing industry and face significant competition.
- Potential product liability risks.

Risks Related to Our Business

- Our ability to become and remain profitable may never be achieved due to the uncertainty of developing and commercializing complex therapies, and we may never achieve or maintain profitability.
- Our limited operating history, which has focused on research and development, makes it difficult to assess our future prospects.
- Our need for additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.
- Our inability to obtain raw materials or key starting materials necessary for product manufacture, such as lentiviral vectors, would adversely affect the clinical development and commercialization of these products, which could, in turn, adversely affect our sales and profitability.

Risks Related to the Development of Our Product Candidates

- The uncertainties of the biopharmaceutical development process for novel and emergent treatment, including the uncertainty of outcomes of clinical trials, and the potential failure of product candidates to show safety or efficacy.
- Potential failure to obtain or maintain regulatory approvals for our product candidates.
- Our primary research and development efforts are focused on CAR-T cell therapies, which are emerging treatments that face significant challenges and hurdles.
- Our product candidates require significant preclinical study and clinical trials, which can be difficult to design and implement.

- Our dependence on enrollment of patients in clinical trials for development of our product candidates.
- Risks associated with investigator-initiated clinical trials, studies that we do not fully control.
- Certain product opportunities may face limited market opportunities.
- Adverse side effects or other safety risks associated with our product candidates.
- Costs and difficulties in the manufacture of complex biologics.

Risks Related to Our Business Operations

- Economic, political, regulatory and other risks associated with international operations.
- Potential difficulties in growing operations and attracting and retaining key personnel.
- Risks associated with potential acquisitions or strategic collaborations.
- Any failure to comply with various governmental laws and regulations may adversely affect our business.
- Risks associated with any failure to implement and maintain effective internal controls over financial reporting, including any impact as a result of the identified material weakness and any future material weaknesses.

Risks Related to our Dependence on Third Parties

- Our dependence on third parties, such as Janssen, for development, manufacturing and commercialization of our product candidates.
- Our reliance on third parties to conduct our preclinical and clinical trials and the potential that such third parties may not perform satisfactorily.
- The availability of reagents, specialized equipment and other specialty materials.

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

- The risks and costs associated with complying with a rigorous, complex and evolving regulatory framework, including clinical trial regulations, pre-marketing regulatory requirements, pricing, reimbursement and cost-containment regulations, and ongoing regulation of approved products.
- The effect of price controls in certain jurisdictions on our revenue and commercialization.

Risks Related to Our Intellectual Property

- Our ability to obtain, maintain, defend and enforce intellectual property rights in our products and disparities in intellectual property rights throughout the world.
- The significant cost and complexity associated with intellectual property proceedings.

Risks Related to Doing Business in China

- Risks related to doing business in China, including the impact of extensive Chinese regulation on the pharmaceutical industry.
- The heightened level of government involvement in the Chinese economy and uncertainties regarding legal protections in the PRC legal system.
- PRC governmental authorities may intervene or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.
- The adverse effect of an ongoing investigation involving our majority shareholder and former CEO and chairman.
- 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 subsidiaries.
- The PRC government may exert more control over offerings conducted outside the PRC and/or investment by non-PRC investors in issuers with operations in China, which could materially and

adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. For example, the approval of, or filing or other procedures with, the CSRC or other governmental authority may be required in connection with issuing our equity securities outside of the PRC under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.

- The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for two consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections. PRC governmental control of currency conversion may limit our ability to utilize our revenues effectively and affect the value of our ADSs.
- PRC regulations relating to offshore investment activities by PRC residents and enterprises may increase our administrative burden and restrict our non-PRC and cross-border investment activity.
- Monetary, economic, political, environmental, social, and trade disputes between the U.S. and China.
- The heightened level of actions by the U.S. Department of Commerce targeting Chinese companies.

Risks Related to Our Organizational Structure

- Our organizational structure may create significant conflicts of interest.
- The impact of GenScript's significant control over us as our majority shareholder.
- The more limited protections afforded to shareholders as a result of our status as a controlled company and a foreign private issuer.

Risks Related to Our Securities

- The risk that our ADSs will be prohibited from trading on a U.S. national securities exchange, such as The Nasdaq Global Select Market, or in U.S. over-the-counter markets because the Public Company Accounting Oversight Board, or the PCAOB, is unable to inspect or investigate our outside independent auditors due to restrictions imposed by the PRC, where our auditors are located.
- Risks associated with owning our ADSs, including volatility in our trading price due to our business and financial performance, and risks from dilution of our ADSs and ordinary shares if we issue additional ADSs or other securities.

Risks Related to Commercialization of CARVYKTI™ and Our Other Product Candidates

We have limited experience as a commercial company and the marketing and sale of CARVYKTI™ or future products may be unsuccessful or have less success than anticipated.

Having received FDA approval for CARVYKTI™ on February 28, 2022, we are beginning to commercialize CARVYKTI™ for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. As CARVYKTI™ is our first approved product and the remainder of our product candidates are in clinical development, we have limited experience as a commercial company and there is limited information about our ability to overcome many of the challenges encountered by companies commercializing products in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling of CARVYKTI™, we, either individually or with a collaboration partner, will need to successfully:

- establish and maintain relationships with qualified treatment centers who will be treating the patients who receive our product and any future products;
- obtain adequate pricing and reimbursement for CARVYKTI™ and any future products in each of the jurisdictions in which we plan to commercialize approved products;
- gain regulatory acceptance for the development and commercialization of the other product candidates in our pipeline; and
- manage spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization for any additional indications of CARVYKTI™, and for any future products.

If we are not successful in accomplishing these objectives, we may not be able to develop product candidates, successfully commercialize CARVYKTI™ or any future products, raise capital, expand our business, or continue our operations.

The commercial success of CARVYKTI™, and of any future products, will depend upon the degree of market acceptance by physicians, third-party payors and others in the medical community.

The commercial success of CARVYKTI™ and of any future products will depend in part on the medical community, patients, and third-party or governmental payers accepting new treatments for our targeted indications in general, and CARVYKTI™ and any future products in particular, as medically useful, cost-effective, and safe. CARVYKTI™ and any other products that we may bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of CARVYKTI™ and of any future products will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the pricing of our product and of any future products;
- publicity concerning our product, any future products, or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts, and the efforts of any of

our collaborators, to educate the medical community and payers on the benefits of our products may require significant resources and may never be successful. These efforts may require more resources than are required by the conventional technologies marketed by certain of our competitors. Any of these factors may cause CARVYKTI™, or any future products, to be unsuccessful or less successful than anticipated.

If the market opportunities for CARVYKTI™ or any future products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

Our projections regarding the number of people who have the potential to benefit from treatment with CARVYKTI™ or any future products are based on 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 the diseases that our product candidates target. The number of patients may turn out to be lower or more difficult to identify than expected.

Even if we obtain significant market share for a product within an approved indication, because the potential target populations for CARVYKTI™ and for the product candidates in our pipeline are small, we may never achieve profitability without obtaining marketing approval for additional indications. In the field of cancer, the FDA often approves new therapies initially only for use in patients with relapsed or advanced disease. For example, the FDA's approval for CARVYKTI™ indicates that the product is for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. While we expect to seek approval for CARVYKTI™ in earlier lines of MM treatment and potentially as a first line therapy, there is no guarantee that we will be successful doing so.

Any of these factors may negatively affect our ability to generate revenues from sales of CARVYKTI™ and any future products and our ability to achieve and maintain profitability. As a consequence, our business may suffer.

We may not be able to successfully create our own manufacturing infrastructure for supply of our requirements of 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. Further, as part of our collaboration with Janssen, we have established a manufacturing facility in the United States for the U.S. commercial supply of CARVYKTI™ and are in the process of establishing manufacturing capabilities in Belgium, which will provide regional product supply and add to our global manufacturing reach.

We will be conducting the manufacturing of cilta-cel globally, which requires that we expand the capacities at these sites as we begin commercialization in the applicable geographic regions following our receipt of marketing authorizations.

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 commercial needs. However, we are still in the process of constructing manufacturing facilities that will allow us to meet commercial sale quantities.

Our long-term plan is to establish additional manufacturing capacity in the United States, China 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 effectively implementing our 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 CARVYKTI™ or any future products product candidates in sufficient quantities to meet the requirements for the contemplated 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.

Moreover, manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production, and ensuring that the product meets required specifications. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot make any assurances that these problems will not occur in the future, or that we will be able to resolve or address problems that occur in a timely manner or with available funds.

Additionally, since the T cells used as starting material for our drug products have a limited window of stability following procurement from a patient, we must establish and employ complex logistical operations, including collecting and shipping, as part of our manufacturing processes. Logistical and shipment delays and problems caused by us, our agents, and other factors not in our control, such as weather, could prevent or delay the delivery of product to patients. If our manufacturing processes fail to perform satisfactorily, we may suffer reputational, operational, and business harm. We also are required to maintain a complex chain of identity and chain of custody with respect to patient material as it moves through the manufacturing process. Failure to maintain chain of identity and chain of custody could result in adverse patient outcomes, loss of product or regulatory action.

In addition, any significant disruption in the supply chain for starting materials necessary for our manufacturing processes could adversely affect our commercialization efforts. We source key materials from third party suppliers. There are a small number of suppliers for certain key materials that are used to manufacture our product and product candidates. We must compete with other market participants for the limited supply of such materials, which may result in increased costs. Moreover, supply chain constraints with respect to such starting materials may impact the execution of our commercialization efforts. For example, as a result of supply chain limitations, we are constrained in the amount of CARVYKTI™ that we are able to manufacture at present, which requires that we make complex and challenging distribution determinations with respect to our limited supply. Such supply chain constraints necessarily limit the commercial benefits that could be achieved from a broader initial distribution.

Finally, to the extent supplies of CARVYKTI™ are limited, we will face bioethical challenges in allocating a limited supply of CARVYKTI™ to a significant patient need. Because such determinations are highly complex and involve a large number of factors, such allocation decisions may be questioned by third parties.

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 full 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 products and product candidates to levels that will allow for a margin in line with our expectations and return on investment in connection with commercialization.

Although we are continuing to build out our commercial capabilities, we have no prior sales or distribution centers and limited capabilities for marketing and market access. We expect to invest significant financial and management resources to establish these capabilities and infrastructure to support commercial operations. If we are unable to establish these commercial capabilities and infrastructure or to enter into agreements with third parties to market and sell our product or any future products, we may be unable to generate sufficient revenue to sustain our business.

Although we are continuing to build out our field team as part of our first commercial launch in the United States, we have no prior sales or distribution experience and limited capabilities for marketing and market access. To successfully commercialize CARVYKTI™ and any other products that may result from our development programs, we will need to develop these capabilities and further expand our infrastructure to support commercial operations in the United States, Europe and other regions, either on our own or with others. Commercializing autologous CAR T therapies such as CARVYKTI™ is resource-intensive and will require substantial investment in commercial capabilities. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform these functions, including marketing and sales functions, we may be unable to compete successfully against these more established companies.

We currently expect to rely heavily on third parties—primarily, our collaboration partner, Janssen—to launch and market CARVYKTI™. If Janssen does not commit sufficient resources to commercialize CARVYKTI™ , we may be unable to generate sufficient product revenue to sustain our business.

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 prior line 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.

Other than CARVYKTI™, our product candidates are in early stages of development. Our competitors with development-stage programs may obtain marketing approval from the FDA, the NMPA, the European Commission, the PMDA or other comparable regulatory authorities for their product candidates more rapidly than we do with respect to our development-stage product candidates, and they could establish a strong market position for either a product or a specific indication 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—including with respect to CARVYKTI™—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.

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 an even greater risk related to any commercialized products. 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 $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we commercialize CARVYKTI™ expand our clinical trials or if we commercialize additional 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 Business

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.

Other than with respect to CARVYKTI™'s FDA-approved indication, we are primarily a clinical-stage biopharmaceutical company with a limited operating history and we have incurred significant net losses since our inception. Our net loss was approximately $403.6 million for the year ended December 31, 2021. We have funded our operations to date primarily with upfront and milestone payments and interest-bearing borrowings from Janssen under our collaboration and license agreement, with proceeds from public offerings and private placements of equity securities, and with capital contributions from GenScript.

While we had revenue of approximately $68.8 million for the year ended December 31, 2021, this was attributable to our recognition of milestone payments we received from Janssen in connection with our collaboration and license agreement with Janssen, or the Janssen Agreement. With the exception of our first product, CARVYKTI™, which was approved by the U.S. Food and Drug Administration, or FDA, on February 28, 2022 for

the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, we have no products approved for commercial sale. We have not yet generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the commercialization of CARVYKTI™ and the research and development of cilta-cel 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.

Except for CARVYKTI™, none of our product candidates have received marketing approval, and we may never be successful in obtaining further marketing approvals or in 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:

- establish sales, marketing and distribution infrastructure for the commercialization of CARVYKTI™ as well as any other product candidates for which we may obtain regulatory approval;
- continue our ongoing and planned research and development of cilta-cel for the treatment of multiple myeloma (or 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 T cell Lymphoma (or TCL), Non-Hodgkins Lymphoma (or NHL), multiple myeloma (MM), hepatocellular carcinoma (HCC), lung cancer (small cell and non-small cell), gastric cancer, pancreatic cancer, and HIV;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for additional 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 commercialization needs;
- 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 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 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.

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 primarily a clinical-stage biopharmaceutical company with a limited operating history. CARVYKTI™, our first approved product, received initial FDA approved on February 28, 2022 and we are now beginning commercialization efforts. As an organization, we have demonstrated limited ability to successfully complete late-stage clinical trials and obtain regulatory approvals, and we have demonstrated no ability to 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 our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, we will need to raise additional capital to complete the development and commercialization of cilta-cel 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 costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for CARVYKTI™ and any other of our product candidates for which we receive marketing approval;
- 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 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.

In addition to cilta-cel, 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.

Our operating results may be adversely affected by inflation.

While we have not experienced inflationary pressures on our operating costs to date, as we begin to commercialize CARVYKTI™, our business may feel more of an impact. Among other things, competition for labor is becoming more acute, and we expect to experience increased labor costs as we hire employees to support our CARVYKTI™ commercialization efforts. In addition, inflation and higher energy costs may drive increased raw material and transportation costs. There is no assurance that we will be able to fully offset any cost increases through cost reduction programs or setting higher prices for our products. If we generally are not able to set our pricing to sufficiently offset these increased costs or if increased costs and prolonged inflation continue, it could materially and adversely affect our business, operating results and profitability. In addition, volatility in certain commodity markets could significantly affect our production cost.

Risks Related to the Development of Our Product Candidates

With the exception of CARVYKTI™, which was approved by FDA on February 28, 2022, all of our product candidates are in clinical development or in preclinical development. If we are unable to continue to advance CARVYKTI™ and to advance our other 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.

While our first product, CARVYKTI™, was approved by the FDA on February 28, 2022 for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, our success depends, in part, on our ability to continue to advance the development of CARVYKTI™ in earlier lines of MM treatment. In collaboration with Janssen, we are currently conducting a Phase 2 trial of cilta-cel in relapsed or refractory MM, or RRMM, patients in China (CARTIFAN-1) and a Phase 1b/2 trial of 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 approximately 157 patients in a Phase 2 multicohort trial of cilta-cel in the United States, Europe and Israel (CARTITUDE-2) in patients with MM in various clinical settings such as in early relapse patients or as a front-line therapy. In addition, the Phase 3 CARTITUDE-4 clinical trial, enrolling approximately 400 patients including sites in the United States, Europe, Australia, Japan and Israel has been initiated. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in Revlimid-refractory MM. Furthermore, we initiated the Phase 3 CARTITUDE-5 clinical trial during August 2021, targeting enrollment at approximately 650 patients approximately 650 patients, including sites in the United States, Europe, Canada, Australia, Korea and

Japan. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in newly diagnosed MM patients for whom hematopoietic stem cell transplant is not planned as an initial therapy.

In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including NHL, AML, TCL, gastric cancer, pancreatic cancer, ovarian cancer, hepatocellular carcinoma, small cell lung cancer, non small cell lung cancer and HIV, all of which are currently in investigator-initiated Phase 1 clinical trials in China. We are also developing allogeneic CAR-T product candidates targeting CD20 for the treatment of NHL and targeting BCMA for MM, which are currently in investigator-initiated Phase 1 clinical trials 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 PRC's National Medical Products Administration, or NMPA, the European Commission, or the EC (or the favorable technical/scientific opinion of the European Medicines Agency, or EMA), and the Japanese Pharmaceutical and Medical Device Agency, or PMDA, or other regulatory agencies, for any of our product candidates. On December 14, 2020, we announced that the FDA has cleared the IND application to evaluate LB1901 in relapsed or refractory TCL. 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 those product candidates. The success in the development of our product candidates will depend on many factors, including:

- completing preclinical studies and receiving regulatory authorizations to conduct clinical trials for our preclinical-stage program product candidates;
- obtaining positive results in our clinical trials to demonstrate 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. With the exception of our first product, CARVYKTI™, which was approved by the FDA on February 28, 2022 for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, we do not currently have any approved products, nor do we have any 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 European Commission, 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 commercial supplies of the materials used to manufacture CARVYKTI™ and our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating and obtaining a sufficient supply of 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 CARVYKTI™ and any other of 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 four CAR-T cell therapy products that involve the genetic modification of patient cells have been approved in the United States and three in 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 of physicians to prescribe approved 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 cilta-cel and our other pipeline programs. All of our product candidates require significant preclinical study and clinical trial before we can seek regulatory approval for and launch a product commercially.

With the exception of our first product, CARVYKTI™, which was approved by the FDA on February 28, 2022 for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, we do not have any products that have gained regulatory approval for marketing. Our business is substantially dependent on our ability to further advance the development of CARVYKTI™, obtain regulatory approval for cilta-cel in other jurisdictions and for additional indications, obtain regulatory approval of our other product candidates, and commercialize CARVYKTI™ and, if approved, our other product candidates. 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 European Commission, on the basis of the technical / scientific opinion issued by 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 EC, 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 clinical- or preclinical-stage 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 European Commission, 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 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 cilta-cel has received orphan drug designation and breakthrough therapy designation from the FDA, has been granted access to the PRIME scheme from the EMA, and received confirmation that the product is eligible for accelerated assessment, 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 obtain or maintain access to the PRIME scheme, 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 European Commission, 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 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 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 that support regulatory approvals. 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 positive data from previously completed and ongoing clinical trials of cilta-cel in RRMM, we are still in the process of conducting additional clinical trials in the United States, China, Japan, several countries in Europe, Australia and Korea 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. Other companies are conducting clinical trials with cell therapies in MM and for other conditions that are targeted by our research, 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 certain reviewers from its Center for Drug Evaluation 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 particular the requirements related to manufacturing quality control, informed consent, data integrity, data management, and all GCP requirements.

Accordingly, our strategy of continuing to explore new opportunities for cell therapy in investigator-initiated clinical trials in China exposes us to the risk 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, and they may elect to discontinue these trials, even if we believe they have scientific merit. As a result, our lack of control over the design, conduct and timing of, and communications with the FDA, NMPA, EMA and PMDA, other comparable regulatory authorities, and relevant Institutional Review Boards and Ethics Committees 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 therapies, 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 CARVYKTI™ has been approved by FDA as a later line therapy for patients with MM, there is no guarantee that cilta-cel will be approved for earlier lines of therapy, nor is there any guarantee that any of our other product candidates, even if approved, will be approved for earlier lines 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 ongoing 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 marketing approval.

In clinical trials conducted by us and 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, encephalopathy 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 respiratory 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. Furthermore, other patients experienced serious adverse events at later stages in treatment follow-up, such as cytopenias, infections and neurotoxicity.

In the 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 the Phase 1b/2 CARTITUDE-1 clinical trial, as of February 11, 2021, CRS was reported in 95 percent of patients. Total CAR-T cell neurotoxicity of any grade was observed in 21 percent of patients, with Grade 3 or higher neurotoxicity observed in 10 percent of patients. There were twenty one deaths during the Phase 1b/2 CARTITUDE-1 trial: ten due to disease progression, 6 were treatment-related as assessed by the investigator, and 5 were due to adverse events unrelated to treatment.

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 our current clinical trials and 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 Committees, the FDA, the NMPA, 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, for CARVYKTI™ or any other of our product candidates that receives marketing approval, if we or others later identify undesirable side effects caused by that product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using the product or during additional clinical trials or required Risk Evaluation and Mitigation Strategy, or REMs, 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;
- if a REMS is not already required for such product, we may be required to create a 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 European Commission, the PMDA or other comparable regulatory authority, and we may never receive such approvals for our product candidates in development. It is impossible to predict accurately when or if any of these 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 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 the 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.

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 full-scale commercialization. While we have established a process which we believe is scalable for full-scale 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 products or 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 our manufacturing will not occur in the future. Any delay or interruption in the supply of commercial product could delay our commercialization program, result in regulatory scrutiny, damage our reputation and impede our profitability. Any delay or interruption in the fulfillment 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 is 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 products and product candidates are manufactured for each particular patient, we are 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. Such treatments 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 products or product candidate, which could result in these patients having 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, cilta-cel (which was approved by the FDA under the trademark CARVYKTI™), faces 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 cilta-cel. 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 the 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 "Item 3.D. Risk Factors—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, 2021, we had approximately 1,071 full-time employees. As our development and commercialization plans progress and strategic plans expand and develop, and as we mature as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and both current 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 effectively commercialize our product candidates depends, 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, any of whom may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific, clinical, 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 existing or future laws and regulations related to privacy or data security could lead to government enforcement

actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs, could limit their use or adoption, and could otherwise negatively affect our operating results and 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 but not limited to health information in connection with our commercialization and development activities 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.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data (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, any scientific data involving state secret, state security, social public interests, commercial secret or personal privacy may not be open and shared; where openness is indeed needed, the purpose, user's qualification, conditions of confidentiality and other factors shall be reviewed, and the informing scope shall be strictly controlled. 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 non-PRC academic journal. China's Cyber Security Law, which became effective in June 2017, created China's national-level data protection for "network operators," which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Furthermore, the Opinions on Strictly Cracking Down on Illegal Securities Activities, which was issued by the General Office of the State Council and another authority on July 6, 2021, requires the speed-up of the revision of the provisions on strengthening the confidentiality and archives management related to issuance and listing of securities outside of the PRC, and improvement to the laws and regulations related to data security, cross-border data flow, and management of confidential information. China's Data Security Laws, which was promulgated by the Standing Committee of PRC National People's Congress, or the SCNPC, on June 10, 2021 and became effective on September 1, 2021, outlines the main system framework of data security protection. The Personal Information Protection Law promulgated by the SCNPC on August 20, 2021 and became effective on November 1, 2021, which outlines the main system framework of personal information protection and processing.

The Measures for Cybersecurity Review were published by the CAC, and 12 other relevant PRC government authorities on December 28, 2021 and became effective on February 15, 2022. These measures provide that, among other things, if a "network platform operator" that possesses personal information of more than one million users intends to go public in a non-PRC country, it must apply for a cybersecurity review with the cybersecurity review office; in such event, the relevant PRC governmental authorities may initiate cybersecurity review if they determine certain network products, services, or data processing activities affect or may affect national security.

Regulations on the Security Protection of Critical Information Infrastructure, which was promulgated by the State Council of the PRC on July 30, 2021 and became effective on September 1, 2021, or the CII Protection Regulations, stipulates the obligations and liabilities of the regulators, society and critical information infrastructure operators, or the CIIOs, in protecting the security of critical information infrastructure, or the CII. According to the CII Protection Regulations, regulators supervising specific industries shall formulate detailed guidance to recognize the CII in the respective sectors, and CIIOs shall take the responsibility to protect the CII's security by performing certain prescribed obligations. For example, CIIOs are required to conduct network security test and risk assessment, report the assessment results to relevant regulatory authorities, and timely rectify the issues identified at least once a year. In addition, drafts of some of these measures have now been published, including the draft rules on the Measures for the Security Assessment of Personal Information and Important Data to be Transmitted Abroad, which may, upon enactment, require security review before transferring human health-related data out of China. On October 29, 2021, the CAC published the Measures on Security Assessment of Cross-border Transfer of Data (Draft for Comments), which provides that data processors are required to make self-assessment of the risks before

transferring data cross-border, and are required to apply for security assessment for cross-border data transfer in any of the following circumstances: (i) transferring personal information and important data collected and produced by CIIOs; (ii) important data is included in the data transferred cross-border; (iii) transferring personal information cross-border by personal information processors which process more than one million individuals' personal information; (iv) transferring more than one hundred thousand individuals' personal information or more than ten thousand individuals' sensitive personal information cumulatively; or (v) other circumstances which require the application for cross-border data transfer security assessment as determined by the CAC.

The draft Regulations for the Administration of Cyber Data Security, or the Draft Data Security Regulations, published by the CAC on November 14, 2021 for public comments until December 13, 2021 reiterates that a data processor who processes personal information of more than 1 million individuals shall go through the cyber security review if it intends to be listed in a non-PRC country, and if a data processor conducts any data processing activities that affect or may affect national security, an application for cyber security review shall also be made by such processor. And the Draft Data Security Regulations require data processors processing important data or being listed outside China shall carry out data security assessment annually by itself or through a third party data security service provider and submit assessment report to local agency of the CAC. The Draft Data Security Regulations provide a broad definition of data processing activities, including collection, storage, usage, processing, transfer, provision, publication, deletion and other activities, and the Draft Data Security Regulations also provide a broad definition of data processor as individuals and entities which autonomously determine the purpose and method during data processing activities. However, the Draft Data Security Regulations provide no further elaboration on what constitutes a situation that "affects or may affect national security" and are subject to further changes before being formally adopted and coming into effect.

As of the date of this Annual Report on Form 20-F, no detailed rules or implementation of the Measures for Cybersecurity Review or the Draft Data Security Regulations have been issued by the CAC, and the PRC governmental authorities may have wide discretion in the interpretation and enforcement of these laws and regulations. It also remains uncertain whether the future regulatory changes would impose additional restrictions on companies like us. We cannot predict the impact of the Draft Data Security Regulations, if any, at this stage, and we will closely monitor and assess any development in the rulemaking process. If the enacted version of the Draft Data Security Regulations requires any clearance of cybersecurity review and other specific actions to be completed by companies like us, we face uncertainties as to whether such clearance can be timely obtained, or at all. If we are not able to comply with the cybersecurity and data privacy requirements in a timely manner, or at all, we may be subject to government enforcement actions and investigations, fines, penalties, or suspension of our non-compliant operations, among other sanctions, which could materially and adversely affect our business and results of operations. We have been making constant efforts to comply with the relevant data protection laws and regulations in the PRC and will endeavor to comply with any update in the applicable laws, regulations or guidelines as issued by any relevant regulatory authorities in the PRC. However, we cannot assure you that we are able to comply with any applicable privacy and data security laws, regulations and guidelines in a timely manner, or at all. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources (effective in July 2019), which require approval/filing from the Science and Technology Administration Department of the PRC State Council where human genetic resources are involved in any international collaborative project and additional approval, filing and backup for any export or cross-border transfer of the human genetic resources samples or associated data or for providing/offering access of the information on human genetic resources to non-PRC entities and the institutions established or actually controlled thereby. We cannot assure you that we have complied or will be able to comply with all applicable human genetic resources related regulations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of human genetic resources samples and associated data and administrative fines. As there are still uncertainties regarding the further enacting of new laws and regulations as well as the revision, interpretation and implementation of those existing laws and regulations, we cannot assure you that we will be able to comply with such regulations in all respects, and we may be ordered to make rectification and terminate any actions that are deemed illegal by the regulatory authorities and become subject to fines and/or other sanctions. As a result, we may be required to suspend our related businesses or face other penalties which may have material adverse effect on our business, operations and financial condition.

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 persons who are in the European Union. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data protection authorities, establishes a limited range of 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, that constitutes 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 and security 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 frequently adopting new laws or amending existing laws, requiring attention to such 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 have and may in the future experience disruptions impacting 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 have and may in the future 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. For instance, the protocols for certain of our clinical trials have been amended to allow local evaluations for patients who could not access the main hospital in which such trial is being conducted;
- 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.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise if we fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our reporting obligations.

On October 19, 2022, our Audit Committee, after meeting with management to consider the relevant facts and circumstances, determined that our financial statements as of and for the years ended December 31, 2021, December 31, 2020 and December 31, 2019 and our financial statements for the interim period ended March 31, 2022 should no longer be relied upon. The Company is amending and restating (the "Restatement") the Audited Affected Financials in this Amended Annual Report.

As a result of the Restatement, the Company concluded that there was a material weakness in its internal control over financial reporting as of December 31, 2021 relating to the lack of adequate review and monitoring of controls over complex agreements, specifically, the Janssen Agreement, and its disclosure controls and procedures were not effective. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected *on a timely basis.*

To address the material weakness, and with the oversight of the Audit Committee, we are committed to implementing remediation measures. These measures, some of which we have already implemented and others which we are in the process of implanting, are intended to both address the identified material weakness and strengthen our overall financial control environment. Our measures include: (i) implementing additional responsive review and monitoring controls for complex agreements, including the Janssen Agreement, including additional review by the Chief Financial Officer and other senior finance staff over critical accounting judgments and estimates, reporting and disclosures; (ii) expanding the capabilities of existing financial reporting personnel through specific continuous training and education in the application of IFRS standards, with a focus on complex agreements, including the Janssen Agreement; and (iii) hiring additional financial reporting personnel with appropriate IFRS accounting experience. We have also engaged additional external resources to aid and supplement our internal resources in the execution of this remediation plan.

While we are undertaking efforts to remediate the material weakness, the material weakness will not be considered remediated until our remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time and we have concluded, through testing, that the newly implemented and enhanced controls are operating effectively. As we continue to evaluate and work to improve our internal controls over financial reporting, we may take additional measures to address these control deficiencies or modify the remediation plan described above. At this time, we cannot predict the success of such efforts or the outcome of our assessment of the remediation efforts. We can give no assurance that our efforts will remediate the material weakness, or that additional material weaknesses will not be identified in the future.

As a public company, we must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. We are subject to reporting obligations under U.S. securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires that 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. Pursuant to Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), our independent registered public accounting firm is required to issue an annual attestation report that addresses the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. The presence of material weaknesses, if identified, 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 maintain effective disclosure controls and procedures and internal controls over financial reporting, we must expend significant resources and provide significant management oversight. There can be no assurance that we will be effective in maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, 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 have broad discretion in the use of our cash and cash equivalents and may invest or spend these in ways with which you do not agree.

Our management has broad discretion in the application of our cash and cash equivalents and could spend such cash and cash equivalents 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 amounts 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 the use of our cash and cash equivalents, we may invest the same in a manner that does not produce income or that loses value

Risks Related to Our Dependence on Third Parties

We depend upon our existing collaboration partner, Janssen, and other third parties, and we 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 cilta-cel.

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 a material breach of agreement or an unforeseen material safety event. If the Janssen Agreement were to be terminated, we could encounter significant delays or other impairments in the commercialization of CARVYKTI™ and further developing cilta-cel, 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.

Furthermore, even though Janssen is required to diligently develop and commercialize cilta-cel, it is possible that Janssen will seek to prioritize other products in its portfolio over cilta-cel, including products that may treat conditions that are the same as or are similar to the conditions for which cilta-cel has either received marketing approval or for which we are conducting research for potential future marketing approvals.

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 cilta-cel. We received an upfront payment of $350.0 million from Janssen in 2018, an additional $200.0 million in milestone payments through December 31, 2021, and a further $50.0 million in milestone payments from December 31, 2021 to the date of this Annual Report. 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, we have been in the process of transitioning away from Genscript for these services to perform them internally, and we expect to continue that process. 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 cilta-cel 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 any 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, including 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 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. Further, in connection with marketing approval, the accompanying label for a product 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 for a product candidate 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 elsewhere 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 must obtain pricing and/or reimbursement approvals before it can be sold in those jurisdictions.

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 (which is a requirement for FDA's approval of CARVYKTI™) 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 European Commission, 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, 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.

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, civil, administrative and criminal 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, overtly or covertly, 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 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 or approval that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or, decreasing an obligation to pay or transmit money or property to the federal government. Pharmaceutical and other healthcare companies have been found liable 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 healthcare 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 federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, obtaining, 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, knowingly and willfully embezzling, stealing, or otherwise without authority converting to the use of any person other than the rightful owner, or intentionally misapplying any of the moneys, funds, securities, premiums, credits, property, or other assets of a healthcare benefit program, willfully preventing, obstructing, misleading, delaying or attempting to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a federal healthcare offense to a criminal investigator and in any matter involving a healthcare benefit program, knowingly and willfully falsifying, concealing or covering up by any trick, scheme, or device a material fact or making any materially false, fictitious, or fraudulent statements or representations, or making or using any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- 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, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH, among other changes, also established four new tiers of civil monetary penalties; amends HIPAA to make business associates of covered entities directly liable for compliance with certain requirements of the federal HIPAA laws and gave state attorneys general new authority to bring civil actions for damages or injunctions on behalf of state residents in the appropriate district court of the United States for violations of the federal HIPAA laws and in the case of any successful action, the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State;
- 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 effective

January 1, 2022, these reporting obligations extend to include information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives; 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 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 has 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 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 countries within the European Union, the pricing and reimbursement of certain pharmaceuticals is subject to governmental control. In these countries, pricing and reimbursement 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 "Item 4.B. Information On The Company—Business Overview —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. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, several 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 eliminated, 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 eliminated the health insurer tax.

It is also unclear how litigation and other efforts to repeal and replace the ACA will impact the ACA in the future.

In addition, other federal health reform measures have been proposed and adopted in the United States that may impact reimbursement by Medicare or other government healthcare programs. 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 2030, with the exception of a temporary suspension of certain mandatory Medicare claim payment reductions until March 31, 2022, unless additional Congressional action is taken. While the Act to Prevent Across- the- Board Direct Spending Cuts and for Other Purposes (April 14, 2021) and the Protecting Medicare and American Farmers from Sequester Cuts Act (December 10, 2021) extended this temporary suspension date, and, under the Statutory Pay-As-You-Go Act of 2010, per the analysis of the Congressional Budget Office, could trigger reductions in Medicare spending of up to four (4) percentage points. 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, which would have significantly cut payment for participating Medicare clinicians, 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. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Additionally, the Centers for Medicare and Medicaid Services' (CMS) FY 2022 Budget Justification request to Congress indicates a greater focus on provider audits, including a doubling of CMS's medical review budget, which means providers will

have additional pressures to costs to respond to these audits and potentially, lengthy denial appeals. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors, or private payors may independently reduce reimbursement under their health plans.

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. As part of the Trump Administration's plans to address drug prices, the FDA released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. On November 23, 2020, a trio of industry groups sued HHS and FDA, seeking to enjoin the final rule, and a few days later, Canada passed an interim order banning the export of certain drugs from Canada. In May 2021, the government filed a motion to dismiss the lawsuit for lack of subject matter jurisdiction, and alternatively, for failure to state a claim.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. HHS was sued over the rule, which was challenged as arbitrary and capricious under the Administrative Procedure Act. Implementation of the rebate rule has been delayed to January 2023, pursuant to the litigation. It is unclear whether OIG will ultimately withdraw or modify the rebate rule prior to the January 2023 effective date. The likelihood of implementation of, or willingness to defend, any of the other reform initiatives is uncertain.

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.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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, environmental, health 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 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 cilta-cel, 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

References to "foreign" in this section entitled "Risks Related to Doing Business in China" refer to non-PRC countries, unless the context indicates otherwise.

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 "Item 4.B. Information On The Company—Business Overview—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. Due partly to reasons beyond our control, we have not obtained such approval in a timely manner in some collaboration projects with PRC partners either. 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. According to PRC laws, entities are required to obtain an export certificate from governmental authorities if they plan to transport, mail or carry China's human genetic resources out of China in projects of international collaboration in scientific research by using China's human genetic resources. The export certificate for China's human genetic resources is a requirement of customs formalities. The failure to obtain such export certificate in relevant export activities could cause governmental authorities to suspend relevant activities, confiscate the human genetic resources illegally collected and preserved and illegal gains, impose fines and may hold such entity liable. If the violation is deemed serious, entities and their responsible persons may be prohibited from engaging in activities such as collection, preservation, usage and outbound transport of China's human genetic resources for a period of time or permanently. In addition, a violation of these laws may result in criminal liability if relevant export activities constitute a crime. There is no assurance that we can always obtain relevant approvals for the export of China's human genetic resources out of China.

Furthermore, under relevant PRC laws, a license for use of laboratory animals is required for performing experimentation on animals. Any failure to fully comply with such requirement may result in the invalidation of our experimental data. With respect to our collaboration partner, medical institution's failure to comply with existing or future laws and regulations regulated by NHC and other administration authorities related to the management of cell therapy investigator-initiated clinical trials in China could lead to government penalties, suspension of related activities, or breach liability. Compliance or the failure to comply with such laws and regulations could increase the costs of, limit and cause significant delay in these investigator-initiated clinical trials and research and development activities, which could materially and adversely affect our business, operation and prospects as well. However, we do not have control over our collaborators and cannot compel them to comply with NHC and other administration authorities' requirements. Therefore, we cannot assure you that any required registration or filing procedures under

laws will be completed in a timely manner, or at all. 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.

Failure to comply with existing or future laws and regulations related to the management of human genetic resources in China could lead to government enforcement actions, which could include civil, administrative or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of, limit and cause significant delay in our clinical studies and research and development activities, and could otherwise materially and adversely affect our operating results, business and prospects.

Laws and regulations related to the management of human genetic resources in China are rapidly evolving and the enforcement thereof is likely to remain uncertain for the foreseeable future. On June 10, 1998, the Ministry of Science and Technology, or MOST, and the Ministry of Health jointly issued the Interim Measures for the Administration of Human Genetic Resources and established the rules for protecting and utilizing human genetic resources, or HGR, in China. MOST and other regulatory agencies in China have been focused on HGR legislation, and proactively sought opinions from the public on draft regulations. In 2015, MOST issued a Guideline on HGR and reinforced its legislative efforts in HGR administration. In May 2019, the Regulation on Human Genetic Resources Management, or the HGR Regulation, was put in place. The State Council promulgated the HGR Regulation on June 10, 2019 and it became effective on July 1, 2019.

The HGR Regulation prohibits foreign entities or individuals or such entities established or actually controlled thereby, or "Foreign Persons," from collecting or preserving China HGR in China, or providing China HGR abroad, whereas activities of collection and preservation of organs, tissues and cells for purposes of clinical diagnosis and treatment, service of blood collection and provision, investigation of illegal activities, doping test and funeral service, are required to be conducted in accordance with other relevant laws and regulations. The HGR Regulation permits Foreign Persons' limited use of China HGR "to carry out scientific research activities," which must be conducted through collaboration with Chinese scientific research institutions, higher education institutions, medical institutions, or enterprises, collectively, the "Chinese Entities." Such activities must be approved by MOST, and the application for approval must be filed jointly by the Foreign Person and the relevant Chinese Entity. The only exception to the approval requirement is "international collaboration in clinical trials" that do not involve the outbound transfer of China HGR materials such as organs, tissues, or cells comprising the human genome, genes, or other genetic substances, collectively, China HGR Materials. Such clinical trial collaboration, however, must still be pre-registered with MOST. There remain significant uncertainties as to how provisions of the HGR Regulation might be interpreted and implemented. Short-term storage of samples of laboratory testing by foreign laboratories or foreign-invested laboratories may also be interpreted as preserving China HGR, thus being subjected to MOST application, approval or pre-registration processes.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC which will become effective from April 15, 2021. The new law, among other things, restates relevant approval or pre-registration requirements of HGR collection, preservation, utilization and external provision, as provided in the HGR Regulation. Moreover, the promulgation of the new law, which takes the form of national law, further demonstrates the commitments of protecting China HGR and safeguarding state biosecurity by the PRC government.

Failure to comply with existing or future HGR laws and regulations, including the HGR Regulation and the Biosecurity Law, may subject us to penalties, including fines, suspension of related activities and confiscation of related HGR and gains generated from conducting these activities, or breach liability. If the circumstances are serious, entities and their responsible person may be prohibited from engaging in activities such as collection, preservation, usage and outbound of China's HGR within a period or permanently. In addition, it may result in

criminal liability if relevant activities constitute crime. There is no assurance that we can always complete all application, approval or pre-registration processes according to existing or future HGR laws and regulations.

We may be adversely affected by an ongoing investigation involving our majority shareholder and our former chief executive officer and Chairman. Although we and Genscript have conducted targeted internal reviews relating to the investigation, Genscript has not conducted a comprehensive internal review of all transactions it handled on behalf of us prior to our initial public offering and there can be no assurance that the investigation will not involve us or that the Authority or other governmental authority will not pursue criminal or civil remedies against us or our directors, officers or employees in the future, including sanctions, monetary penalties and regulatory actions, which could adversely affect us.

Our majority shareholder, Genscript, and Dr. Fangliang Zhang, our former chairman and chief executive officer, and the former chairman and chief executive officer of Genscript, are currently under investigation by the Customs Anti-Smuggling Department of Zhenjiang, or the Authority, in the PRC. The Authority's inspection included places of business in Nanjing and Zhenjiang, China, of Genscript, and certain of its subsidiaries, including our location in Nanjing. The inspections are in connection with what we believe to be an investigation relating to suspected violations of import and export regulations under the laws of the PRC, which has, to date, focused on Genscript's import and export activity preceding our initial public offering in June 2020, at which time we were a subsidiary of Genscript and Dr. Zhang was chairman and chief executive officer of Genscript. Following a period of residential surveillance and arrest by PRC law enforcement, Dr. Zhang was released on bail by the Authority on February 9, 2021. Two Genscript employees had also been placed under arrest. Five of our employees have been questioned by the PRC authorities about their prior roles at Genscript. One of these five employees, who was previously a Genscript employee, was briefly detained and this employee is currently released on bail. In May 2021, Dr. Zhang and the four employees of Genscript, along with two PRC subsidiaries of Genscript, were notified by the Authority that the investigation was complete, and that their respective matter had been handed over to the Zhenjiang Municipal People's Procuratorate, or the Procuratorate, for examination and possible prosecution. In July 2021, the Procuratorate returned the case to the Authority for supplementary investigation. As of the date of this Annual Report on Form 20-F, the supplementary investigation is completed and the Authority has handed the case back to the Procuratorate. Whether or when the Procuratorate will pursue pressing any charges against Genscript, Dr. Zhang or Genscript employees remains unknown to us. To the best of our knowledge, no charges have been filed to date against Dr. Zhang, Genscript or us and the Authority has not notified us that we are a target of the Authority's investigation.

The Audit Committee of our Board of Directors engaged external counsel to conduct an internal review of our import and export transactions. The review identified no apparent issues with respect to transactions conducted since our initial public offering in June 2020. However, transactions prior to July 2020 were handled by Genscript on our behalf, which limits our ability to review such transactions. While Genscript, with the assistance of its external counsel, conducted a targeted review based on feedback from its communications with the Authority, it has not conducted a comprehensive internal review of all transactions it handled on behalf of us prior to our initial public offering. Accordingly, our ability to ascertain the risk of our exposure to the Authority's investigation is limited and there is a risk that we may become a subject of the Authority's investigation, and thereafter subject to proceedings, penalties and restrictions on our activities, which could adversely affect us.

While no charges have been filed against us or any of our officers or directors, and we understand that we are not a target of the Authority's investigation at this time, we believe that the investigation has had an adverse impact on the price of our ADSs and ordinary shares, and could continue to have such an adverse impact, particularly if charges are brought against Genscript or Dr. Zhang or, if PRC authorities seek to impose restrictions on Genscript's or our activities, or if the Authority decides to investigate us, our officers, employees or directors in the context of its investigation of Genscript and Dr. Zhang or otherwise, or if any of our or Genscript's executive officers are subjected to residential surveillance, detention, arrest, charges or imprisonment. As of December 31, 2021, (i) Dr. Zhang beneficially owns, indirectly through Genscript Corporation, 15.5% of the issued and outstanding shares of Genscript, comprised of 14.09% held directly by Genscript Corporation and 1.41% held through his trust, (ii) Genscript, in turn, beneficially owns 56.6% of our ordinary shares, and (iii) two out of seven of the members of our board of directors are employees of Genscript.

Furthermore, despite the fact that Dr. Zhang is no longer one of our executive officers or directors, Dr. Zhang may still be able to influence us and/or Genscript, and such influence, or the perception that Dr. Zhang exerts such influence over us and/or Genscript, may lead to further investigations by the Authority or other governmental authorities, and have an adverse impact on the price of our ADSs and ordinary shares. In each situation, our management's attention may be diverted, management of our operations could be adversely affected, significant expenses could be incurred, our reputation and ability to raise capital in the future may be harmed, and there could be a material adverse effect on our business, financial condition, results of operations, and prospects, especially if there is an adverse outcome.

Additionally, any investigation could damage our reputation or cause our existing collaboration partner, Janssen, and other third parties to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

Separately, Genscript has conveyed that in the course of the Authority's inspection of Genscript, the Authority has also identified nine imports, which Genscript handled on behalf of the Company prior to the IPO, in respect of which there may be minor non-compliance issues concerning import declarations, which are distinct from the matters that have been the focus of the Authority's investigation. Genscript has informed us that it believes that Genscript is the target of the Authority's inquiries with respect to these import declaration matters, and the Authority has not contacted us with respect to such import declaration matters.

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 non-PRC 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 subsidiaries are 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, the PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to a significant degree of interpretation by PRC

regulatory agencies and courts. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of these decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. Therefore, it is possible that our existing operations may be found not to be in full compliance with relevant laws and regulations in the future. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

In addition, the PRC government has recently announced its plans to enhance its regulatory oversight of PRC companies listing outside of the PRC. The Opinions on Strictly Cracking Down on Illegal Securities Activities issued on July 6, 2021 called for:

- tightening oversight of data security, cross-border data flow and administration of classified information, as well as amendments to relevant regulation to specify responsibilities of PRC companies listed outside of the PRC with respect to data security and information security;
- enhanced oversight of companies listed outside of the PRC as well as equity fundraising and listing by PRC companies outside of the PRC; and
- extraterritorial application of China's securities laws.

As the Opinions on Strictly Cracking Down on Illegal Securities Activities were recently issued, there are great uncertainties with respect to the interpretation and implementation thereof. The PRC government may promulgate relevant laws, rules and regulations that may impose additional and significant obligations and liabilities on Chinese companies listed outside of the PRC regarding data security, cross-border data flow, and compliance with China's securities laws. It is uncertain whether or how these new laws, rules and regulations and the interpretation and implementation thereof may affect us, but among other things, our ability to obtain external financing through the issuance of equity securities outside of the PRC could be negatively affected.

PRC governmental authorities may intervene or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.

The PRC government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political and societal goals. The PRC government has recently published new policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could require us to seek permission from PRC authorities to continue to operate our business in the PRC, which could adversely affect our business, financial condition and results of operations, as well as adversely impact the value of the ADSs, causing them to significantly decline in value. Furthermore, recent statements made by the PRC government have indicated an intent to increase the government's oversight and control over offerings of companies with significant operations in China that are to be conducted in foreign markets, as well as foreign investment in issuers with operations in China like us. Any such action, once taken by the PRC government, could result in action taken by the PRC against our PRC subsidiaries and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline.

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 Annual Report based on foreign laws. It may also be difficult for regulators outside of the PRC or you to conduct investigations or collect evidence within China.

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.

It may also be difficult for you or regulators outside of the PRC to conduct investigations or collect evidence within China. For example, in China, there are significant legal and other obstacles to obtaining information, documents and materials needed for regulatory investigations or litigation outside China or otherwise with respect to foreign entities. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such regulatory cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no securities regulator outside of the PRC is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no entity or individual may provide the documents and materials relating to securities business activities to parties outside of the PRC. While detailed interpretation of or implementing rules under Article 177 have yet to be promulgated, the inability for a securities regulator outside of the PRC to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated 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. As we commence with 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 or non-PRC individuals, 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 any 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 limit our ability to utilize our revenues effectively and affect the value of our ADSs.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Under our current corporate structure, our Cayman Islands holding company may rely on dividend payments from our PRC subsidiaries to fund any cash and financing requirements we may have in the future. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service -related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. Specifically, under the existing exchange restrictions, without prior approval of SAFE, cash generated from the operations of our PRC subsidiaries in China may be used to pay dividends to our company. However, 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. As a result, we need to obtain SAFE approval or complete SAFE registration to use cash generated from the operations of our PRC subsidiaries to pay off their respective debt in a currency other than RMB owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than RMB.

In light of the recent flood of capital outflows of China due to the weakening of RMB, the PRC government has imposed more restrictive foreign exchange policies and stepped up scrutiny of major outbound capital movement including overseas direct investment. More restrictions and substantial vetting process are put in place by SAFE to regulate cross-border transactions falling under the capital account. If any of our shareholders regulated by such policies fails to satisfy the applicable overseas direct investment filing or approval requirement timely or at all, it may be subject to penalties from the relevant PRC authorities. The PRC government may at its discretion further restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign 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.

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 our business. For example, to the extent that we need to convert U.S. dollars 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 Annual Report, 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 non-PRC 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 the SAMR 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 funds 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 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 or filing requirements for employee stock ownership plans or share option plans may subject the 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 a public company listed outside of the PRC 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 a public company listed outside of the PRC, 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 public company listed outside of the PRC 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 are subject to the Stock Option Rules. However, we do not have control over our PRC resident participants and cannot compel them to comply with SAFE registrations.

Therefore, we cannot assure you that any required registration under SAFE registrations will be completed in a timely manner, or at all. 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. Furthermore, failure to complete the SAFE registrations may limit our PRC resident participants' ability to make payment under our share incentive plan or receive dividends or sales proceeds related thereto, or limit our ability to contribute additional capital into our wholly-foreign owned enterprises in China and limit our wholly-foreign owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional share incentive plans for our directors and employees under PRC laws.

In addition, the State Taxation Administration issued the Notice on Several Measures for Further Deepening the Reform of "Simplifying Administration and Decentralizing Powers, Combining Decentralization with Appropriate Control, and Optimizing Services" and Cultivating and Stimulating the Vitality of Market Participants, or the Notice, in October 2021, which requires that any enterprise implementing any equity (stock) incentive plan submit a Report Form of Equity Incentives and other materials to the competent tax authority within 15 days of the next month after deciding to implement equity incentives or before the end of 2021 for equity incentive plans that have been implemented but not yet completed, including domestic enterprises that provide equity incentives for employees with equity of enterprises outside of the PRC. However, as the Notice is newly issued, there are still substantial uncertainties as to its interpretation and implementations in practice. Therefore, we cannot assure you that any required registration or filing under the Notice or other regulations will be completed in a timely manner, or at all. If we or our participants fail to comply with these regulations, we and/or our participants may be subject to fines and other legal sanctions.

The approval of, or filing or other procedures with, the CSRC or other governmental authority may be required in connection with issuing our equity securities to non-PRC investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.

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. The M&A Rules, among other things, requires offshore SPVs formed for the purpose of a listing outside of the PRC and controlled by PRC companies or individuals, to obtain the CSRC approval prior to listing their securities on a stock exchange outside of the PRC. 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 was not required under the M&A Rules in the context of our initial public offering because the ownership structure of our PRC subsidiaries 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.

Furthermore, the recently issued Opinions on Strictly Cracking Down on Illegal Securities Activities emphasized the need to strengthen the supervision on listings by companies with operations in China outside of the PRC and provided that the special provisions of the State Council on issuance and listing of shares outside of the PRC by those companies limited by shares will be revised. There are still uncertainties regarding the interpretation and implementation of these Opinions, and further explanations or detailed rules and regulations with respect to these Opinions may be issued in the future which could impose additional requirements on us. On December 24, 2021, the CSRC issued the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (collectively, the "Draft Overseas Listing Regulations"), which has a comment period that expired on January 23, 2022. The Draft Overseas Listing Regulations require, among others, that companies with subsidiaries in China that seek to offer and list securities in markets outside of the PRC, either through direct or indirect means, are required to file the required documents with the CSRC within three working days after its application for listing on a stock exchange outside of the PRC is submitted and report to CSRC after such offering and listing is completed.

As of the date of this Amendment No. 1, the Draft Overseas Listing Regulations are both still in draft forms and there are uncertainties regarding the final forms of the Draft Overseas Listing Regulations as well as the interpretation and implementation thereof after promulgation. As the CSRC may formulate and publish guidelines for filings in the future. In a Q&A released on its official website, the respondent CSRC official indicated that the proposed new filing requirement will start with new companies and the existing companies seeking to carry out activities like follow-on financing. As for the filings for the existing companies, the regulator will grant adequate transition period and apply separate arrangements. Given the substantial uncertainties surrounding the latest CSRC filing requirements at this stage, we cannot assure you that we will be able to complete the filings and fully comply with the relevant new rules on a timely basis, if at all.

In addition, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements on us. If it is determined in the future that approval and filing from the CSRC or other regulatory authorities or other procedures, including the cybersecurity review under the Measures for Cybersecurity Review and the Draft Data Security Regulations, are required for our offshore offerings, it is uncertain whether we can or how long it will take us to obtain such approval or complete such filing procedures and any such approval or filing could be rescinded or rejected. Any failure to obtain or delay in obtaining such approval or completing such filing procedures for our offshore offerings, or a rescission of any such approval or filing if obtained by us, would subject us to sanctions by the CSRC or other PRC regulatory authorities for failure to seek CSRC approval or filing or other government authorization for our offshore offerings. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the proceeds from our offshore offerings into China or take other actions that could materially and adversely affect our business, financial condition, results of operations, and prospects, as well as the trading price of our listed securities.

The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by non-PRC 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 non-PRC 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 non-PRC 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 companies outside of the PRC 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. Furthermore, according to the Measures for the Security Review of Foreign Investment, or the New Security Review Measures, promulgated by the National

Development and Reform Commission, or NDRC, and MOFCOM on December 19, 2020, a foreign investment security review working mechanism will be established to be responsible for organizing, coordinating and guiding the security review of foreign investment. If a proposed foreign investment meets the conditions as stipulated in the New Security Review Measures, the foreign investor or the relevant domestic party shall report such case to the review working mechanism, in order to obtain the security review clearance before proceeding with the proposed foreign investment. However, as the New Security Review Measures are newly issued, there are still substantial uncertainties as to its interpretation and implementations in practice. 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 the NDRC 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 a holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity outside of the PRC 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 holding company outside of the PRC 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 Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for two consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect

the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections.

As an auditor of U.S. publicly traded companies and a PCAOB-registered accounting firm, the independent registered public accounting firm that issued the audit report included in this Annual Report 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 auditor is located in the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

PCAOB inspections are able to identify deficiencies in the inspected firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating our auditor's audits and quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections of our auditor.

The inability of the PCAOB to conduct an inspection of our auditor makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Accordingly, investors may have a lower level of confidence in our reported financial information and procedures and the quality of our financial statements than if our auditor were subject to PCAOB inspections.

Further, U.S. legislators and regulators have in recent years voiced concerns about risks associated with investing in companies that are based in or have substantial operations in emerging markets, including China. In particular, lawmakers have highlighted the increased risks associated with companies whose independent auditors are unable to be inspected by the PCAOB. As part of this continued focus in the United States on access to audit and other information currently protected by national law, in particular China's, on December 18, 2020, the U.S. president signed the HFCA Act into law. On November 5, 2021, the SEC approved the PCAOB's Rule 6100, Board Determinations Under the "Holding Foreign Companies Accountable Act." Rule 6100 provides a framework for the PCAOB to use to determine whether it is unable to inspect or investigate registered public accounting firms located in a jurisdiction outside of the United States because of a position taken by one or more authorities in that jurisdiction. On December 2, 2021, the SEC adopted final rules implementing the HFCA Act.

The HFCA Act requires the SEC to identify and maintain a list of U.S. listed companies whose audit reports are prepared by auditors that the PCAOB is unable to inspect or investigate completely because of restrictions imposed by the authorities in a jurisdiction outside of the U.S.. The HFCA Act also requires SEC-identified public companies to (i) submit documentation establishing that the company is not owned or controlled by a governmental entity in the jurisdiction that restricts PCAOB inspections and (ii) make certain additional disclosures in their SEC filings regarding, among other things, the fact that the PCAOB is unable to inspect its audit firm, the percentage of the company's shares owned by governmental entities in such jurisdiction outside of the U.S, whether governmental entities in such jurisdiction outside of the U.S. have a controlling financial interest with respect to the company, the name of any Chinese Communist Party members on the company's board of directors, and whether there are any charters of the Chinese Communist Party included in the company's organizational documents (including the text of any such charter). For issuers remaining on the SEC-identified companies list for two consecutive years, the securities of such company would be prohibited from trading on a U.S. national securities exchange, such as The Nasdaq Global Select Market, or in U.S. over-the-counter markets.

On June 22, 2021, the U.S. Senate passed a bill which, if passed by the U.S. House of Representatives and signed into law, would reduce the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two. On December 16, 2021, the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by local authorities. The PCAOB made these determinations pursuant to PCAOB Rule 6100, which provides a framework for how the PCAOB fulfills its responsibilities under the HFCA Act. On February 4, 2022, the U.S. House of Representatives passed the America Competes Act of 2022, which includes the exact same amendments as the bill passed by the Senate. The America Competes Act however includes a broader range of legislation not related to the HFCA Act in response to the U.S. Innovation and Competition Act passed by the Senate in 2021. The U.S. House of Representatives and U.S. Senate

will need to agree on amendments to these respective bills to align the legislation and pass their amended bills before the President can sign the amended bills into law. It is unclear when the U.S. Senate and U.S. House of Representatives will resolve the differences in the U.S. Innovation and Competition Act and the America Competes Act of 2022 bills currently passed, or when the U.S. President will sign on the bills to make the amendment into law, or at all. If this provision is enacted into law and the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act is reduced from three years to two, then our shares and ADSs could be prohibited from trading in the United States in 2023.

On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission and the Ministry of Finance of the People's Republic of China, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. The Statement of Protocol gives the PCAOB sole discretion to select the firms, audit engagements and potential violations it inspects and investigates and put in place procedures for PCAOB inspectors and investigators to view complete audit work papers with all information included and for the PCAOB to retain information as needed. In addition, the Statement of Protocol grants the PCAOB direct access to interview and take testimony from all personnel associated with the audits the PCAOB inspects or investigates. While significant, the Statement of Protocol is only a first step. Uncertainties still exist as to whether and how this new Statement of Protocol will be implemented. The PCAOB is also required to reassess its determinations discussed above by the end of 2022.

Our prior auditor for the fiscal years ended December 31, 2021 and 2020, Ernst & Young Hua Ming LLP, is an independent registered public accounting firm that issues the audit reports included elsewhere in the Original 20-F. The PCAOB previously identified Ernst & Young Hua Ming LLP as one of the registered public accounting firms that the PCAOB is unable to inspect or investigate completely and we were conclusively identified as a "Commission-Identified Issuer" on May 4, 2022. On December 15, 2022, the PCAOB announced that it was able to conduct inspections and investigations completely of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong in 2022. The PCAOB vacated its previous 2021 determinations accordingly. While vacating those determinations, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately reconsider the need to issue new determinations consistent with the HFCA Act and PCAOB's Rule 6100. On May 3, 2022, our Audit Committee (i) resolved that Ernst & Young Hua Ming LLP would resign as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to be filed with the SEC, effective on June 1, 2022 and (ii) approved the engagement of Ernst & Young LLP, located in the United States, as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting for the fiscal year ended December 31, 2022 to be filed with the SEC and the Company subsequently entered into an engagement letter with Ernst & Young LLP. However, there are no guarantees that engaging Ernst & Young LLP will remove us from being a "Commission-Identified Issuer". Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and making any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act.

The enactment of the HFCA Act and AHFCAA and the implications of any additional rulemaking efforts to increase U.S. regulatory access to audit information in China could cause investor uncertainty for affected SEC registrants, including us, and the market price of our ADSs could be materially adversely affected. Any actions that Legend Biotech takes in response to the HFCA Act and compliance with the requirements of the HFCA Act for so long as Legend Biotech remains an SEC-identified company may require Legend Biotech to incur additional legal, accounting and other expenses, which may be significant.

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 subsidiaries, Nanjing Legend Biotech Co., Ltd., or Legend Nanjing, and Hainan Chuanji Biotech Co., Ltd., or Legend Hainan, are currently considered to be foreign invested entities. Legend Hainan was established in October, 2021. As of the date of this Annual Report on Form 20-F, Legend Hainan is not engaged in substantive business operations in the PRC.

The latest version of the "negative list," namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2021), which was promulgated by the MOFCOM and the NDRC, became effective on January 1, 2022.The Negative List 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 Annual Report on Form 20-F, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" specified in the Negative List and the application of this regulation remains unclear. The Encouraged Industry Catalogue for Foreign Investment (2020), or the 2020 Encouraged Industry Catalogue, which was promulgated by the MOFCOM and the NDRC, became effective on January 27, 2021, provides that foreign investment is encouraged in the development and production of cell therapy drugs except in areas where foreign investment is prohibited. Further, the Technical Guidelines for Clinical Trials of Immune cell Therapy Products (Trial), or Technical Guidelines for Clinical Trials, which was published by the Center for Drug Evaluation of National Medical Products Administration, or the CDE, on February 10, 2021, provides that CAR-T, as a kind of immune cell therapy products, has the nature of gene therapy products. The Technical Guidelines for Clinical Trials was issued for sponsors' references, and is not compulsory or to identify the regulatory nature or classification of immune cell therapy products, and is subject to modifications and improvements from time to time. On December 3, 2021, the CDE published the Technical Guidelines for Non-clinical Research and Evaluation of Gene Therapy Products (Trial), or the Technical Guidelines for Gene Therapy Products, and Technical Guidelines for Non-clinical Research of Gene Modified Cell Therapy Products (Trial), or the Technical Guidelines for Gene Modified Cell Therapy Products, which became effective as of the date of promulgation. The Technical Guidelines for Gene Therapy Products provides that it is applicable to gene therapy products other than genetically modified cells therapy products, and genetically modified cells therapy products, such as CAR-T cell therapy products, shall refer to the Technical Guidelines for Gene Modified Cell Therapy Products, which was formulated according to the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial).

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" under the negative list. 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" under the negative list, Legend Nanjing would be prohibited from engaging in the research or development of such CAR-T cell therapies or other 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, a certain employee, located outside of the PRC, of our PRC subsidiary has not obtained required work permit, which may subject our PRC subsidiary to fines and penalty.

The market price of our ADSs and our business may be significantly affected by the U.S. Department of Commerce's Entity List.

On December 16, 2021, the U.S. Department of Commerce's Bureau of Industry and Security, or the BIS, issued a final rule adding 37 entities under 40 entries to its Entity List, which contains a list of names of certain persons outside of the U.S. (including businesses, research institutions, government and private organizations, individuals, and other types of legal persons) that are subject to specific license requirements for the export, re-export and/or transfer of specified items. According to a press release issued by the U.S. Department of Commerce on December 16, 2021, the BIS's actions were taken, in part, "to address the ongoing threats to U.S. national security and foreign policy presented by the People's Republic of China (PRC)'s efforts to develop and deploy biotechnology and other technologies for military applications and human rights abuses." Of the 40 entries that were added to the Entity List pursuant to the BIS's final rule, 34 are located in the PRC, and of such entries, 12 are biotechnology entities (i.e., one biotechnology entity together with 11 of its research institutes). Although we believe that we do not engage in any activity that the BIS's actions seek to address, there can be no assurance that we will not, in the future, be added to the Entity List.

If relations between China and the United States deteriorate, our business, operating results and financial condition could be adversely affected.

At various times during recent years, the United States and China have had significant disagreements over monetary, economic, political, environmental and social issues, and future relations between these two countries

may deteriorate. Changes in political conditions and changes in the state of China-U.S. relations are difficult to predict and could adversely affect our business, operating results and financial condition. Any deterioration in political or trade relations could harm our business. We cannot predict what effect any changes in China-U.S. relations may have on our ability to access capital or effectively do business in the United States and China.

Moreover, any political or trade controversies between the United States and China, whether or not directly related to our business, could cause investors to be unwilling to hold or buy our ADSs and consequently cause the trading price of our ADSs to decline. In addition, any adoption of more stringent rules or regulations in China related to monetary, economic, political, environmental or social issues, particularly as those matters relate to relations with the United States, could harm our business, financial condition or prospects.

Risks Related to Our Organizational Structure

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

As of March 1, 2022, Genscript controls a majority of the voting power of our outstanding ordinary shares. As a result, we are 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 have used these exemptions and we intend to 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. Therefore, Genscript has 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 ordinary shares. Any material transaction between us and Genscript or any other subsidiary of Genscript will be subject to our related party transaction policy, which requires 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.

As a result of being a public company, we have incurred costs and expect to continue to incur additional costs, and we may not manage to comply with our internal control procedures and corporate governance structures.

To comply with the requirements imposed on us as a public company, we have incurred, and expect to continue to incur, significant legal, insurance, accounting and other expenses that we did not as a private company. The increased costs may require us to reduce costs in other areas of our business. In addition, our board of directors, management and administrative staff are required to perform additional tasks. For example, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. We have invested, and intend to continue to invest, resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from research and development activities. These laws, regulations and standards 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, enforcement proceedings and higher costs necessitated by ongoing revisions to disclosure and governance practices, which could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

We currently 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 Act (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 Act of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, please refer to Exhibit 2.5 filed with this Annual Report on Form 20-F.

Provisions in our amended and restated memorandum and articles of association may prevent or frustrate attempts by our shareholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our ADSs may be lower as a result.

There are provisions in our amended and restated memorandum and articles of association that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other shareholders. For example, our board of directors has the authority to issue up to 1,000,000 shares of an additional class or classes of shares, which could include preference shares. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the other classes of shares without any further vote or action by our shareholders. The issuance of such shares may delay or prevent a change of control transaction. As a result, the market price of our ADSs and the voting and other rights of our shareholders may be adversely affected. An issuance of other classes of shares may result in the loss of voting control to other shareholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- shareholders are entitled to remove directors only for cause;
- shareholders are not permitted to take actions by written consent;
- shareholders must give advance notice to nominate directors or submit proposals for consideration at annual general meetings.

These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our ADSs.

Raising additional capital may cause dilution to our holders, 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, collaboration and license 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.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, holders of our ADSs will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. 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.

Risks Related to Our Securities

The trading price of our ADSs may be volatile.

The trading price of our ADSs has been and may continue 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 Annual Report, these factors include:

- the Commercialization of CARVYKTI™;
- 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;
- the investigation by the Authority into Genscript and Dr. Zhang;
- 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.

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, the market price of our ADSs could decline significantly.

Additionally, certain holders of ordinary shares, or their transferees, have rights, subject to some conditions, to require us to file (or, if filed, keep in effect) 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. Once the resale of these shares is registered, they can 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.

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 ADS holders in a timely manner, but we cannot assure you that ADS holders will receive voting materials in time to instruct the depositary to vote, and it is possible that such ADS holders, 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, holders of our ADSs may not be able to exercise their right to vote and may lack recourse if such ADSs are not voted as their holders request. In addition, ADS holders 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 a 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, such 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.

Holders of ADSs 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 on our ordinary shares, in the event we declare and pay any dividends, the depositary for the ADSs has agreed to pay to holders of ADSs 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. Holders of ADSs will receive these distributions in proportion to the number of our ordinary shares such holder's 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 Holders of ADSs 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 such holders. These restrictions may have an adverse effect on the value of ADSs.

An ADS holder's right to participate in any future rights offerings may be limited, which may cause dilution to such holder.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to ADS holder 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 ADS holder 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, holders of ADSs may be unable to participate in our rights offerings and may experience dilution.

Because we do not anticipate paying any cash dividends on our ADSs or ordinary shares in the foreseeable future, capital appreciation, if any, will be the sole source of gains for holders of our ADSs and ordinary shares, and these holders may never receive a return on their 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, holders of our ordinary shares and ADSs should not rely on an investment in these securities 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 and ordinary shares will be the sole source of gains for the foreseeable future for the holders of these securities. These factors could harm the value of our ADSs.

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 certain 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 or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares or ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares or ADSs.

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 ADSs, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from our initial public offering, follow-on offerings, and other fundraising activities in our business. Based on our operating history and the composition of our income and valuation of our assets, including goodwill, we do not believe we were a PFIC for our taxable year ending December 31, 2021. There can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. 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, including the current taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2021, and also expresses no opinion with regard to our expectations regarding our PFIC status for the current or future taxable years.

The tax consequences that would apply if we are 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.

As a result of the ownership of 50% or more of our stock by Genscript, which also owns 50% or more of one or more U.S. corporations, we and certain of our non-U.S. subsidiaries may be treated as "controlled foreign corporations" for U.S. federal income tax purposes. 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 us and each of our non-U.S. subsidiaries that 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 the controlled foreign corporation makes any distributions. In addition, a United States shareholder that realizes gain from the sale or exchange of shares in a controlled foreign corporation may be required to classify a portion of such gain as dividend income rather than capital gain. 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 furnish to any United States 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 Base Erosion and Profit Shifting Project of the Organisation for Economic Co-operation and Development, or the OECD, 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. The OECD has published a package of measures for reform as a product of the Base Erosion and Profit Shifting Project, which include the reallocation of global profits of large multinational companies to market jurisdictions based on customer location as well as the introduction of a global minimum tax. Many of the package's proposed measures require amendments to the domestic tax legislation of various jurisdictions. 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.

If equity research analysts 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 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.

Holders of ADSs may be subject to limitations on transfers of their 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.

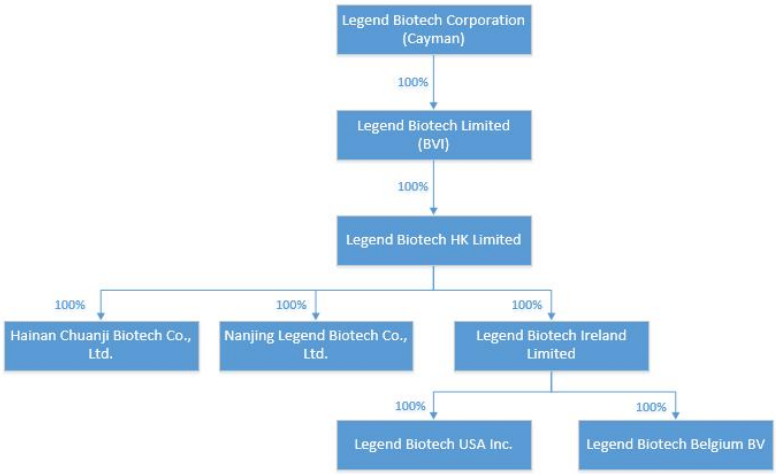
The market price of our ADSs may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal name is Legend Biotech Corporation and our commercial name is Legend Biotech. Our company was incorporated on May 27, 2015 as an exempted company in the Cayman Islands with limited liability under the Companies Act of the Cayman Islands. Legend Biotech is a Cayman Islands holding company and not a Chinese operating company. We operate through our operating subsidiaries located primarily in the United States, PRC and European Union. Our operations in the PRC, in addition to our business presence elsewhere in the world, are enabled by our subsidiaries based therein.

The following diagram illustrates our corporate structure, including our parent Cayman Islands holding company, subsidiaries, and consolidated affiliated entities, as of the date of this Annual Report on Form 20-F:



Our principal executive offices are located at 2101 Cottontail Lane, Somerset, NJ 08873, and our phone number is (737) 317-5050. 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. Our agent for service of process in the United States is Ying Huang, Ph.D., Chief Executive Officer, Legend Biotech Corporation, 2101 Cottontail Lane, Somerset, New Jersey 08873.

Our capital expenditures for the years ended December 31, 2021, 2020, and 2019 amounted to $44.5 million, $50.0 million, and $46.8 million, respectively. These expenditures primarily consisted of property, plant and equipment and collaboration assets. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance our research and development programs and grow our operations. We anticipate our capital expenditure in 2021 to be financed from our cash and cash equivalents on hand. Primarily, these capital expenditures will be made both in the United States and China, where our principal research and development facilities are currently located.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC and can be accessed at www.sec.gov. We maintain a corporate website at www.legendbiotech.com. The information contained in, or accessible from, our website or any other website does not constitute a part of this Annual Report on Form 20-F.

B. Business Overview

We are primarily 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 1,000 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, ciltacabtagene autoleucel, or cilta-cel (referred to as LCAR- B38M for purposes of our LEGEND-2 trial), 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. Clinical trial results achieved to date demonstrate that cilta-cel 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.

On February 28, 2022, cilta-cel was approved by FDA under the trademark CARVYKTI™ for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. We have established a sales, marketing and operational infrastructure to support the launch of CARVYKTI™ in the United States.

Cilta-cel has been granted breakthrough therapy designation by the FDA, Priority Medicines, or PRIME, designation, enabling accelerated assessment, by the EMA, and breakthrough therapy designation by the CDE. In January 2021, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA accepted a request for an accelerated assessment of the marketing authorization application, or MAA. Orphan Drug Designation has been granted for cilta-cel by the FDA, the European Commission, Japan Ministry of Health, Labour and Welfare, Switzerland Swissmedic, and South Korea Ministry of Food and Drug Safety. Submission of cilta-cel's MAA to the EMA for the treatment of RRMM was completed in April 2021.

On December 13, 2021, we announced new and updated results from the CARTITUDE clinical development program studying cilta-cel in the treatment of multiple myeloma, which were presented at the 63rd American Society of Hematology Annual Meeting and Exposition.

In our Phase 1b/2 CARTITUDE-1 trial, longer-term results in 97 patients with RRMM continued to show a high overall response rate, or ORR, of 98 percent. After 21.7 months of follow-up, 83 percent of patients treated with cilta-cel achieved a stringent complete response, or sCR, which was higher than the 67 percent sCR rate reported at a median of approximately 1 year of follow up. Further, 95 percent of patients achieved a very good partial response, or VGPR, or better. Median progression-free survival, or PFS, and median overall survival, or OS, have not been reached, but the 2-year PFS rate was 61 percent and the 2-year OS rate was 74 percent. Of the 61 patients evaluable for minimal residual disease, or MRD, 92 percent were MRD-negative at the 10-5 cutoff threshold. The two-year PFS rates in patients with sustained MRD negativity for at least 6 and 12 months were 91 percent and 100 percent, respectively. The longer-term data showed no new safety signals and there were no new events of cilta-cel-related neurotoxicity or movement and neurocognitive treatment emergent adverse events reported since the median approximate 1 year follow-up.

We also presented new results from our Phase 2 multicohort CARTITUDE-2 trial, which is evaluating cilta-cel safety and efficacy in various clinical settings for patients with multiple myeloma. Updated data from Cohort A of the trial examined the efficacy and safety of cilta-cel in 20 patients with progressive multiple myeloma after 1-3 prior lines of therapy and who are lenalidomide-refractory. At a longer median follow-up of 14.3 months, patients experienced early and deep responses with a manageable safety profile consistent with the CARTITUDE-1 trial. ORR was 95 percent, which included 85 percent of patients achieving CR or better and 90 percent achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.6 months. The 6-month and 12-month PFS rates were 95 percent and 84 percent, respectively.

The first data from Cohort B of the CARTITUDE-2 trial was also presented. Cohort B included 19 patients who were in early relapse after initial therapy that included a proteasome inhibitor, or PI, and immunomodulatory drug, or IMiD. Data showed early and deep responses with a manageable safety profile. At a median follow-up of 10.6 months, ORR was 95 percent, which included 79 percent of patients achieving CR or better and 90 percent of patients achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.5 months. The 6-month and 12-month PFS rates were 90 percent and 84 percent, respectively.

The safety profile seen in CARTITUDE-2 Cohorts A and B were consistent with data previously reported from CARTITUDE-1. CRS occurred in 95 percent of patients in Cohort A and 84 percent of patients in Cohort B, which were mostly grades 1/2 with median time to onset of 7 to 8 days and median duration of approximately 4 days.

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, cilta-cel, 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. Following FDA's approval of CARVYKTI™, we are continuing to develop cilta-cel for potential further improvements in the treatment of 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.

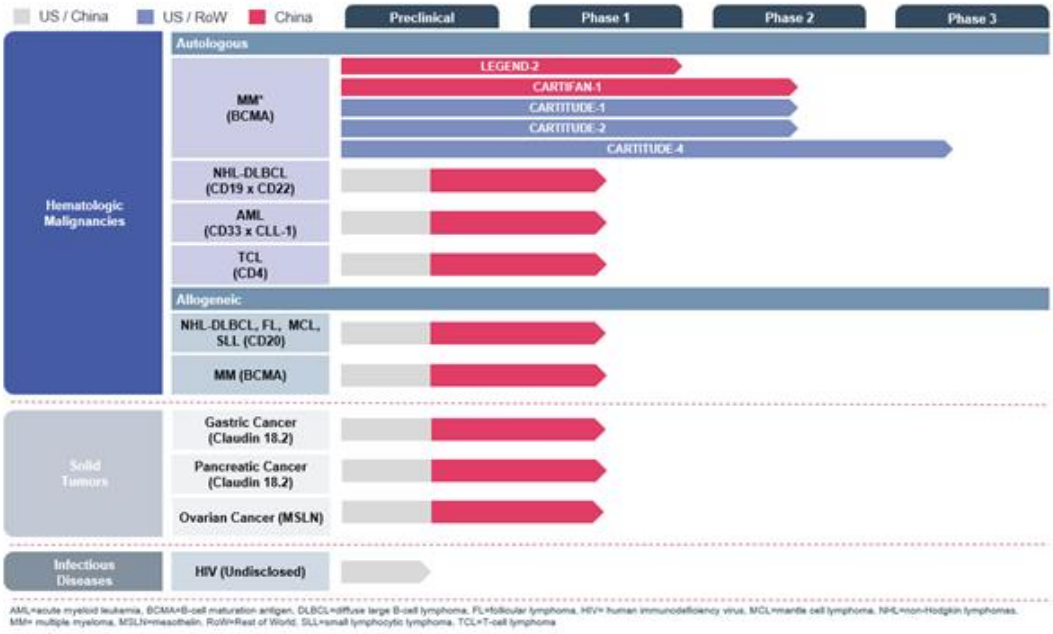
We believe that cilta-cel has the potential to transform the treatment of MM. Following the results from our Phase 1 clinical trial in China, which we refer to as LEGEND-2, we are conducting a Phase 2 registrational trial of cilta-cel in RRMM patients in China, which we refer to as CARTIFAN-1 in support of our planned submission in China. Based on feedback from China's Center for Drug Evaluation, or CDE, we intend to provide data from more Chinese patients receiving cilta-cel in order to support the submission. We're continuing to work with CDE in preparation for the submission. Further, we continue to conduct long-term follow-up activities for our CARTITUDE-1 Phase 1b/2 registrational trial of cilta-cel in RRMM patients in the United States and Japan.

In conjunction with our collaboration partner Janssen, we submitted a cilta-cel MAA to the EMA in April 2021 and an NDA to the PMDA in December 2021. We extended the timeline for the submission of cilta-cel NDA to CDE in China. Based on feedback from CDE, we intend to provide data from more Chinese patients receiving cilta-cel as manufactured through the current process in order to support the application.

In addition to the trials we are conducting to support our initial regulatory submissions, we are conducting multiple clinical trials to evaluate cilta-cel as an earlier line of therapy for MM. In November 2019, we and our strategic partner Janssen began enrolling an aggregate of approximately 160 patients in a Phase 2 multicohort trial of cilta-cel in the United States, Europe and Israel, which we refer to as CARTITUDE-2, in patients with MM in various clinical settings such as in early relapse patients or as a front-line therapy. Based on those results, we intend to explore expanding our investigation in those patient populations to potentially support regulatory approval submissions upon the agreement of regulatory agencies. In addition, the Phase 3 CARTITUDE-4 clinical trial, which includes approximately 400 patients in the United States, Europe, Australia, Japan and Israel, completed enrollment during October 2021. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in Revlimid- refractory MM. Furthermore, we initiated the Phase 3 CARTITUDE-5 clinical trial during August 2021, targeting enrollment at approximately 650 patients, including sites in the United States, Europe, Canada, Australia, Korea and Japan. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in newly diagnosed MM patients for whom hematopoietic stem cell transplant is not planned as an initial therapy.

We have established a global collaboration with Janssen for cilta-cel, 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, an additional $200.0 million in milestone payments through December 31, 2021, and a further $50.0 million in milestone payments from December 31, 2021 to the date of this Annual Report.

In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including, gastric cancer, and T cell Lymphoma, or TCL, both of which are currently in investigator-initiated Phase 1 clinical trials, or IITs, in China. TCL is also in a phase 1 clinical trial under an IND in the United States. In addition, we are developing CAR-T product candidates targeting CD20/CD22/CD19 for the treatment of Non-Hodgkins Lymphoma, or NHL, diffuse large B-cell lymphoma, or DLBCL, and acute lymphoblastic leukemia, or ALL. We also have several allogeneic platforms under development targeting BCMA for the treatment of multiple myeloma, or MM. Allogeneic cells are cells from a donor. Furthermore, we have several product candidates in early preclinical for the treatment of solid tumors as well as infectious diseases. Our pipeline of product candidates is summarized in the table below.



*In collaboration with Janssen. †Phase 1 IIT in China. ‡Multiple allogeneic platforms under development.

BCMA = B-cell maturation antigen; HCC = hepatocellular carcinoma; NSCLC = non-small cell lung cancer; GPC3 = Glypican-3; SCLC = small cell lung cancer; DLL3 = delta-like ligand 3; HIV = human immunodeficiency virus.

We are led by Ying Huang, Ph.D., our Chief Executive Officer, Chief Financial Officer and a member of our Board of Directors, who 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), and also Lori Macomber, our Vice President, Finance. We have assembled a team with broad experience in biopharmaceutical drug discovery, development and commercialization.

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 cilta-cel through registrational trials and obtain approval for the treatment of RRMM globally.** We believe we have demonstrated that cilta-cel can deliver deep and durable anti-tumor responses, resulting in increased survival in RRMM patients. On February 28, 2022, cilta-cel was approved by FDA under the trademark CARVYKTI™ for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. We also plan to seek regulatory approval of cilta-cel in other key geographies, including in Europe, China and Japan. Furthermore, we intend to aggressively pursue clinical development of cilta-cel 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 cilta-cel designed to support regulatory approvals in the major markets of 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 cilta-cel 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 antigen 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, cilta-cel, 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 cilta-cel.

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 370 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.

The 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 establishing a European manufacturing site for future supply.

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

Cilta-cel for the Treatment of Multiple Myeloma

Cilta-cel is a CAR-T cell therapy that we are developing for the treatment of MM. In a Phase 1 first-in-human clinical trial (LEGEND-2), treatment of 57 RRMM patients with LCAR-B38M CAR-T cells 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 • ≥90% reduction in serum M-protein plus urine M-protein level <100 mg/24 h
PR	• ≥50% reduction of serum M-protein plus reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h • If the serum and urine M-protein are unmeasurable, a ≥50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria and if serum-free light assay is also unmeasurable, ≥50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma-cell percentage was ≥30% • In addition to these criteria, if present at baseline, a ≥50% 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 cilta-cel in RRMM patients in China (CARTIFAN-1) and a Phase 1b/2 trial in RRMM patients in the United States and Japan (CARTITUDE-1). The CARTITUDE-1 Phase 1b/2 registrational trial has completed enrollment. For the Phase 1b portion of the CARTITUDE-1 trial, the primary endpoint was to characterize safety and establish the dose and, for the Phase 2 portion, the primary endpoint was to evaluate efficacy by ORR. Secondary endpoints included efficacy, duration of and timing to response, progression-free survival, overall survival, pharmacokinetic and pharmacodynamic markers, and presence of anti-JNJ-4528 antibodies. In the United States, 97 patients were treated with cilta-cel in the combined Phase 1b/2 CARTITUDE-1 trial. At a median follow-up of 21.7 months (data as of July 22, 2021), the overall response rate was 98% which deepened over time highlighted by a stringent complete response (sCR) rate of 83%. The median time to first response was 1 month and the median time to best response was 2.6 months. The median duration of response (mDOR), median progression free survival (mPFS) and median overall survival (mOS) were not reached with a 2-year PFS rate of 61%. The most common hematologic adverse events observed were neutropenia (81%), thrombocytopenia (79%), leukopenia (62%) and lymphopenia (53%). With respect to adverse events of special interest, cytokine release syndrome (CRS) of any grade occurred in 95% of patients and neurotoxicity of any grade (including movement and neurocognitive adverse events) occurred in 21% of patients. Cilta-cel has a manageable safety profile with no new safety signals observed with longer follow-up.

Cilta-cel has been granted breakthrough therapy designation by the FDA, PRIME designation, enabling accelerated assessment, by the EMA, and breakthrough therapy designation by CDE. In January 2021, the CHMP also accepted a request for an accelerated assessment of the MAA. Orphan drug designation has been granted for cilta-cel by the FDA, the European Commission, Japan Ministry of Health, Labour and Welfare, Switzerland Swissmedic, and South Korea Ministry of Food and Drug Safety. A rolling submission of the cilta-cel BLA to the FDA was initiated in December 2020 and completed in March 2021. A cilta-cel MAA was submitted to the EMA in April of 2021 and a NDA was submitted to PMDA in December 2021 for the treatment of RRMM. We extended the timeline for the submission of the cilta-cel NDA to the CDE in China. Based on feedback from the CDE, we intend to provide data from more Chinese patients receiving cilta-cel as manufactured through the current process in order to support the application.

Clinical results received to date demonstrate that cilta-cel has the potential to deliver deep and durable anti- tumor responses in RRMM patients with a manageable safety profile. We have not halted any of our clinical trials

with respect to cilta-cel due to the COVID-19 pandemic. In addition, our manufacturing facilities in the United States and China are functional and we are fully supportive if a patient, a physician and a medical center are ready to enroll or dose a patient. We have also established a COVID-19 operations team to monitor patient's scheduled visits and determine mitigations, including engaging in regular communications with physicians and medical centers.

In 2017, we entered into a global collaboration with Janssen for cilta-cel, 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, an additional $200.0 million in milestone payments through December 31, 2021, and a further $50.0 million in milestone payments from December 31, 2021 to the date of this Annual Report.

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. For 2021, the American Cancer Society projected that about 34,920 new MM cases would be diagnosed and about 12,410 deaths were expected to occur in the United States.

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 55.6 percent. Treatment choices for MM vary with the aggressiveness of the disease and overall health of the patients.

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

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

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

BCMA

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

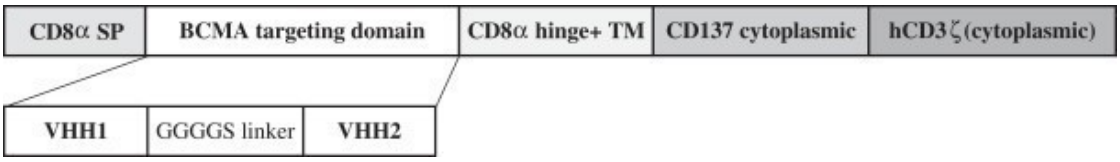
Tissue distribution of BCMA, as determined using quantitative analysis of transcription levels, show that BCMA is generally expressed only in lymphoid cells and not in other tissues in the body. The expression level of BCMA in plasmacytomas, or MM tumors, is hundreds to thousands of times higher than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

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

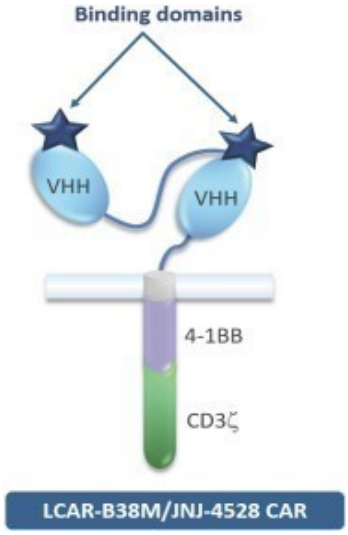
Our Solution, Cilta-cel

Cilta-cel 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 cilta-cel 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.

Cilta-cel CAR construct



CAR construct of cilta-cel has two antigen-binding domains



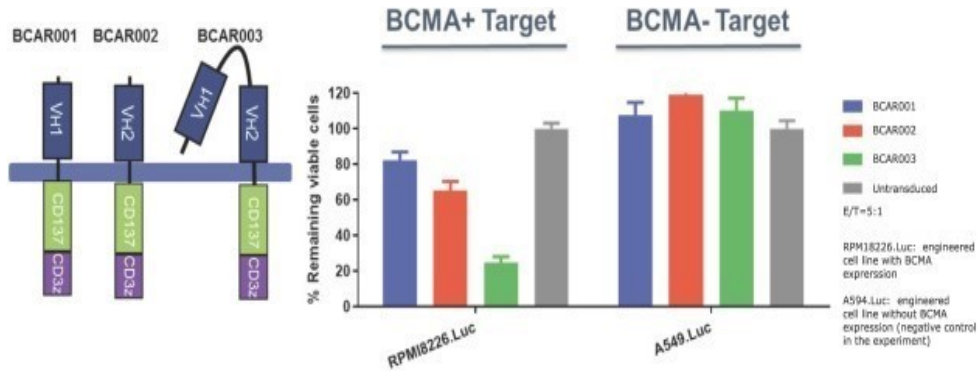
Same antigen dual binding domain CAR

We believe cilta-cel 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)

LEGEND-2 is a first-in-human investigator-initiated phase 1 study in China to evaluate the safety of LCAR-B38M CAR-T cells as well as provide initial proof-of-concept efficacy in patients with relapsed or refractory multiple myeloma. Patient enrollment in this study began in 2016 and accrued a total of 74 patients across 4 academic sites in China. Data from the highest enrolling site (Xi'an) was previously presented at the ASH 2019 Annual Meeting. Of the 57 patients enrolled at the XI'an site with a median follow-up of 25 months, the overall median progression-free survival (mPFS) was 19.9 months and 28.2 months for those patients achieving a complete response (CR). The median overall survival (mOS) was 36.1 months and not estimable for those patients achieving a CR. In this study, LCAR-B38M displayed a safety profile consistent with other safety reports of BCMA-targeting CAR-T therapies. Cytokine release syndrome and cytopenias were the most observed adverse events in this study and long-term follow-up data collection is still ongoing.

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, CARTITUDE-4 and CARTITUDE-5 trials.

CARTIFAN-1 (China)

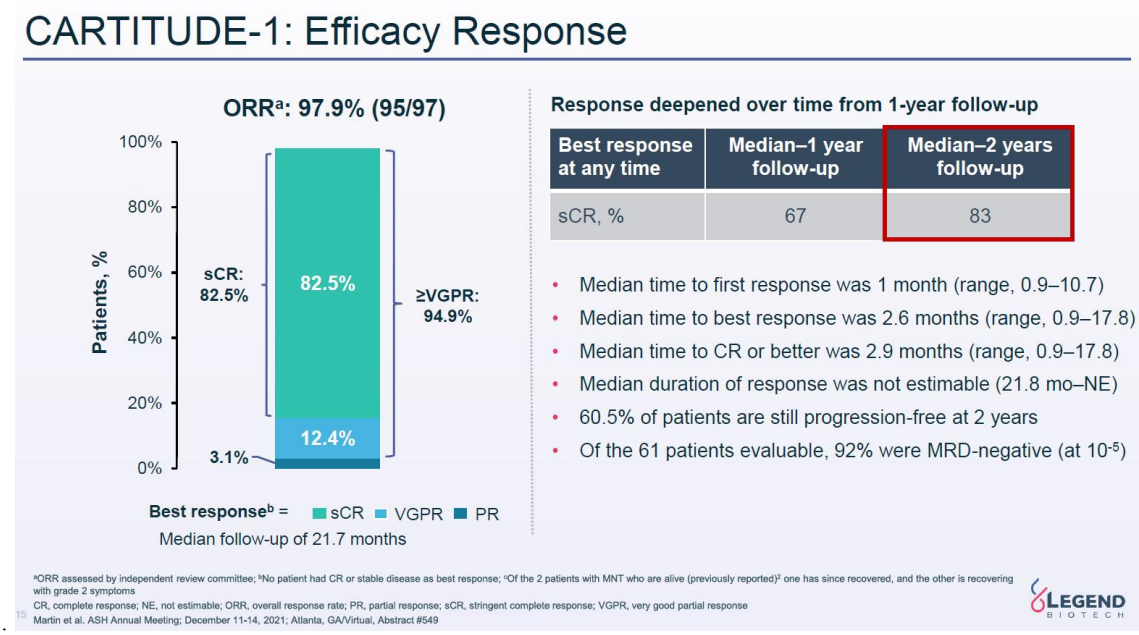
We have completed enrolling RRMM patients in a pivotal Phase 2 trial, which we refer to as CARTIFAN-1, involving 8 sites in China. The primary endpoint of this trial is ORR. We extended the timeline for the submission of the cilta-cel NDA to CDE in China. Based on feedback from CDE, we intend to provide data from more Chinese patients receiving cilta-cel as manufactured through the current process in order to support the application.

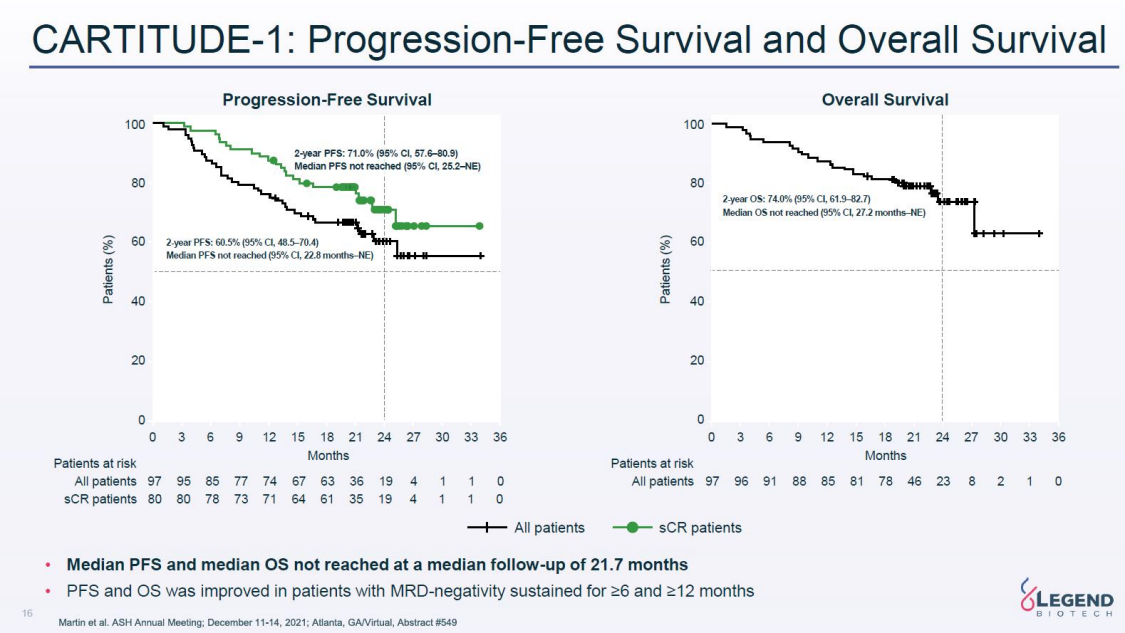
CARTITUDE-1 (United States and Japan)

Together with Janssen, we have completed enrollment of patients in a Phase 1b/2 clinical trial of cilta-cel, across 17 sites in the United States and 4 sites in Japan and 97 patients had been dosed in the Phase 1b/2 trial in the United States. These 97 patients had failed a median of six prior lines of therapies (with a range of 3-18 prior lines of therapies). All patients were exposed to immunomodulatory drugs, proteasome inhibitors and anti-CD38 therapies, and 99 percent of patients were refractory to last line of therapy. For the Phase 1b portion of the CARTITUDE-1 trial, the primary endpoint was to characterize safety and establish the dose and for the Phase 2 portion, the primary endpoint was to evaluate efficacy by overall response rate (ORR). Secondary endpoints included efficacy, duration of and timing to response, progression-free survival, overall survival, pharmacokinetic and pharmacodynamic markers, and presence of anti-JNJ-4528 antibodies. For the CARTITUDE-1 trial, patients received cilta-cel infusion following apheresis and lymphodepletion with cyclophosphamide and fludarabine daily for three days. The median administered dose of cilta-cel was 0.71 x 106 CAR+ viable T cells/kg (range 0.51 – 0.95 x 106).

We have completed enrolling patients in the Phase 2 portion of the CARTITUDE-1 trial and the latest results from the combined Phase 1b/2 CARTITUDE-1 study were presented at the 2021 American Society of Hematology Annual Meeting. In collaboration with Janssen, we intend to present additional data from the CARTITUDE-1 trial at a major medical conference in 2022.

As of July 22, 2021 (median follow-up of 21.7 months), 97 patients with RRMM continued to show a high overall response rate (ORR) of 98%. with 83% of patients achieving a stringent complete response (sCR). Median progression-free survival (mPFS), and median overall survival (mOS), have not been reached, but the 2-year PFS rate was 61% and the 2-year OS rate was 74%. Of the 61 patients evaluable for minimal residual disease (MRD), 92% were MRD-negative at the 10^{-5} cutoff threshold. The two-year PFS rates in patients with sustained MRD negativity for at least 6 and 12 months were 91% and 100%, respectively. The longer-term data showed no new safety signals and there were no new events of cilta-cel-related neurotoxicity or movement and neurocognitive treatment emergent adverse events reported since the median approximate one year follow-up.





Collectively, we believe these results demonstrate that cilta-cel has a manageable safety profile at the recommended Phase 2 dose and can deliver early, deep, and durable responses in heavily pretreated RRMM patients.

Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, the rolling submission of the cilta-cel BLA to the FDA was initiated in December 2020 and completed in April 2021. A cilta-cel MAA was submitted to EMA in April 2021 and an NDA was submitted to PMDA in December 2021.

CARTITUDE-2 (United States, Belgium, France, Germany, Netherlands, Spain, Israel)

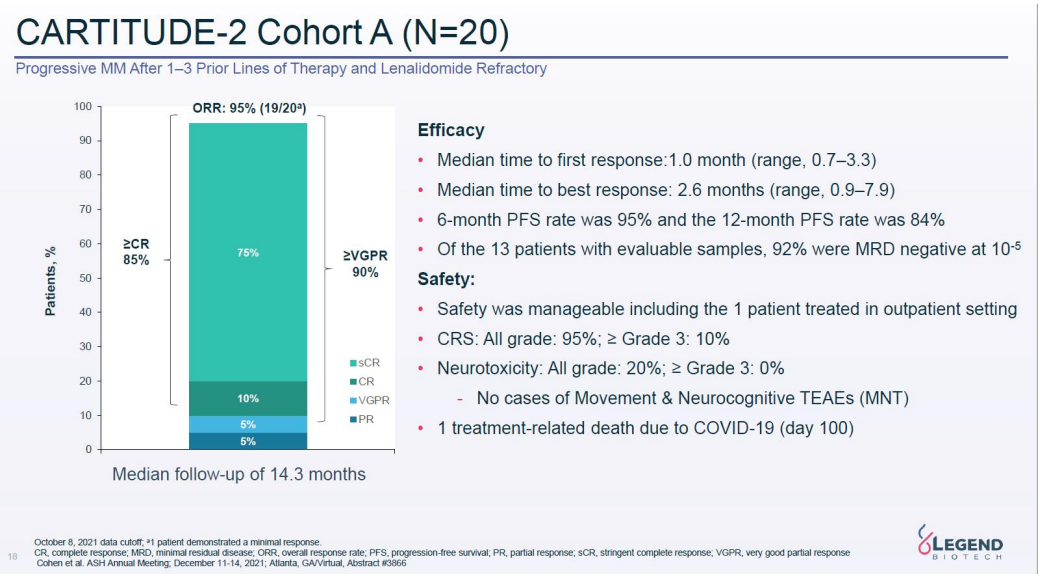
We and Janssen began enrolling patients in November 2019 in a multi-cohort, open-label Phase 2 trial of JNJ-4528 in the United States, Europe and Israel, which we refer to as CARTITUDE-2. CARTITUDE-2 consists of the following six cohorts, with enrollment of approximately 157 patients:

- Treatment of patients with progressive MM with cilta-cel after one to three prior lines of therapy
- Treatment of MM patients with cilta-cel with early relapse after a front-line therapy
- Treatment of RRMM patients with cilta-cel that have failed therapy with a proteasome inhibitor, immunomodulatory therapy, daratumumab, and anti-BCMA therapy
- Treatment of MM patients with cilta-cel and lenalidomide who have not achieved a CR after HSCT
- Treatment of newly diagnosed MM patients, transplant was not planned
- Treatment of newly diagnosed MM patients with standard risk disease

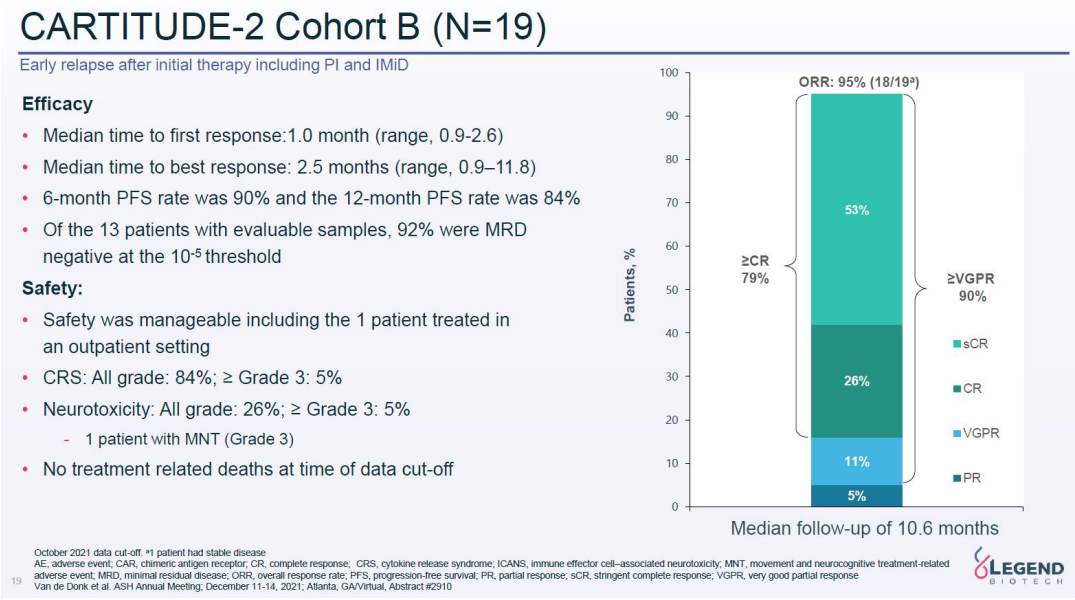
The primary endpoint in each cohort of this trial is the percentage of patients with negative MRD one year after treatment. Based on the results of each cohort, we intend to explore expanding our investigation in those patient populations to potentially support regulatory approval submissions upon the 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. In collaboration with Janssen, we intend to present additional data from the CARTITUDE-2 trial at major medical conferences in 2022.

Cohort A of the study evaluated the efficacy and safety of cilta-cel in 20 patients with progressive MM after 1-3 prior lines of therapy and were refractory to lenalidomide. As of October 8, 2021 (median follow-up of 14.3 months), the overall response rate (ORR) was 95% with a complete response (CR) or better rate of 85%. Median time to first response was 1.0 month and the median time to best response was 2.6 months respectively. The median DOR was not reached and the 6-month PFS rate was 95% and the 12 month PFS rate was 84%. Of MRD-evaluable patients (n=13), 92.3% were MRD-negative at 10^{-5}. Hematologic adverse events in ≥20% of patients were neutropenia, thrombocytopenia, anemia, lymphopenia and leukopenia. CRS occurred in 95% of patients and CAR T-cell neurotoxicity occurred in 20% of patients. Three patients (15%) had immune effector cell associated neurotoxicity syndrome (ICANS) with no movement and neurocognitive treatment emergent adverse events observed. One death occurred due to COVID-19 (assessed as treatment-related by the investigator).



Cohort B of the study evaluated the efficacy and safety of cilta-cel in 19 patients with early relapse MM after a front-line therapy. As of October 8, 2021 (median follow-up was 10.6 months), the overall response rate was 95% with 79% of patients achieved ≥ CR. The median time to first response was 1 month and median time to best response was 2.5 months. Of patients who were MRD-evaluable (n=13), 12 patients (92.3%) were MRD negative.. The hematologic TEAEs that were observed in approximately 20% of patients included neutropenia, thrombocytopenia, anemia, lymphopenia and leukopenia. CRS occurred in 16 (84.0%) patients, And immune effector cell associated neurotoxicity syndrome (ICANS) occurred in 1 patient. One patient experienced movement and neurocognitive TEAEs on day 38 post cilta-cel infusion.



CARTITUDE-4 (Australia, Austria, Belgium, Denmark, France, Germany, Italy, Israel, Japan, Republic of Korea, Netherlands, Poland, Spain, Sweden, United Kingdom, United States)

We and Janssen are conducting a 400 patient, randomized, open-label Phase 3 trial of cilta-cel in Revlimid- refractory MM patients who received one to three prior lines of therapy, which we refer to as CARTITUDE-4. Patients will be randomized 1:1 to receive standard of care (investigator choice between pomalidomide/ bortezomib/dexamethasone or daratumumab/pomalidomide/dexamethasone) or be treated with a single administration of cilta-cel. The primary endpoint of this trial will be progression free survival.

CARTITUDE-5 (Argentina, Australia, Austria, Belgium, Brazil, Canada, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Israel, Japan, Republic of Korea, Netherlands, Norway, Poland, Portugal, Russian Federation, Spain, Sweden, Switzerland, United Kingdom, United States)

We and Janssen are conducting a 650 patient, randomized, open-label, global, multicenter, Phase 3 trial in patients with newly diagnosed MM, which we refer to as CARTITUDE-5. Patients will be randomized 1:1 to receive standard of care with VRd induction followed by lenalidomide (Revlimid), and dexamethasone maintenance or VRd induction followed by a single administration of cilta-cel (no maintenance). The primary endpoint of this trial will be progression free survival.

Future Clinical Plans

Based on the current results which demonstrated that cilta-cel 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 cilta-cel 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, the FDA has cleared the IND application for LB1901 in relapsed or refractory TCL in December 2020. We initiated a Phase 1 clinical trial of LB1901 in relapsed or refractory TCL in the United States in 2021.

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

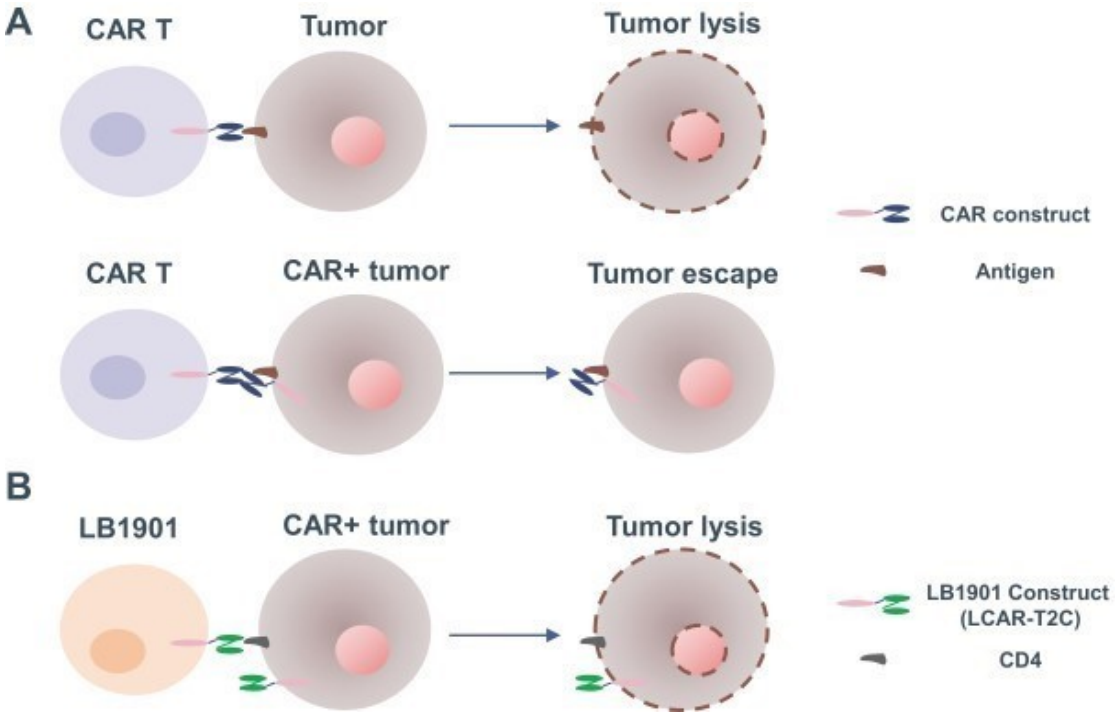
LB1901 is an investigational autologous anti-CD4 CAR-T cell product candidate containing an antibody binding domain derived from a human immunoglobulin transgenic mouse. The LB1901 CAR construct consists of a human CD8α SP, scFv CD4-targeting domain, a CD8α hinge + TM domain, a CD137 (4-1BB) costimulatory 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 patient 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. In addition, the manufacturing process of LB1901 is enhanced by using enriched CD8 T cells for transduction.

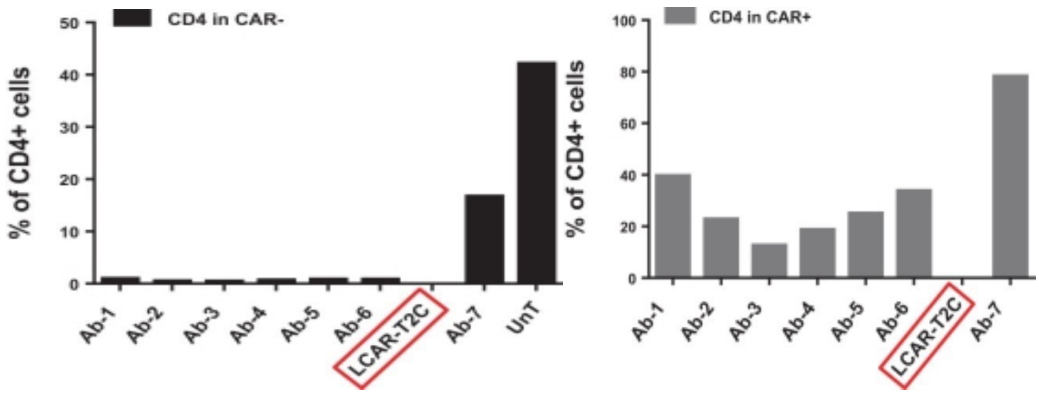
LB1901 was selected to avoid resistance due to inadvertent transduction of the CAR construct into tumor cells



Preclinical Data

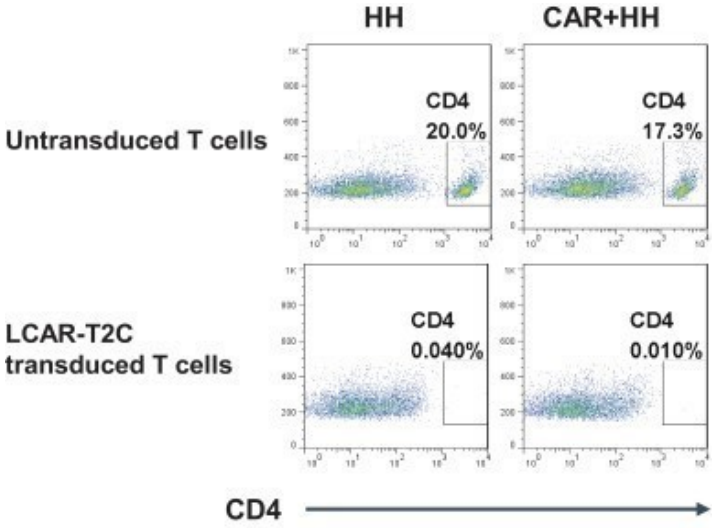
In a preclinical study, we observed that LB1901 as well as a number of other CAR constructs that we tested led to potent killing of T cells expressing CD4. LB1901, however, was the only CAR construct we tested that eliminated CD4 T cells into which the CAR construct was inserted.

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



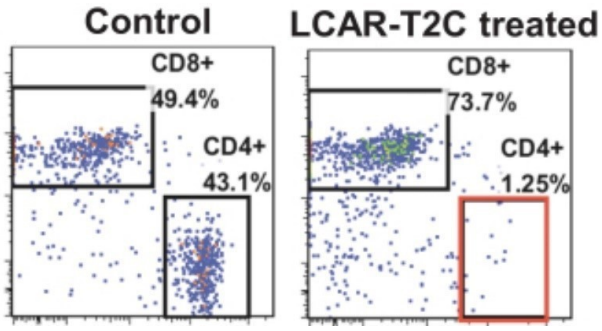
To confirm the ability of LB1901 to effectively target CD4 tumor cells that also express the CAR construct, we deliberately transduced HH, a CD4+ human tumor cell line derived from a patient with CTCL, with the LB1901 CAR construct. The preclinical results showed that LB1901 has the ability to eliminate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



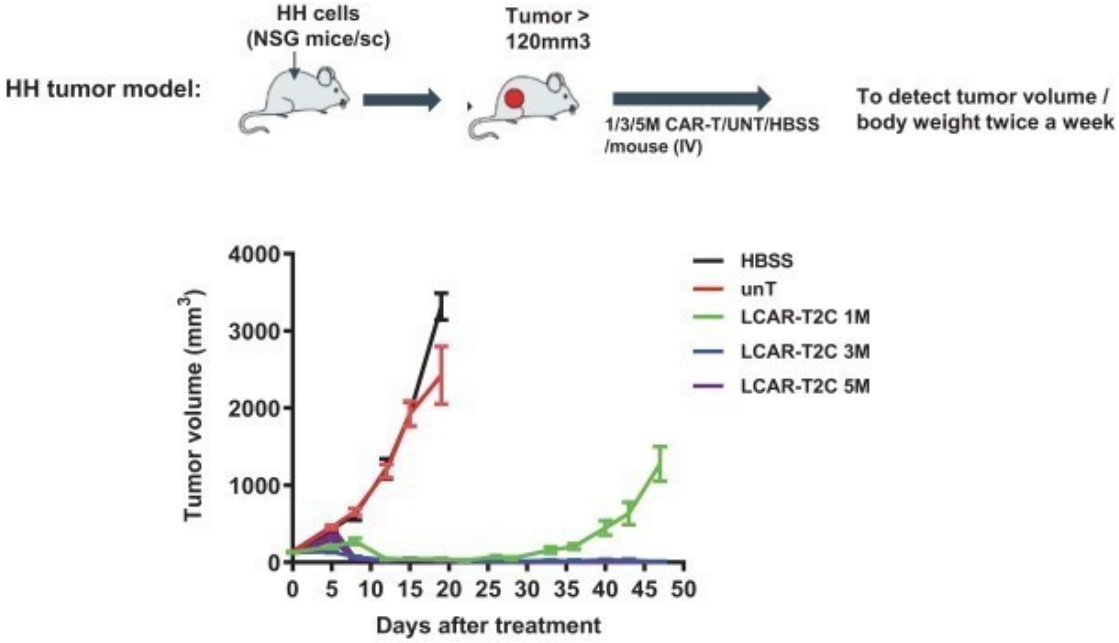
We have observed that LB1901 leads to selective killing of multiple CD4+ T cell lines. We have also observed that CD4+ T cell killing occurs in humanized mice treated with LB1901. In untreated mice, the CD4+ cells represented 43.1 percent of T cells. After treatment with LB1901, the percentage of CD4+ 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, the FDA has cleared the IND application for LB1901 in relapsed or refractory T cell lymphoma in December 2020. We expect to initiate a Phase 1 clinical trial of LB1901 in relapsed or refractory TCL in the United States in 2021.

LB1901 Recent Events

On February 11, 2021, we were informed by the FDA via e-mail communication that our Phase 1 clinical trial for LB1901 had been placed on clinical hold. At that time, one patient has been dosed in the clinical trial. Before receiving the FDA's communication, we had, in accordance with the protocol, paused the clinical trial due to low CD4+ T-cell counts in the patient's peripheral blood and notified the FDA. We subsequently received an official clinical hold letter from FDA dated March 1, 2022. In the letter, FDA stated that the reason for the hold is because the related IND does not contain sufficient information required by 21 CFR 312.23 to assess the risks to subjects.

Other Ongoing Investigator-Initiated and Preclinical Programs in China

In addition to cilta-cel and LB1901, we have a broad portfolio of product candidates, both autologous and allogeneic, 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

We are evaluating an autologous CAR-T therapy targeting GPC3 in a Phase 1 single arm, open-label investigator-initiated trial in patients with relapsed and refractory B-cell lymphoma.

We are evaluating an autologous CAR-T therapy targeting CD33 and CLL-1 in a Phase 1 single arm, open-label investigator-initiated trial in patients with advanced hepatocellular carcinoma.

We are evaluating an autologous CAR-T therapy targeting claudin 18.2 in a Phase 1 single arm, open-label investigator-initiated trial in patients with advanced gastric cancer and pancreatic ductal adenocarcinoma.

We are evaluating an autologous CAR-T therapy in targeting mesothelin in a Phase 1 single-arm, open-label investigator initiated trial in patients with relapsed or refractory epithelial ovarian cancer.

We are evaluating 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 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.

In addition, we have developed an allogenic gamma delta (γδ) T cell product candidate targeting BCMA. We are evaluating the allogenic gamma delta T therapy in targeting BCMA in a Phase 1, single-arm, open-label investigator initiated trial in patients with relapsed or refractory multiple myeloma.

We are also developing an allogeneic CAR-NK cell product candidate targeting BCMA.

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 cilta-cel.

Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize cilta-cel. We and Janssen will collaborate to develop and commercialize cilta-cel 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 cilta-cel. 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 paid us an upfront fee of $350.0 million and we were eligible to receive up to an additional $1.35 billion in milestone payments from Janssen. Of the $1.35 billion, we may not receive up to $280 million due to mutually agreed upon modifications to our clinical development plan that resulted in the decision to not conduct certain trials as originally planned. We have previously received the following milestone payments:

- $25 million, $30 million, and $30 million in January 2019, September 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial,
- a milestone payment of $25 million in September 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%,
- a milestone payment of $75 million in January 2021 in connection with the initiation of a rolling submission of a Biologics License Application to the U.S. FDA, for cilta-cel and

- a milestone payment of $15 million in July 2021 in connection with the submission of a Marketing Authorization to the EMA; and
- milestone payments of $50 million during February 2022 in connection with the submission of an NDA to the PMDA in Japan and the enrollment of a specified numbers of patients in our CARTITUDE-5 clinical trial.

Additionally, we are eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $695 million consisting of $485 million for the achievement of specified future development and regulatory milestones and $210 million for the achievement of specified net trade sales milestones.

Furthermore, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. Outstanding advances accrue interest at the London Interbank Offered Rate (LIBOR) published by the Wall Street Journal plus 2.5%. Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the collaboration and license agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the collaboration and license agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest. As of December 31, 2021, the aggregate outstanding principal amount of such advances and interest were approximately $119.7 million and $0.8 million, respectively.

During the term of the Janssen Agreement neither we nor Janssen may develop or commercialize cilta-cel 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 cilta-cel 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 cilta-cel without compensation to Janssen.

In connection with the Jansen Agreement, Legend Biotech and Janssen entered into the Interim Product Supply Agreement dated as of February 28, 2022, or the IPSA, pursuant to which Legend Biotech will supply cilta-cel to Janssen for clinical and commercial use worldwide (excluding Greater China). Under the IPSA, Janssen pays Legend Biotech a transfer price for supplied product based on the total costs necessary to produce and supply such product. Ultimately, however, the cost for commercial supply and clinical supply of product are shared equally by Legend Biotech and Janssen as "Allowable Expenses" and "Development Costs," respectively, under the Collaboration Agreement. The IPSA will remain in effect until the earlier of (1) the 45th day after marketing authorization for cilta-cel is granted by the European Medicines Agency and (2) the date determined by the joint manufacturing committee, or JMC, that has been established under the Janssen Agreement. The IPSA will also terminate if the Collaboration Agreement expires or is terminated. We expect to enter into a product supply agreement with Janssen that will replace the IPA.

Raw Materials

We currently source certain biological materials – such as cells, chemicals, water, cytokines, vectors, nucleic acids, antibodies, medium, serum, buffers —that are necessary to produce our product candidates from specialized third parties. We acquire these raw and starting materials through service agreements and do not systematically have

long-term supply contracts in place. However, we believe that competitive pricing is achieved because there are a number of potential long-term replacements to each of our suppliers. Generally, the prices of the principal biological raw and starting materials that we purchase are stable or fluctuate within a limited range. To the extent that we are exposed to price fluctuations, we generally do not expect, in the near term, to be able to pass on cost increases because of the early development stage of our product candidates.

Commercialization

We have established a sales, marketing and operational infrastructure to support the launch of CARVYKTI™ in the United States. According to our collaboration and license agreement with Janssen, 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 cilta-cel in all countries excluding the United States and Greater China in accordance with a specified plan, which will be developed with involvement of our senior commercial representative. 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 commercial strategies for each product candidate. These strategies may include further expansion of our external sales organization, entering into joint marketing collaboration agreements with other drug development companies, or out-licensing products to other drug development companies.

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 candidates and platform technologies. As of December 31, 2021, we own 13 issued patents covering our clinical and preclinical products and our patent portfolio for such products is currently comprised of 72 pending patent applications around the world. 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 Item 3.D. “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 Item 3.D. "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 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 Item 3.D. "Risk Factors—Risks Related to Our Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Item 3.D. Risk Factors—Risks Related to Our 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 cilta-cel BCMA product candidate. A total of 85 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. As of December 31, 2021, we have obtained 13 granted patents regarding to cilta-cel (including two U.S. patents, two Chinese patents, two Australian patents, two Japanese patents, two Yemeni patents, two South African patents and one Malaysian patent), two U.S. pending patent applications, and 70 pending patent application outside of the United States. If issued, composition of matter claims issuing from these applications are projected to expire in 2036 and 2037.

Regarding cilta-cel BCMA-targeting CAR-T cell therapy for multiple myeloma, we own one non-provisional PCT application outside the United States filed in December 2021 and one provisional PCT application outside the United States filed in November 2021. Janssen is our co-applicant for these applications. If issued, composition of matter claims issuing from these applications are projected to expire in 2041 and 2042.

Regarding our LB1901 CD4 product candidate, we own one patent application outside of the United States and one published PCT application filed in July 2019 that in January 2021 entered the national phase, including in the United States, Greater China, Europe, South Korea, Japan, Singapore and Australia. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

Regarding our MSLN product candidate, we own one patent application outside of the United States and one pending PCT application filed in August 2019 that in February 2021 entered the national phase, including in the United States, Greater China, Europe, South Korea, Japan, Canada, Israel, Singapore and Australia. If issued, composition of matter claims issuing from this application are projected to expire in 2039 and 2040.

Regarding our HIV product candidate, we own one patent application outside of the United States, one published PCT application filed in July 2019 that in January 2021 entered the national phase, two published PCT applications filed in May 2020 that in November 2021 entered the national phase, and one pending PCT application filed in February 2022. National phase applications from these PCTs were filed broadly to acquire patent coverage in a variety of jurisdictions, including in the United States, Greater China, Europe, South Korea, Japan, Singapore and Australia. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2041.

Regarding our Claudin 18.2 product candidate, we own one PCT application outside of the United States filed in 2020 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.

Regarding our allogenic CD20 product candidate, 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 published PCT application filed in August 2020 that is due for national phase entry in 2022. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

Regarding our CD19/CD20/CD22 product candidate, we own four patent applications outside of the United States filed in July 2021 filed in July 2021 that are due for national phase entry in 2023. If issued, composition of matter claims issuing from this application are projected to expire in 2041.

Regarding our LB1901 CD33/CLL-1 product candidate, we own two patent applications outside of the United States and two pending PCT applications filed in September 2019 that in March 2021 entered the national phase, including in the United States, Greater China, Europe, Canada and Australia. 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 cilta-cel 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 as well as follicular lymphoma. Kite also has another marketed autologous CAR-T product, Tecartus, which is indicated for adult patients with relapsed or refractory mantle cell lymphoma (MCL) or adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). In 2021, Bristol-Myers Squibb received FDA approval of its anti-CD19 CAR-T therapy, Breyanzi (liso-cel) via the Juno Therapeutics/Celgene acquisition, as well as the first anti-BCMA CAR-T therapy, Abecma (ide-cel), in collaboration with bluebird bio.

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, Arcellx, Celyad, Gracell, IASO/Innovent, Poseida Therapeutics, Novartis and Precision Biosciences;
- Academic medical centers pursuing independent development of BCMA CAR-T technologies; and
- Additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Regeneron, GSK, Bristol-Myers Squibb, Johnson & Johnson (the parent company of Janssen, our collaboration partner for cilta-cel) and Pfizer.

In that regard, Janssen, our cilta-cel collaboration partner, filed a biologics license application with FDA during the fourth quarter of 2021 for taclistamab, an off-the-shelf, T-cell directing, bispecific antibody targeting both BCMA and CD3.

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 cilta-cel, 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. With the exception of our first product, CARVYKTI™, which was approved by the FDA on February 28, 2022 for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, none of our product candidates has been approved by the FDA for marketing in the United States. 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 ship and 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.

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.

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.

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 fileable, 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 can be 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 identify 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. The FDA also may condition approval on, among other things, changes to proposed labeling, the development of adequate controls and specifications or post-approval safety measures. For example, as has occurred with FDA's approval of CARVYKTI™, the FDA may approve the BLA with a REMS program 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. 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 FDA 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 and/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 consistent with 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 the product be highly similar and 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 of first licensure for the reference product. In addition, the FDA may not approve a biosimilar product until 12 years from the date of first licensure of the reference product. 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 and to what extent 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 for, or the purchase or recommendation of an item or service for which payment may be made, directly or indirectly, under any federal healthcare program; federal civil and criminal false claims laws, including the civil False Claims Act, which prohibits, among other things, presenting, or causing to be presented, false or fraudulent claims for payment or approval to the federal government, including federal healthcare programs, and its criminal equivalent; the Civil Monetary Penalties Law, which prohibits, among other things, individuals or entities from knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal health care program; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully (1) executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program (2) obtaining 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, (3) falsifying, concealing, or covering up by any trick, scheme, or device a material fact, and (4) making, in any matter involving a healthcare benefit program, any materially false, fictitious, or fraudulent statements or representations, or making or using any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services, 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, their business associates, as well as their covered subcontractors 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 for transparency purposes, information related to payments (both direct and indirect) 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 (which data submitted on or after January 1, 2022 has been extended to include information related to payments and other transfers of value provided in the calendar year 2021 and after to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives); 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 our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we 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 eliminated, 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 eliminated 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. It is also unclear how 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 2030 with the exception of a temporary suspension of certain mandatory Medicare claim payment reductions until March 31, 2022, 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.

Also at the federal level, the FDA released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. On November 23, 2020, a trio of industry groups sued HHS and FDA, seeking to enjoin the final rule, and a few days later, Canada passed an interim order banning the export of certain drugs from Canada. In May 2021, the government filed a motion to dismiss the lawsuit for lack of subject matter jurisdiction, and alternatively, for failure to state a claim.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. HHS was sued over the rule, which was challenged as arbitrary and capricious under the Administrative Procedure Act. Implementation of the rebate rule has been delayed to January 2023, pursuant to the litigation. It is unclear whether OIG will ultimately withdraw or modify the rebate rule prior to the January 2023 effective date. The likelihood of implementation of, or willingness to defend, any of the other administration reform initiatives is uncertain. However, the Biden administration has stated that it will continue to work on healthcare access and affordability with an expectation that it will protect and build on the ACA. 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.

We expect health reform initiatives to continue. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

European Union (EU) Regulation

As in the U.S., 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 in the EU is subject to a complex set of laws, rules and regulations affecting our business.

EU Drug Development

In the EU, pharmaceutical product development typically involves preclinical laboratory and animal tests as well as clinical trials. Satisfaction of EU pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation, as well as animal studies, to assess the characteristics and potential pharmacology, pharmacokinetics and toxicity of the product. The conduct of the preclinical tests must comply with EU and national regulations and requirements, including Good Laboratory Practices, or GLP.

Clinical trials in the EU must be conducted, like in the US, in compliance with applicable regulations, Good Clinical Practices, or GCP, as well as under protocols detailing the objectives of the trial and the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. In the EU, each protocol involving testing on patients and subsequent protocol amendments must be submitted to the relevant regulatory agency as part of a new CTA and to one or more Ethics Committees for their review. Analogously to the U.S., clinical trials that are deployed to support Marketing Authorization Applications, or MAAs, are typically conducted in three sequential phases.

On January 31, 2022, Regulation EU No 536/2014 (the Clinical Trial Regulation, or CTR) became fully applicable in the EU. The CTR established a centralized application procedure where one of the National Competent Authorities, or NCAs, of the EU Member States where the trial is to be deployed takes the lead in reviewing certain aspects of the application, while the other NCAs have a lesser involvement than they had under the previous regime established by Directive 2001/20/EC (the Clinical Trials Directive, or CTD). The CTD indeed introduced the first set of harmonized rules on clinical trials in the EU but resulted in a patchwork of different national regimes. The CTR was adopted with a view to introducing a more uniform set of the rules across the EU for the authorization of clinical trials. Such authorization still involves NCAs and Ethics Committees of each of the EU Member States where the trial is to be conducted. However, the relevant procedures have now been streamlined with a view to facilitating a swifter and more seamless authorization and deployment of multi-center trials occurring in more than one EU Member State. More in particular, the CTR allows sponsors to rely on one single submission for CTAs regardless of the number of EU Member States where the trial takes place and based on a single harmonized application. Furthermore, under the CTR, deadlines for regulatory approvals are shortened with a view to accelerating the authorization process. The CTR also established an EU Portal which is designed to act as a single entry point for submission of data and information relating to clinical trials. The CTD will continue to apply in parallel to the CTR for a transitional period.

Under the CTR, NCAs may order the temporary halt or permanent discontinuation of a clinical trial at any time or impose other sanctions if they believe that the clinical trial is not being conducted in accordance with applicable requirements or presents an unacceptable risk to the clinical trial patients. An Ethics Committee may also require the clinical trial to be halted, either temporarily or permanently, for failure to comply with the applicable requirements, or may impose other conditions.

After completion of the required clinical testing, a MAA is prepared and submitted to the EMA (if pan-European MA is sought), or NCA in case of a purely national authorization procedure, as discussed below.

Disclosure of Clinical Trial Information in the EU

In the EU, there is an increasing trend requiring public disclosure of development data, in particular clinical trial data. These data were traditionally regarded as Confidential Commercial Information, or CCI; however, under policies adopted in the EU, clinical study data submitted to the EMA in MAAs, including preclinical data, and patient level data, may be subject to public disclosure. This is confirmed in the CTR, according to which clinical trial applications and all the related documentation are uploaded and stored in the Clinical Trials Information System, or CTIS, which is managed by the EMA.

Confirming the transparency principle, the CTR provides that the information stored in the CTIS is publicly accessible unless confidentiality is justified on the basis of a limited set of exceptions. These exceptions, which - as such - are to be interpreted narrowly in the EU, include the protection of CCI, in particular through taking into account the status of the MA for the applicable product. However, CCI protection is not afforded in those cases where the authorities conclude that there is an overriding public interest in disclosure. Case law of the Court of Justice of the European Union has also confirmed the absence of a general presumption of confidentiality over documents containing clinical and preclinical data provided to the EMA in support of a MAA.

EU Marketing Authorization

In the EU, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. The same rules also apply in the EFTA Member States (Norway, Iceland and Liechtenstein). There are two types of marketing authorizations, namely: (i) the "Community MA", which is issued by the European Commission through the so-called "centralized procedure", based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP of the EMA, and which is valid throughout the entire territory of the European Economic Area, or EEA; and (ii) "national MAs," which are issued by the competent NCAs and only cover their respective national territory.

The centralized procedure is mandatory for certain types of products, namely: medicinal products derived from certain biotechnology processes, orphan medicinal products, medicinal products containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other autoimmune dysfunctions and viral diseases. The centralized procedure is also mandatory for Advanced Therapy Medicinal Products, or ATMPs, which comprise gene therapy, somatic cell therapy and tissue engineered products. The centralized procedure is, instead, optional for other products containing a new active substance not yet authorized in the EEA, or for products that are deemed to constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the Centralized Procedure, the CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each Member State's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. In case of ATMPs, the CHMP must consult with the Committee for Advanced Therapies, or CAT, on any scientific assessment necessary to draw up its scientific opinion. The CHMP has 210 days to adopt an opinion as to whether a MA should be granted. The process usually takes longer as additional information is requested, which triggers clock-stops in the procedural timelines. At the end of the review period, the CHMP provides an opinion to the EC. If the opinion is favorable, the EC may then adopt a decision to grant the MA. In the event of a negative opinion, the company may request a re-examination of the application within 15 days of receipt of the negative opinion. The company then has 60 days to provide the CHMP with detailed grounds for requesting the re-examination. Within 60 days of providing this information, the CHMP must re-examine its opinion. The European Commission follows the recommendation of the CHMP in almost all cases.

In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days. This is usually when the product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. We received confirmation from the EMA that our product cilta-cel is eligible for accelerated assessment.

Under the above-described procedures, before granting the MA, the relevant authorities make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

EU Adaptive Pathways

The EMA has an adaptive pathways approach which allows for early and progressive patient access to a medicine in cases of high medical need. To achieve this goal, several approaches are envisaged including for example identifying small populations with severe disease where a medicine's benefit-risk balance could be favorable or making more use of real-world data where appropriate to support clinical trial data. The adaptive pathways concept applies primarily to treatments in areas of high medical need where it is difficult to collect data

via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach builds on regulatory processes already in place within the existing EU legal framework. These include conditional MAs.

A conditional MA may be granted prior to the submission of comprehensive clinical data if the benefit of the immediate availability on the market of the product is deemed to outweigh the risk inherent in the fact that additional data are still required. In emergency situations, a MA for such medicinal products may be granted also where comprehensive pre-clinical or pharmaceutical data have not been provided. Under this procedure a MA can be granted as soon as sufficient data becomes available to demonstrate that the drug's benefits outweigh its risks, with safeguards and controls in place post-authorization. This procedure can also be combined with a rolling review of data during the development of a promising medicine, to further expedite its evaluation. Conditional MAs are typically subject to obligations that are reviewed annually. These include the obligation to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is favorable. Conditional MAs are valid for one year, renewable.

EMA Prime Scheme

The EMA launched its PRIME regulatory initiative to enhance support for the development of therapies that target an unmet medical need. The initiative focuses on drugs that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These therapies are considered priority medicines within the EU. Through PRIME, the EMA offers early, proactive and enhanced support to drug developers to optimize the generation of robust data on a therapy’s benefits and risks and enable accelerated assessment of drug applications.

Our product cilta-cel has been granted access to the PRIME scheme and received confirmation that the product is eligible for accelerated assessment.

Post-approval Requirements in the EU

Following approval, the EMA, or the NCAs, as applicable, may impose certain post-approval requirements related to a product such obligation to perform Post-Authorization Efficacy Studies, or PAES, or Post-Authorization Safety Studies, or PASS, imposed as conditions to the MA, or other Risk Minimization Measures, or RMMs, such as educational programs or controlled access programs, which may sometimes vary from one EU Member State to another. Moreover, if a company obtains original approval for a product via an accelerated approval pathway, the company will be typically required to conduct a post-marketing confirmatory trial to verify and describe the clinical benefit in support of full approval. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of the MA for a product.

Moreover, NCAs closely regulate the marketing and promotion of approved products, including for example standards and regulations for direct-to-consumer advertising (which is prohibited in the EU for prescription products), off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Furthermore, approved products may be marketed only for the approved indications and in accordance with the provisions of the approved label. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, may require a submission to and approval by the European Commission, or by one or more NCAs, as applicable.

In addition, adverse event reporting and submission of periodic reports is required following marketing approval. Either the European Commission, or NCAs, as applicable, may also require post-marketing testing, known as Phase 4 testing, a risk evaluation and mitigation strategy, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as the manufacture, packaging, and labeling procedures must to applicable current Good Manufacturing Practices (or cGMPs) after approval. Drug and biological product manufacturers and certain of their subcontractors are subject to periodic unannounced inspections during which the inspectors audit manufacturing facilities to assess compliance with cGMPs. MAs may be suspended or withdrawn if, for example, the MA holder fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously

unrecognized problems are subsequently discovered. Moreover, stringent rules have been introduced in the EU to fight medicine falsifications and to ensure that the trade in medicines is subject to rigorous controls.

Furthermore, EU harmonized rules prohibit gifts, pecuniary advantages or benefits in kind to Health Care Professionals, or HCPs, unless they are inexpensive and relevant to the practice of medicine or pharmacy. Similarly, strict rules apply to hospitality at sales promotion events. Based on these rules, a body of industry guidelines and sometimes national laws in force in individual EU Member States has been introduced to fight improper payments or other transfers of value to HCPs, and in general inducements that may have a broadly promotional character. Historically, pharmaceutical companies have been the target of anti-corruption and similar investigations, as well as of wide media attention, sometimes resulting in significant penalties, image and other costs for such companies.

Finally, very stringent data privacy requirements apply in the EU. In particular, Regulation (EU) 2016/679 (the General Data Protection Regulation, or GDPR) requires that personal data only be collected for specified, explicit and legal purposes, and the data may then only be processed in a manner consistent with those purposes. Personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the EEA (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. The GDPR also requires companies processing personal data to implement adequate technical measures in order to ensure the most appropriate level of security which may vary depending on different factors such as the categories of processed personal data, the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For instance, the GDPR requires companies to make detailed disclosures to data subjects, provides for conditions under which a valid consent for processing can be obtained, requires the appointment of a data protection officer where sensitive personal data (e.g., health data) is processed on a large scale, imposes mandatory data breach notification throughout the EEA and imposes additional obligations when contracting with service providers or partners. In addition, to the extent a company processes, controls or otherwise uses “special category” of personal data (including patients’ health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data.

Pricing and Reimbursement in the EU

In most European countries medicinal products cannot be commercially launched until pricing and/or reimbursement is approved. Typically, Governments closely regulate drug pricing and reimbursement and often have a significant discretion in determining whether a product will be reimbursed at all and, if it is, how much it will be paid. Negotiating prices with governmental authorities can delay commercialization of our products. Payers in many countries use a variety of cost-containment measures that can include referencing prices in other countries and using those reference prices to set their own price, mandatory price cuts and rebates. This international patchwork of price regulation can lead to different prices across countries and some cross-border trade in our products from markets with lower prices. Even after a price is negotiated, countries can, and often do, request or require adjustments to the price and other concessions over time.

Data Exclusivity And Market Exclusivity in the EU

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon MA. The data exclusivity period prevents generic applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic

indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Designation in the EU

Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan drug designation must be submitted before the MAA.

Medicinal products receiving orphan designation can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a MA may be granted to a similar product for the same indication at any time if: (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

EU Supplementary Protection Certificates

In the EU, Supplementary Protection Certificates, or SPCs, are available to extend a patent term for up to five years to compensate patent protection lost during regulatory review. SPCs must be applied for and granted on a country-by-country basis.

Additional Protection for Pediatric Indications in the EU

In the EU, companies developing a new medicinal product must agree to a Pediatric Investigation Plan, or PIP, with the EMA and must conduct pediatric clinical trials in accordance with such PIP, unless a deferral or waiver is granted by the EMA on request by the applicant (e.g., because the relevant disease or condition occurs only in adults). The PIP requirement also applies when a MA holder intends to add a new indication, pharmaceutical form or route of administration for a medicinal product that has already been authorized. The MAA must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Once all the studies and measures agreed have been conducted in accordance with the PIP, products are eligible for a six month extension of the SPC, if any is in effect at the time of approval or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is granted subject to specific conditions and, in particular, that: (i) the applicant demonstrates having complied with all the measures contained in the PIP; (ii) the summary of product characteristics, and if appropriate the package leaflet, reflects the results of studies conducted in compliance with such PIP; and (iii) the product is authorized in all EU Member States. The rewards for conducting studies in the pediatric population can be granted irrespective of the fact that the information generated in compliance with the agreed PIP fails to lead to the authorization of a pediatric indication.

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 took 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 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.

According to the DRR, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of chemical drugs shall be categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs an others, and the registration applications of biological products shall be categorized by innovative biological products, improved new biological products, and biological products on the market (including biological similar drugs) and others.

The Registration Category of Biological Products and the Data Requirements for Declaration, issued by NMPA on June 29, 2020 and effective from July 1, 2020, which replaced the former category of therapeutic biological products and stipulated that the therapeutic biological products should be classified into 3 Categories, and Category I refers to therapeutic biological products that have not been marketed anywhere in the world, Category II refers to improved new therapeutic biological products and Category III refers to therapeutic biological products that have been marketed in China or abroad.

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. The Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation was replaced by the Announcement on the Release of Three Documents including the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) issued by the NMPA on July 7, 2020, the three documents are namely the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial), Procedures for the Evaluation and Approval of the Listing Application for Conditional Approval of Drugs (Trial) and Procedures for Prioritized Evaluation and Approval for Drug Marketing (Trial), among others, which allow the applicant to apply for the breakthrough therapy drug procedure during the Phase I and II clinical trials and normally no later than the commencement of Phase III clinical trials for the innovative or improved drugs which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there exists no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over the existing treatments. In addition, when applying for the marketing license of a drug, for drugs with obvious clinical value, the applicant can apply for the prioritized evaluation and approval procedure.

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, the NMPA and the NHC 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.

The DRR has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduced four procedures for expedited marketing registration of drugs, which are procedures for ground-breaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval and procedures for special examination and approval:

- Procedures for ground-breaking therapeutic drugs: during the drug clinical trials for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or for which there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approaches, the applicant may request for application of procedures for ground-breaking therapeutic drugs.
- Procedures for conditional approval: during the drug clinical trials for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach and for which the clinical trial of such drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health and for which the clinical trial of such drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed if its benefits outweigh the risks according to the evaluation.
- Procedures for prioritized reviews and approval: at the time of the drugs' marketing registration, drugs that have obvious clinical value may apply for application of procedures for prioritized review and

approval, including (i) clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for ground-breaking therapeutic drugs; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.

- Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency. Drugs included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

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 approval outside the PRC 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 approval requirements outside the PRC, 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, clinical trials of drugs are subject to approval and a bioequivalence test shall be filed. Clinical trials of drugs are required to comply with the PRC's GCP and must be carried out by drug clinical trial organizations which have completed filings pursuant to relevant provisions and which comply with the relevant provisions. 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

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 non-PRC-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. The State Council of PRC issued the Regulations on the Administration of Human Genetic Resources, or the HGR Regulation, which became effective on July 1, 2019. The HGR Regulation regulate the collection, preservation, usage and external provision of China's human genetic resources. According to this regulation, "human genetic resource" includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Ministry of Science and Technology is responsible for the management of human genetic resources at the national level, and the administrative departments of science and technology under the provincial governments are responsible for the management of human genetic resources at local level. Entities, individuals and such entities established or actually controlled outside the PRC are not allowed to collect or preserve China's human genetic resources (including organs, tissues, cells and other genetic materials of human genome and gene) or provide human genetic resources abroad, while they are prohibited from using China's human genetic resources unless they have obtained an approval from relevant PRC government authority or have filed with relevant government authority for international cooperation with a Chinese entity. The HGR Regulation formalized the approval requirements pertinent to research collaborations between Chinese and non-PRC-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.

Biosecurity Law

On October 17, 2020, the Standing Committee of the National People's Congress adopted the Biosecurity Law of the People's Republic of China, which became effective on April 15, 2021 (the "Biosecurity Law"). The Biosecurity Law establishes an integrated system to regulate biosecurity related activities in China, including the security regulation of HGR and biological resources. The Biosecurity Law expressly declares that China has sovereignty over its HGR, and further endorsed the HGR Regulation, by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese HGR by non-PRC entities in China. The Biosecurity Law is a law adopted by China's highest legislative authority, it gives China's major regulatory authority of HGR, the Ministry of Science and Technology, significantly more power and discretion to regulate HGR, and it is expected that the overall regulatory landscape of Chinese HGR will evolve and become even more rigorous and sophisticated. Failure to comply with the requirement under the Biosecurity Law will result in the penalties, including fines, suspension of related activities and confiscation of related HGR and gains generated from conducting these activities.

*Trial Exemptions and Acceptance of N*on-PRC *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 non-PRC 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 and the NHIC 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 non-PRC-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

Pursuant to the DRR, a clinical trial consists of Phases I, II, III and IV clinical trial as well as a bioequivalence trial. Based on the characteristics of drugs and the research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research. 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.

To improve the quality of clinical trials, the CFDA promulgated the PRC's GCP on August 6, 2003 which was further amended on April 23, 2020 and came into effect on July 1, 2020. In order to ensure the quality of clinical trials and the safety of human subjects, the PRC's GCP provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the PRC's GCP enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials. The PRC's GCP stipulated that the sponsor shall bear the expenses for medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons connected with the clinical trial. The sponsor and investigator shall pay the human subject the compensation or indemnification in a timely manner. 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

According to the DRR, the applicant may submit an application for drug marketing registration to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the marketing authorization holders and the manufacturer.

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. According to the Measures on the Supervision and Administration of the Manufacture of Drugs, promulgated on August 5, 2004 with the latest amendment being effective as of July 1, 2020, to the extent the marketing authorization holder does not manufacture the drug but through contract manufacturing organization, the marketing authorization holder shall apply for drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

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.

The Technical Guidelines for Clinical Trials of Immune Cell Therapy Products (Trial), or the Technical Guidelines for Clinical Trials, which was published by the CDE on February 10, 2021, provides that CAR-T, as a kind of immune cell therapy product, has the nature of gene therapy products. The Technical Guidelines for Clinical Trials, whose content is not mandatory, is intended to provide suggestions and recommendations on certain technical issues in clinical trials of immune cell therapy products, rather than to identify the regulatory nature or classification of immune cell therapy products. On December 3, 2021, the CDE published the Technical Guidelines for Non-clinical Research and Evaluation of Gene Therapy Products (Trial), or the Technical Guidelines for Gene Therapy Products, and Technical Guidelines for Non-clinical Research of Gene Modified Cell Therapy Products (Trial), the Technical Guidelines for Gene Modified Cell Therapy Products, which became effective as of the date of promulgation. The Technical Guidelines for Gene Modified Cell Therapy Products, which was formulated according to the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial), was issued to regulate and guide non-clinical research and evaluation of genetically modified cells therapy products, such as CAR-T cell therapy products. The CDE issued the Technical Guidelines for the Clinical Risk Management Plan on Application for Marketing Approval of Chimeric Antigen Receptor T Cell (CAR-T) Therapy Products on January 29, 2022, which became effective as of the date of promulgation, to regulate and guide the drafting of the clinical risk management plans on application for marketing approval of CAR-T therapy products.

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, or the Tort Law, 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. The Civil Code of the PRC, which was promulgated on May 28, 2020 and became effective on January 1, 2021, amalgamated and replaced the General Principles of the Civil Law of the PRC and the Tort Law effective January 1, 2021. The rules on tort law in the Civil Code of the PRC are generally consistent with the General Principles of the Civil Law of the PRC and the Tort Law.

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 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. In July 2020, the new DRR took effect, and the five-year monitoring period was removed accordingly.

Furthermore, the CDE issued the Guidelines for Acceptance and Review of Registration of Biological Products on July 2, 2020, and according to the Appendix II of such guidelines, the description of the monitoring period of the same type of therapeutic biological products was also removed.

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

According to the Patent Law issued by the Standing Committee of the NPC on October 17, 2020 became effective on June 1, 2021, the patent administration department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years.

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. 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 latest version of the NRDL, which was released in 2021 and was implemented on January 1, 2022, includes 2,860 drugs.

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

References to "foreign" in this section entitled "Other PRC National-and Provincial-Level Laws and Regulations" refer to countries outside the PRC, unless the context indicates otherwise.

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.

Privacy and Data Security Protections

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.

Scientific data

In March, 2018, the General Office of the State Council promulgated the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. Pursuant to the Scientific Data Measures, the scientific data involving state secrets, national security, social or public interests, trade secrets and individual privacy shall be kept confidential; where it is necessary to disclose such data, the purposes of utilization, qualifications of users and confidentiality conditions, among others, shall be examined, and the scope of those with access thereto shall be strictly controlled. Enterprises in the PRC must seek governmental approval before any scientific data involving a state secret is provided during foreign contacts and cooperation. Upon approval by the competent departments, corporate entities shall undergo the relevant formalities as required, and sign confidentiality agreements with users. Furthermore, any researcher conducting research funded in part or in whole by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before that data may be published in any foreign academic journal.

Personal information

Pursuant to the Civil Code of the PRC, the personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or publish personal information of others. In addition, the processing of personal information shall follow the principles of lawfulness, appropriateness and necessity. The Personal Information Protection Law promulgated by the SCNPC on August 20, 2021, which became effective on November 1, 2021, outlines the main system framework of personal information protection and processing. The Personal Information Protection Law sets forth detailed rules on handling personal information and legal responsibilities, including but not limited to the scope of personal information and the ways of processing personal information, the establishment of rules for processing personal information, and the individual's rights and the

processor's obligations in the processing of personal information. The Personal Information Protection Law also strengthens the punishment for those who illegally process personal information.

Data security

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC, which became effective on June 1, 2017, pursuant to which network operators are to fulfill their obligations to safeguard security of the network when conducting business and providing services. Network operators may not collect personal information irrelevant to the services they provide or collect or use the personal information in violation of the provisions of applicable laws or agreements concluded with theirs users, and CIIOs are required to store in the PRC all the personal information and important data collected and produced within the PRC.

On June 10, 2021, the SCNPC promulgated the China's Data Security Law, or the Data Security Law, which came into effect on September 1, 2021. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data activities, and introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, and the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, illegally acquired or used. The Data Security Law also provides for a national security review procedure for data activities that may affect national security.

The Measures for Cybersecurity Review, which was published by the CAC and 12 other relevant PRC government authorities on December 28, 2021, became effective on February 15, 2022. The Measures for Cybersecurity Review provides that, among other things, (i) the purchase of network products and services by a CIIO and the data processing activities of a "network platform operator" that affect or may affect national security shall be subject to the cybersecurity review; and (ii) if a "network platform operator" that possesses personal information of more than one million users intends to go public in a foreign country, it must apply for a cybersecurity review with the cybersecurity review office.

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. The Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021) issued by the MOFCOM and the NDRC on December 27, 2021 and took into effect from January 1, 2022. 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. The Encouraged Industry Catalogue for Foreign Investment (2020), or the 2020 Encouraged Industry Catalogue, which became effective on January 27, 2021, provides that foreign investment is encouraged in the development and production of cell therapy drugs except in areas where foreign investment is prohibited.

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 a public company listed on a foreign exchange, 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 company listed on a foreign exchange, 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 a company listed on a foreign exchange 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 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 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 have recently completed the renovation of a significant portion of the warehouse space into GMP manufacturing space for the development and potential commercialization of our pipeline. We believe 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.

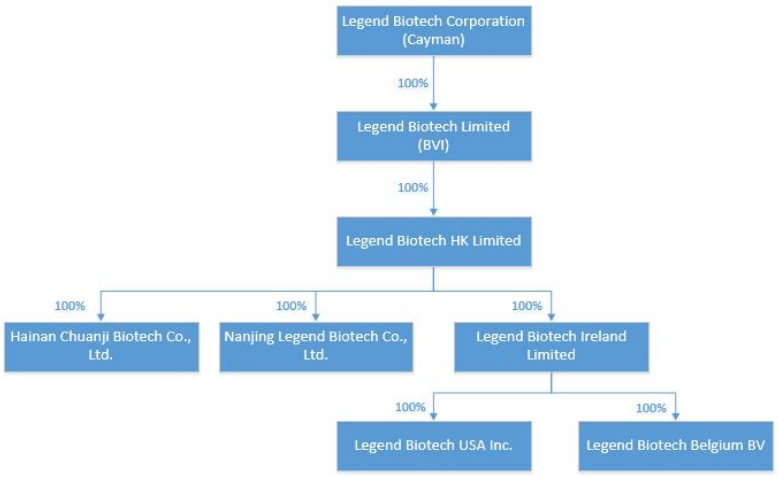
Recent Development

On February 28, 2022, FDA approved our product CARVYKTI™ (ciltacabtagene autoleucel) for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. CARVYKTI™ marks the first product approved by a health authority for Legend Biotech. A one-time infusion for adult patients with MM, CARVYKTI™ is a CAR-T therapy with two BCMA-targeting antibodies. In December 2017, Legend Biotech entered into an exclusive worldwide collaboration and license agreement with Janssen to develop and commercialize CARVYKTI™.

CARVYKTI™ will be manufactured by using the patient's own T cells at a cellular immunotherapy manufacturing facility jointly established by Legend and Janssen in Raritan, New Jersey, and delivered to patients through a certified network of treatment centers across the United States. A REMS program will be implemented at these certified centers to support appropriate use of CARVYKTI™, including training on the monitoring and management of cytokine release syndrome and neurologic toxicities.

C. Organizational Structure Chart

The following diagram illustrates our corporate structure, including our parent company, subsidiaries, and consolidated affiliated entities, as of the date of this Annual Report on Form 20-F:



D. Property, Plants and Equipment

Principal Executive Offices

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renovation of a significant portion of the warehouse space into GMP manufacturing space for the development and potential commercialization of our pipeline. We believe 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.

Additional U.S. Facilities

We lease or expect to lease the following additional facilities in the United States:

- We have a research facility located at 10 Knightsbridge Road, Piscataway, New Jersey 08854, where we lease approximately 22,000 square feet from a subsidiary of Genscript.
- We are party to a lease with Janssen under which we expect to lease an approximately 106,000 square foot manufacturing facility from Janssen located in Raritan, New Jersey. That lease will become effective on a future date in connection with the FDA's approval of our or BLA for cilta-cel, which we referred to as the Facility Transition Date. For this facility, which we collaboratively operate with Janssen, we continue to invest in manufacturing, quality, information technology and distribution capabilities to support the launch of CARVYKTI™.

European Union

We lease or expect to lease the following facilities in the European Union:

- We are party to leases with Janssen under which we expect to lease two facilities in Ghent, Belgium that will be used primarily for manufacturing. Those leases, which include facilities of approximately 180,900 and 30,000 square feet, respectively, will become effective upon the Facility Transition Date.
- We have an administrative office facility located in Ghent, Belgium, where lease approximately 4,500 feet.
- We have a research facility located in Dublin, Ireland, where we lease approximately 8,300 square feet.

For our manufacturing sites in Europe, we are starting to prepare for building the manufacturing and distribution capabilities to support the Europe and rest of world.

PRC

We lease the following facilities in the PRC:

Address	Scheduled Lease Expiration	Leased Area	Use of Premises
3rd and 4th Floors, Building 6, Nanjing Life Science Town, 568 Longmian Avenue, Jiangning District, Nanjing	31-Dec-2026	1,924 square meters	Office and GMP manufacturing
1st and 2nd Floors, Building 6, North District, Life Science Town	31-Dec-2026	1,668 square meters	Office and GMP manufacturing
3rd, 4th and 5th Floors, Building 3, Nanjing Life Science Town	30-May-2023	2,038 square meters	Office and laboratory
Room 209, 2nd Floor, 298 Xiangke Road, Zhangjiang High-tech Park, Shanghai	30-Jun-2024	351.56 square meters	Office
4th Floor, Block A, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	23-Jul-2022	2,940.67 square meters	Office
4th Floor, Block E, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	31-Dec-2025	7,250 square meters	Laboratory
1st Floor, Building 5, 28 Yongxi Road, Jiangning District, Nanjing*	30-Jun-2025	1,000 square meters	Office and laboratory
Room 1818, 1859, 1860, 1861, 1862, 1865, 18th Floor, Building 9, 91 Jianguo Road, Chaoyang District, Beijing	31-May-2022	330 square meters	Office
Office 307-11, 3rd floor, Incubation building, Hainan Ecological Software Park, Laocheng High-tech Industry Demonstration District, Hainan Province	30-Apr-2022	3 Cubic Seats	Office
1st and 3rd Floors, Block B, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	1st floor: 25-Aug-2024; 3rd floor: 14-Sept-2024	1,279.8 square meters	Warehouse

In China, we are shifting strategies for a BCMA commercial production site and evaluating capabilities within Nanjing.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not Applicable

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements appearing elsewhere in this Annual Report on Form 20-F. This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this Annual Report on Form 20-F are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under "Item 3.D. Risk Factors." Actual results could differ materially from those projected in the forward-looking statements.

Restatement of Previously Issued Consolidated Financial Statements

This "Operating and Financial Review and Prospects" discussion has been updated to reflect the effects of the Restatement described in Note 2.2 Restatement of Previously Issued Consolidated Financial Statements of the Notes to Consolidated Financial Statements in Part III, Item 18 of this Amended Annual Report.

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 1,000 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, ciltacabtagene autoleucel, or cilta-cel, is a CAR-T cell therapy we are jointly developing with our strategic partner, Janssen, for the treatment of MM. Clinical trial results achieved to date demonstrate that cilta-cel has the potential to deliver deep and durable anti-tumor responses in RRMM patients with a manageable safety profile. On February 28, 2022, FDA approved our product CARVYKTI™ (cilta-cel) for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. CARVYKTI™ marks the first product approved by a health authority for the Company.

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. With the exception of CARVYKTI™, we do not have any product candidates approved for sale and have not generated any revenue from product sales. From inception through December 31, 2021, we have funded our operations primarily with:

- $3.9 million in capital contributions from Genscript;
- $160.5 million in gross proceeds from the sale of our Series A Preference Shares;
- $600 million in upfront and milestone payments from Janssen under our collaboration and license agreement;
- $450.1 million in net proceeds from our IPO and an additional concurrent $12 million private placement with Genscript;
- $300 million in net proceeds from our private placement to an investor and related warrant issuance in May 2021;
- $323.4 million in net proceeds from our public offering of ADSs that closed in December 2021; and
- $119.7 million in advances from Janssen under our collaboration and license agreement.

Since inception, we have incurred significant operating losses. Our net losses were $403.6 million and $266.4 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had accumulated losses of $520.1 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 cilta-cel for the treatment of RRMM;
- continue our ongoing and planned clinical development for our other product candidates;
- 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.

Our Collaboration with Janssen

In December 2017, we entered into a collaboration and license agreement with Janssen for the worldwide development and commercialization of cilta-cel.

Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize cilta-cel. We and Janssen will collaborate to develop and commercialize cilta-cel 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 cilta-cel. 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 paid us an upfront fee of $350.0 million and we were eligible to receive up to an additional $1.35 billion in milestone payments from Janssen. Of the $1.35 billion, we may not receive up to $280 million due to mutually agreed upon modifications to our clinical development plan that resulted in the decision to not conduct certain trials as originally planned. We have previously received the following milestone payments:

- $25 million, $30 million, and $30 million in January 2019, September 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial,
- a milestone payment of $25.0 million in September 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%,
- a milestone payment of $75 million in January 2021 in connection with the initiation of a rolling submission of a Biologics License Application to the U.S. FDA, for cilta-cel and
- a milestone payment of $15 million in July 2021 in connection with the submission of a Marketing Authorization to the EMA; and
- milestone payments of $50 million during February 2022 in connection with the submission of an NDA to the PMDA in Japan and the enrollment of a specified numbers of patients in our CARTITUDE-5 clinical trial.

Additionally, we are eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $695 million consisting of $485 million for the achievement of specified future development and regulatory milestones and $210 million for the achievement of specified net trade sales milestones.

Furthermore, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. Outstanding advances accrue interest at the London Interbank Offered Rate (LIBOR) published by the Wall Street Journal plus 2.5%. Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the collaboration and license agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the collaboration and license agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest. As of December 31, 2021, the aggregate outstanding principal amount of such advances and interest were approximately $119.7 million and $0.8 million, respectively.

Impact of COVID-19 on Our Business

The COVID-19 situation is very fluid across the world where each country or the sites within a country could be impacted differently. For the year ended December 31, 2021, COVID-19 has had limited impact on our operations.

We are in the process of assessing the situation case by case as the pandemic evolves. In the US, we have 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, we are working closely with investigators, putting patient's safety first, while trying our 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 in 2020. 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 we are experiencing lower enrollment rates in CARTIFAN-1 trial.

Product manufacturing in both the US and China have continued. Currently we have not experienced any material impact to our material supply chain. Increased quantities of certain raw materials and consumables have been stocked as an appropriate safety measure. We have established robust sourcing strategies for all necessary materials and does not expect any significant impact.

There are still uncertainties of COVID-19's future impact on our business, results of operations and financial condition, and the extent of the impact will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the development and progress of distribution of COVID-19 vaccines and other medical treatments, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. If the situation materially deteriorates, our business, results of operations and financial condition could be materially and adversely affected. We will continue to monitor and assess the impact of the ongoing development of the pandemic on our financial position and operating results and respond accordingly.

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 cilta-cel 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, 2021 and 2020, our total research and development expenses were $204.4 million and $164.0 million, respectively, for our BCMA program and $108.9 million and $68.2 million, respectively, for all other non-BCMA programs.

From inception through December 31, 2021, we have incurred approximately $777.2 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 cilta-cel for the treatment of RRMM and the initiation and continuation of our preclinical and clinical trials for our other product candidates. Following our initial public offering, our accounting, audit, legal, regulatory, investor and public relations, and compliance and director and officer insurance costs have increased, and we anticipate that they will continue to increase as we continue to further enhance our public company infrastructure.

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 marketing and development of cilta-cel.

Other Income and Gains

Other income and gains consist 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.

Revenue recognition

Upfront fees

Upfront payment is allocated to the single performance obligation (described below) in the Janssen Agreement. The upfront fees of $350 million were included in the transaction price upon contract inception in 2017 and were recognized when the single performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The $350 million upfront fees were 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 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 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, adjusts its estimate of the overall transaction price.

The milestone payments were allocated to the single performance obligation in the Janssen Agreement. We recognized license revenue of $50 million for the milestones included in the initial transaction price in 2018, the year in which the performance obligation was satisfied and it was highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract would not occur. The $50 million milestone fees were fully received by us in 2019.

In consideration for the licenses and other rights granted to Janssen, Janssen paid us an upfront fee of $350.0 million and we were eligible to receive up to an additional $1.35 billion in milestone payments from Janssen. Of the $1.35 billion, we may not receive up to $280 million due to mutually agreed upon modifications to our clinical development plan that resulted in the decision to not conduct certain trials as originally planned. We have previously received the following milestone payments:

- $25 million, $30 million, and $30 million in January 2019, September 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial,
- a milestone payment of $25 million in September 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%,
- a milestone payment of $75 million in January 2021 in connection with the initiation of a rolling submission of a Biologics License Application to the U.S. FDA, for cilta-cel and
- a milestone payment of $15 million in July 2021 in connection with the submission of a Marketing Authorization to the EMA; and
- milestone payments of $50 million during February 2022 in connection with the submission of an NDA to the PMDA in Japan and the enrollment of a specified numbers of patients in our CARTITUDE-5 clinical trial.

Additionally, we are eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $695 million consisting of $485 million for the achievement of specified future development and regulatory milestones and $210 million for the achievement of specified net trade sales milestones. Subsequent development, manufacturing and regulatory milestones will be recognized in full in the period in which it is highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract will not occur, as they are associated with the performance obligation to deliver the license of intellectual property, including a technology transfer service, that was satisfied in 2018. We will recognize revenue for sales-

based milestones when the milestone is achieved pursuant to the royalty recognition constraint. We have assessed that achievement of the remaining milestones is highly uncertain and the related milestone payments are not included in the transaction price.

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. The Company evaluated that the license is a single performance obligation in the Janssen Agreement, including a technology transfer service, which represent a right to use the Company'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.

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

Share-based compensation

The fair value of share options granted by the Company 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 equity-settled share option. The fair value of each restricted stock unit is determined by reference to market price of our shares at the respective grant date.

The compensation expense recognized for all share-based awards is measured by reference to the fair value at the date at which they are granted and is net of estimated forfeitures. The Company estimates forfeiture rates based on historical analysis of option an RSU forfeitures. If actual forfeitures vary from estimated forfeitures, adjustments to the compensation expense may be required.

For the years ended December 31, 2021, 2020 and 2019, the equity-settled share option expense was $2.4 million, $1.9 million and $1.3 million, respectively, and the equity-settled RSU expense was $17.8 million, $2.9 million and zero, respectively. Further details are contained in notes 27 and 28 to the 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 cash balance.

Pursuant to our collaboration and license agreement with Janssen, the advances we receive from Janssen accrue interest at the rate of LIBOR plus 2.5%. Accordingly, changes in LIBOR could result in fluctuations in our cash flows. For example, based on the $119.7 million aggregate principal amount of advances outstanding from Janssen as of December 31, 2021, a 0.5% (fifty basis point) per annum increase in LIBOR would result in an additional $0.6 million per year in interest payable by the Company.

Inflation generally affects us by increasing the cost of labor and raw materials, which increases the costs of clinical trials and, in the event we commercialize any products, the costs of production. 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, 2021, 2020 and 2019. We also do not believe that we are exposed to any material foreign currency exchange rate risk.

A. Operating Results

Comparison of Fiscal Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the fiscal years ended December 31, 2021 and 2020:

	Fiscal Year Ended December 31,		
	2021 (as restated)	2020 (as restated)	Variance
	(in thousands)		
Consolidated Statement of Operations Data:			
Revenue	68,826	75,000	(6,174)
Operating expenses:			
Research and development expenses	(313,346)	(232,160)	(81,186)
Administrative expenses	(46,961)	(23,134)	(23,827)
Selling and distribution expenses	(102,542)	(49,571)	(52,971)
Other income and gains	3,059	6,119	(3,060)
Other expenses	(9,132)	(346)	(8,786)
Fair value loss of warrant liability	(6,200)	—	(6,200)
Fair value loss of convertible redeemable preferred shares	—	(79,984)	79,984
Finance costs	(900)	(4,209)	3,309
Loss before tax	(407,196)	(308,285)	(98,911)
Income tax credit	3,614	41,912	(38,298)
Loss for the period	(403,582)	(266,373)	(137,209)

Revenue

Revenue for the year ended December 31, 2021 was $68.8 million, compared to $75.0 million for the year ended December 31, 2020. This decrease of $6.2 million was primarily driven by a decrease in revenue recognized from milestones of lower value in the year ended December 31, 2021. 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, 2021 were $313.3 million, compared to $232.2 million for the year ended December 31, 2020. This increase of $81.1 million was primarily due to continuous research and development activities in cilta-cel and for other pipeline items in the year ended December 31, 2021.

Administrative Expenses

Administrative expenses for the year ended December 31, 2021 were $47.0 million, compared to $23.1 million for the year ended December 31, 2020. This increase of $23.9 million was primarily due to our expansion of supporting administrative functions to facilitate continuous business expansion, research and development activities and establishment of commercialization infrastructure.

Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2021 were $102.5 million, compared to $49.6 million for the year ended December 31, 2020. This increase of $52.9 million was primarily due to increased costs associated with commercial preparation activities for the launch of cilta-cel in the U.S.

Other Income and Gains

Other income and gains for the year ended December 31, 2021 was $3.1 million, compared to $6.1 million for the year ended December 31, 2020. This decrease of $3.0 million was primarily driven by less interest income from time deposits of lower average interest rate and less government grants.

Other Expenses

Other expenses for the year ended December 31, 2021 was $9.1 million, compared to $0.3 million for the year ended December 31, 2020. The increase of $8.8 million was primarily due to foreign exchange loss and loss from disposal of assets.

Finance Costs

Finance costs for the year ended December 31, 2021 was $0.9 million, mainly composed of interest for advance funding, which is interest-bearing borrowings funded by Janssen under our collaboration and license agreement and constituted by principal and applicable interests upon such principal. Finance costs for the year ended December 31, 2020 was $4.2 million, resulting from the finance costs for the issuance of convertible redeemable preferred shares (Series A Preferred Shares) that were fully converted into ordinary shares upon the completion of our initial public offering in June 2020.

Fair Value Loss of Warrant Liability

Fair value loss of warrant liability was $6.2 million for the year ended December 31, 2021 which was caused by changes in fair value of a warrant that we issued to an institutional investor through a private placement transaction in May 2021 with an initial fair value of $81.7 million at the issuance date. Concurrently, ordinary shares were sold to the same institutional investor in a private placement transaction. The warrant was assessed as a financial liability with a fair value of $87.9 million as of December 31, 2021.

Fair Value Loss of Convertible Redeemable Preferred Shares

For the year ended December 31, 2020, the Company reported a one-time non-cash charge of $80.0 million caused by changes of fair value of Series A Preferred Shares. Upon consummation of the Company's U.S. initial public offering, all outstanding Series A Preferred Shares were converted into ordinary shares of the Company and all accrued but unpaid dividends were settled in the form of ordinary shares of the Company. No such fair value loss was experienced in 2021 as the Company has no outstanding Series A Preferred Shares after the listing.

Income Tax Credit

Income tax credit for the year ended December 31, 2021 was $3.6 million compared to $41.9 million of income tax credit for the year ended December 31, 2020.

Comparison of Fiscal Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the fiscal years ended December 31, 2020 and 2019:

	Fiscal Year Ended December 31,		
	2020 (as restated)	2019 (as restated)	Variance
	(in thousands)		
Consolidated Statement of Operations Data:			
Revenue	75,000	59,980	15,020
Operating expenses:			
Research and development expenses	(232,160)	(161,943)	(70,217)
Administrative expenses	(23,134)	(6,751)	(16,383)
Selling and distribution expenses	(49,571)	(25,620)	(23,951)
Other income and gains	6,119	7,459	(1,340)
Other expenses	(346)	(221)	(125)
Fair value loss of convertible redeemable preferred shares	(79,984)	—	(79,984)
Finance costs	(4,209)	(223)	(3,986)
Loss before tax	(308,285)	(127,319)	(180,966)
Income tax credit	41,912	25,729	16,183
Loss for the period	(266,373)	(101,590)	(164,783)

Revenue

Revenue for the year ended December 31, 2020 was $75.0 million, compared to $60.0 million for the year ended December 31, 2019. This increase of $15.0 million was primarily driven by an increase in revenue recognized from the milestone achieved of higher value in the year ended December 31, 2020. 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, 2020 were $232.2 million, compared to $161.9 million for the year ended December 31, 2019. This increase of $70.3 million was primarily due to a higher number of clinical trials, a higher number of patients enrolled in those trials and a higher number of research and development product candidates in the year ended December 31, 2020.

Administrative Expenses

Administrative expenses for the year ended December 31, 2020 were $23.1 million, compared to $6.8 million for the year ended December 31, 2019. This increase of $16.3 million was primarily due to our expansion of supporting administrative functions to aid continued research and development activities.

Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2020 were $49.6 million, compared to $25.6 million for the year ended December 31, 2019. This increase of $24.0 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel.

Other Income and Gains

Other income and gains for the year ended December 31, 2020 was $6.1 million, compared to $7.5 million for the year ended December 31, 2019. This decrease of $1.4 million was primarily driven by reduced average interest rates for time deposits that generate interest income.

Other Expenses

Other expenses for the year ended December 31, 2020 were $0.3 million, compared to $0.2 million for the year ended December 31, 2019. The increase was primarily due to foreign exchange losses.

Income Tax Credit

Income tax credit for the year ended December 31, 2020 was $41.9 million compared to $25.7 million of income tax credit for the year ended December 31, 2019.

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 2.5 to our consolidated financial statements included in this Annual Report for a description of our other significant accounting policies.

Revenue Recognition

Upfront fees

Upfront payment is allocated to the single performance obligation in the Janssen Agreement. The upfront fees from Janssen of $350.0 million were included in the transaction price upon contract inception in 2017 and were recognized when the performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The $350 million upfront fees were 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 highly probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is highly 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 highly 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 highly 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 single performance obligation in the Janssen Agreement. We recognized license revenue of $50 million for the milestones included in the initial transaction price in 2018, the year in which the performance obligation was satisfied and it was highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract would not occur. The $50 million milestone fees were fully received by us in 2019.

In consideration for the licenses and other rights granted to Janssen, Janssen paid us an upfront fee of $350.0 million and we were eligible to receive up to an additional $1.35 billion in milestone payments from Janssen. Of the $1.35 billion, we may not receive up to $280 million due to mutually agreed upon modifications to our clinical development plan that resulted in the decision to not conduct certain trials as originally planned. We have previously received the following milestone payments:

- $25 million, $30 million, and $30 million in January 2019, September 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial,
- a milestone payment of $25 million in September 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%,
- a milestone payment of $75 million in January 2021 in connection with the initiation of a rolling submission of a Biologics License Application to the U.S. FDA, for cilta-cel and
- a milestone payment of $15 million in July 2021 in connection with the submission of a Marketing Authorization to the EMA; and
- milestone payments of $50 million during February 2022 in connection with the submission of an NDA to the PMDA in Japan and the enrollment of a specified numbers of patients in our CARTITUDE-5 clinical trial.

Additionally, we are eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $695 million consisting of $485 million for the achievement of specified future development and regulatory milestones and $210 million for the achievement of specified net trade sales milestones. Subsequent development, manufacturing and regulatory milestones will be recognized in full in the period in which it is highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract will not occur, as they are associated with the performance obligation to deliver the license of intellectual property, including a technology transfer service, that was satisfied in 2018. We will recognize revenue for sales-based milestones when the milestone is achieved pursuant to the royalty recognition constraint. We have assessed that achievement of the remaining milestones is highly uncertain and the related milestone payments are not included in the transaction price.

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 license is a single performance obligation in the Janssen Agreement, including a technology transfer service, which represents 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.

Share-Based Compensation

We operate a share option scheme and a restricted stock unit 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 of share option is determined by an external value using a binomial model, and the fair value of each restricted stock unit is determined by reference to market price of our shares at the respective grant date. See notes 27 and 28 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 20-F 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,	
	2021	2020
Expected life of options (years)	10	10
Expected volatility	73.2%-76.4%	73.0%-87.2%
Risk-free interest rate	0.03%-1.72%	0.07%-0.91%
Dividend yield	0%	0%

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

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

Issued But Not Yet Effective Reporting Standards

See note 2.4 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 20-F for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Foreign Currency Exchange Impact

We do not believe that we are exposed to any material foreign currency exchange rate risk.

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 cash balance.

Pursuant to our collaboration and license agreement with Janssen, the advances we receive from Janssen accrue interest at the rate of LIBOR plus 2.5%. Accordingly, changes in LIBOR could result in fluctuations in our cash flows. For example, based on the $119.7 million aggregate principal amount of advances outstanding from Janssen as of December 31, 2021, a 0.5% (fifty basis point) per annum increase in LIBOR would result in an additional $0.6 million per year in interest payable by the Company.

Inflation generally affects us by increasing the cost of labor and raw materials, which increases the costs of clinical trials and, in the event we commercialize any products, the costs of production. 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, 2021, 2020 or 2019.

B. 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.

With the exception of our first product, CARVYKTI™, which was approved by the FDA on February 28, 2022 for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, we do not currently have any approved products and we have never generated any revenue from product sales. From inception through December 31, 2021, we have funded our operations primarily with:

- $3.9 million in capital contributions from Genscript;
- $160.5 million in gross proceeds from the sale of our Series A Preference Shares;
- $600 million in upfront and milestone payments from Janssen under our collaboration and license agreement;
- $450.1 million in net proceeds from our IPO and an additional concurrent $12 million private placement with Genscript;
- $300 million in net proceeds from our private placement to an investor and related warrant issuance in May 2021;
- $323.4 million in net proceeds from our public offering of ADSs that closed in December 2021; and
- $119.7 million in advances from Janssen under our collaboration and license agreement.

As of December 31, 2021, the Company had approximately $688.9 million of cash and cash equivalents, approximately $168.2 million of time deposits, approximately $29.9 million of financial assets measured at amortized cost and accumulated losses of $520.1million.

Certain of our subsidiaries, including those registered as non-PRC-wholly-owned enterprises in China, are required to set aside at least 10.0% of their after-tax profits to their general reserves until such reserves reach 50.0% of their registered capital. Under PRC regulations, non-PRC-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 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. Although we do not currently require any such dividends from our PRC subsidiaries to fund our operations, should we require additional sources of liquidity in the future, such restrictions may have a material adverse effect on our liquidity and capital resources. For more information, see "Item 4.B-Business Overview - Government Regulation - PRC Regulation - Other PRC National- and Provincial-Level Laws and Regulations - Regulations Relating to Dividend Distributions."

Cash Flows

The following table shows a summary of our cash flow:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Net cash used in operating activities	$ (198,465)	$ (223,005)	$ (83,065)
Net cash used in investing activities	(194,983)	(24,169)	(58,652)
Net cash from financing activities	626,663	618,879	14,666
Net increase/(decrease) in cash and cash equivalents	$ 233,215	$ 371,705	$ (127,051)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was $198.5 million, primarily as a result of net loss before tax of $361.4 million after adjusting for non-cash items, and changes in operating assets and liabilities. Non-cash items mainly include $6.2 million of fair value loss of warrant liability and $20.2 million of equity-settled share-based compensation expenses. Changes in operating assets and liabilities mainly include a decrease in trade receivables of $24.6 million primarily resulted from receipt of a milestone payment of $75.0 million offset by an increase of $50.0 million in milestone payments achieved and an increase of $0.4 million in royalty revenue receivable during the year; an increase of $140.7 million in other payables and accruals mainly due to an increase in collaboration expenses payables; and offset by an increase of $3.0 million in prepayments, other receivables and other assets.

Net cash used in operating activities for the year ended December 31, 2020 was $223.0 million, primarily as a result of net loss before tax of $212.5 million after adjusting for non-cash items, and changes in operating assets and liabilities. Non-cash items are mainly from $80.0 million of fair value loss of convertible redeemable preferred shares. Changes in operating assets and liabilities mainly include an increase in trade receivables of $45.0 million due to receipt of a milestone payment.

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 $126.2 million after adjusting 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, 2021 was $195.0 million, consisting primarily of purchases of property, plant and equipment of $42.2 million, purchase of intangible assets of $3.2 million, prepayment to collaborator for collaboration right-of-use assets of $1.7 million, purchase of financial assets

measured at amortized cost of $29.8 million and purchases of time deposits of $298.1 million, partially offset by a decrease in time deposits of $180.0 million.

Net cash used in investing activities for the year ended December 31, 2020 was $24.2 million, consisting primarily of purchases of property, plant, equipment of $26.3 million, purchase of intangible assets of $4.0 million, prepayment to collaborator for collaboration right-of-use assets of $19.5 million and purchase of time deposits of $50.0 million, offset by recovered the time deposits of $75.6 million.

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 $26.8 million, prepayment to collaborator for collaboration right-of-use assets of $11.9 million and purchases of time deposits of $75.6 million, partially offset by collection of cash advances from related parties of $63.0 million.

Financing Activities

Net cash from financing activities for the year ended December 31, 2021 was $626.7 million, consisting primarily of net proceeds from issuance of ordinary shares for follow-on public offering of $323.4 million in December, issuance of ordinary shares and warrant to an institutional investor of $300.0 million in May and proceeds from exercise of share option of $4.6 million, partially offset by principal portion of lease payments of $1.4 million.

Net cash provided by financing activities in the year ended December 31, 2020 was $618.9 million, consisting primarily of proceeds of $150.5 million and $10.0 million from sale of Series A Preference Shares in March and April 2020, respectively, issuance of ordinary shares for private placement by GenScript of $12.0 million, IPO net proceeds of $450.1 million and exercise of share option proceeds of $1.5 million, partially offset by lease payments of $2.6 million and convertible redeemable preferred shares payments of $2.5 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.

Capital Expenditure

Our capital expenditures for the years ended December 31, 2021, 2020 and 2019 amounted to $44.5 million, $50.0 million and $46.8 million, respectively. These expenditures primarily consisted of property, plant, equipment and collaboration assets.

As of December 31, 2021 and 2020, we had commitments for capital expenditures of approximately $25.9 million and $33.6 million, respectively, primarily for 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. We anticipate our capital expenditure in 2022 to be financed from our cash and cash equivalents on hand. Primarily, these capital expenditures will be made both in the United States and China, where our principal research and development facilities are currently located.

Funding Requirements

The following table sets forth our contractual obligations and commitments as of December 31, 2021:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Lease obligations	$ 1,002	$ 1,072	$ 402	$ 265	$ 2,741
Capital commitment	$ 20,905	$ 4,992	—	—	$ 25,897
Total	$ 21,907	$ 6,064	$ 402	$ 265	$ 28,638

This includes capital commitments, as well as payments due under operating leases for our facilities in New Jersey, Ireland and China.

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.

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, following FDA's approval of CARVYKTI™, 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, 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.

Although consequences of the COVID-19 pandemic and resulting economic uncertainty could adversely affect our liquidity and capital resources in the future, and cash requirements may fluctuate based on the timing and extent of many factors such as those discussed below, we currently expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 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.

In addition to cilta-cel, we have a broad portfolio of earlier-stage 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, holders of our ADSs will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. 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 that we would otherwise prefer to develop and market ourselves.

Under our December 2017 collaboration and license agreement with Janssen Biotech for the worldwide development and commercialization of cilta-cel, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. Outstanding advances accrue interest at the London Interbank Offered Rate (LIBOR) published by the Wall Street Journal plus 2.5%. Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the collaboration and license agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the collaboration and license agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest. As of December 31, 2021, the aggregate outstanding principal amount of such advances and interest were approximately $119.7 million and $0.8 million, respectively.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in the "Item 4.B. Information on the Company—Business Overview" and "Item 5 Operating and Financial Review and Prospects" sections of this Annual Report on Form 20-F above.

D. Trend Information

Other than as described elsewhere in this Annual Report on Form 20-F, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

E. Critical Accounting Estimates

See notes 2 and 3 to our consolidated financial statements for a description of our significant accounting policies, including significant accounting judgements and estimates.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth certain information relating to our current directors and executive officers as of March 1, 2022:

Name	Age	Position
Executive Officers		
Ying Huang, Ph.D.	49	Chief Executive Office and Chief Financial Officer
Lori Macomber	51	Vice President, Finance
Non-Employee Directors		
Ye (Sally) Wang, M.S.	53	Chairwoman of the Board of Directors
Ying Huang, Ph.D.	49	Director
Li Zhu Ph.D.	72	Director
Darren Xiaohui Ji, M.D., Ph.D.	60	Independent Director
Corazon D. Sanders Ph.D.	65	Independent Director
Yau Wai Man Philip, CPA	45	Independent Director
Patrick Casey, Ph.D.	65	Independent Director

Executive Officers

Ying Huang, Ph.D., has served as our chief executive officer since September 2020 and as our chief financial officer since July 2019. Dr. Huang has also been a director of Quanta Therapeutics, Inc., a privately-held company, since February 2022. 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. In December 2021, Dr. Huang was appointed to our Board of Directors as a Class I director.

Lori Macomber, has served as our vice president, finance, since March 2021, in which capacity Ms. Macomber serves as our principal financial officer and principal accounting officer. Ms. Macomber has served as our vice president of supply chain finance and controller since September 2019. Prior to joining us, Ms. Macomber served as Business Unit Controller at Ametek PDS, a leading supplier of components and systems for the aerospace and defense industries, from March 2018 to September 2019 and as U.S. CFO and Controller of Cello Health from April 2017 until February 2018. Before this Ms. Macomber held various positions, most recently AVP Finance Site Leader, at Eli Lilly & Company where she was employed from May 2010 until April 2017. Ms. Macomber holds a Bachelor of Science in Accounting from Pennsylvania State University and is a Certified Public Accountant.

Employee Directors

Ying Huang, Ph.D. has served as our director since December 2021. Dr. Huang has also served as our chief executive officer since September 2020 and as our chief financial officer since July 2019.

Non-Employee Directors

Ye (Sally) Wang, M.S., has served as the chairwoman of our board of directors since November 2020 and as our director since May 2015. Ms. Wang served as the Chief Operating Officer of Genscript from April 2014 to November 2017, 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 became the holding company of the Genscript group of companies. Prior to joining Genscript, she worked as an Environmental Monitoring Engineer at Shenzhen Futian Environment Protection Surveillance Station. Ms. Wang also serves as a director for Probio Technology Limited, Bestzyme Biotech Corporation, MapleBio (Nanjing) Co., Ltd., and CustomArray, Inc.. Ms. Wang is a Partner for Nanjing Genbest Enterprise Management Center and is a Trustee and President of Ren-Shiu Foundation, Inc. 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.

Li Zhu, Ph.D., has served as our director since November 2020. Dr. Zhu is the Chief Strategy Officer for Genscript since November 2020. Previously, Dr. Zhu was the Vice President of Strategy of Genscript from 2010 to February 2017, served as Chief Strategy Officer of Genscript from February 2017 to July 2019 and served as a consultant for Genscript from July 2019 to November 2020. Before joining Genscript, Dr. Zhu worked at Clontech Laboratories, Inc. as a Director of Molecular Biology from 1990 to 2000. Dr. Zhu founded Genetastix Corporation, Inc., a biotech company focused on yeast-based antibody discovery, and served as President and Chief Executive Officer from 2000 to 2005. Dr. Zhu then worked at biotech companies in China, serving as Vice President of Research at Cathay Biotech, Inc. from 2006 to 2008, and as vice president of HUYA Biomedical Technology (Shanghai) Co., Limited from 2009 to 2009. Dr. Zhu holds a B.S. in biology from the East China Normal University and a Ph.D. in molecular biology and immunology from Stanford University.

Darren Xiaohui Ji, M.D., Ph.D., has served as our director since May 2020. Dr. Ji currently serves as chief executive officer and chairman of Elpiscience Biopharmaceuticals, Inc., a clinical stage immunotherapy company that he co-founded in June 2017. He also served as a Venture Partner of Lilly Asia Ventures (LAV), a position he held from January 2017 to December 2019. Prior to that, Dr. Ji was Global Head and Vice President of Business Development in Asia and Emerging Markets at F. Hofmann-La Roche Ltd. from 2013 to December 2016. Dr. Ji started his career at Procter & Gamble Pharmaceuticals with responsibilities in drug R&D and business development from 1997 to 2007. He then co-founded and managed as CEO PharmaLegacy Laboratories in Shanghai in 2008. From 2008 to 2013, he served as a board member of the BayHelix Group, a community of business leaders of Chinese Heritage in life science. Dr. Ji holds an M.D. from China Medical University, a Ph.D. from University of Sheffield in the United Kingdom and an M.B.A. from the University of Chicago.

Corazon (Corsee) Sanders, Ph.D., has served as our director since May 2020. Dr. Sanders has been a member of the board of directors of Molecular Templates, Inc. since December 2019, of AltruBio Inc. (f/k/a AbGenomics Holdings Inc.) since March 2020, of Beigene, Ltd since August 2020, and of Ultragenyx Pharmaceuticals, Inc. since June 2021. Dr. Sanders previously served as a Strategic Advisor to the Office of the Celgene Chief Medical Officer from March 2018 to November 2019. Prior to that, Dr. Sanders was a Member of the Juno Therapeutics Executive Committee as Executive Vice President of Development Operations, with responsibilities for strategic operations, quantitative sciences, biosample and clinical operations from January 2017 to March 2018. Dr. Sanders was a Member of the Genentech/Roche Late Stage Portfolio Committee from 2009 to 2017, and Global Head of the Genentech/Roche Late Stage Clinical Operations from 2012 to 2017. Dr. Sanders also serves as a Strategic Advisor to the Fred Hutchinson Cancer Research Center and, since July 2019, has been a member of its Board of Trustees. Dr. Sanders holds a B.S. and M.S. in statistics, graduating Magna Cum Laude from the University of the Philippines, and an M.A. and Ph.D. in statistics from the Wharton Doctoral Program at the University of Pennsylvania.

Yau Wai Man Philip, CPA, has served as our director since May 2020. Mr. Yau has been the chief financial officer of C. & J. Clarks International Limited since October 2021. Prior to that, he was the non-executive vice chairman of AMTD Group, at which he led strategy development, corporate finance and investment functions from 2016 to December 2019. From 2011 to March 2016, he worked at Ernst & Young China Practice as a partner, risk advisory China South market leader, serving clients in Greater China, where he advised on finance, management, and business issues. From 2006 to 2011, he worked at Protiviti Shanghai Co., Ltd. as a managing director and Shenzhen office leader, where he was primarily responsible for overall management of the company. From 1997 to 2006, he worked at PricewaterhouseCoopers and Arthur Andersen & Co., his most recent position being senior manager in the risk consulting practice. Mr. Yau is a certified public accountant in the United States, a fellow member of the Hong Kong Institute of Certified Public Accountants, and a certified internal auditor with the Institute of Internal Auditors. Mr. Yau holds a B.A. in accounting from the Lundquist College of Business of

University of Oregon in the United States and an Executive M.B.A. from a joint school program by Kellogg School of Management, Northwestern University and the Hong Kong University of Science and Technology.

Patrick Casey, Ph.D., has served as our director since December 2020. Dr. Casey has been the Senior Vice Dean of Research at the Duke-NUS Medical School and a James B. Duke Professor of Pharmacology and Cancer Biology at Duke University since 2005. Dr. Casey also serves as an Assistant Professor of Molecular Cancer Biology and Biochemistry at Duke University Medical Center, a position he has held since 1990. He was also the founding director of the Duke Center for Chemical Biology, an organization of Duke scientists dedicated to research and training in the application of fundamental chemical principles to the study of biology and the basis of disease and therapies. Dr. Casey holds a B.A. in biology and chemistry from Augustana University, a Ph.D. in biochemistry from the Brandeis University and did postdoctoral work at the University of Texas Southwestern Medical Center in Dallas.

Family Relationships

There are no family relationships among any of our executive officers or directors.

B. Compensation

Compensation of Directors and Executive Officers

For the year ended December 31, 2021, we paid an aggregate of $2,672,441.04 in cash and benefits to our executive officers, including former executive officers, Dr. Yuan Xu and Dr. Frank Zhang, and non-employee directors. During the year ended December 31, 2021, we paid our non-employee directors $300,000. For the year ended December 31, 2021, stock options to purchase 30,000 ordinary shares with an exercise price of $14.12 per ordinary share and an expiration date of March 28, 2031 were issued to Patrick Casey, PhD, our new non-employee director, as compensation under the Share Option Scheme and restricted share unit awards for 54,172 ordinary shares were issued to non-employee directors as compensation under the 2020 Restricted Shares Plan. For additional information about share incentive grants to our officers and directors, see Item 6.B. “Directors, Senior Management and Employees — Compensation — 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.

Our board of directors has adopted a non-employee director compensation policy, pursuant to which each of our directors who is not an employee of our company or affiliated with an entity that beneficially owns 5% or more of our outstanding shares of common stock, which is Dr. Ji, Dr. Sanders, Mr. Yau and Dr. Casey, is eligible to receive compensation for service on our board of directors and committees of our board of directors. Each eligible director receives an annual cash retainer of $75,000 for serving on our board of directors. All annual cash compensation amounts are payable in equal quarterly installments in advance within the first 30 days of each quarter in which the service will occur. During the year ended December 31, 2021, our board of directors approved a one-time payment of $15,000 each for non-employee directors Dr. Darren Xiaohui Ji, Dr. Corazon D. Sanders and Mr. Yau Wai Man. This payment was approved in light of the substantial time commitment contributed by such non-employee directors during the course of the year ended December 31, 2020.

In addition, as of the pricing of our initial public offering, each eligible director was granted an option to purchase 30,000 ordinary shares, with an exercise price of $11.50 per share, with one-fifth of the shares vesting on the first anniversary of the date of grant and the remaining shares vesting in four equal annual installments thereafter, subject to continued service as a director through the applicable vesting date, as well as a restricted share unit award for 17,391 ordinary shares, with one-third of the shares vesting on the first anniversary of the date of grant and the remaining shares vesting in eight equal quarterly installments thereafter, subject to continued service as a director through the applicable vesting date. Each new eligible director who joins our board of directors will be granted an option to purchase 30,000 ordinary shares, with one-fifth of the shares vesting on the first anniversary of the date of grant and the remaining shares vesting in four equal annual installments thereafter, subject to continued service as a director through the applicable vesting date. Each new eligible director who joins our board of directors will also receive a restricted share unit award for a number of ordinary shares equal to $200,000 divided by one half of the closing price of our ADSs on the date of grant.

Additionally, on the date of each annual general shareholders meeting, each eligible director who continues to serve as a director following the meeting will be granted a restricted share unit award for a number of ordinary shares equal to $200,000 divided by one half of the closing price of our ADSs on the date of grant. The restricted share unit awards granted pursuant to our non-employee director compensation policy will vest one-third on the first anniversary of the date of grant and the remaining shares vest in eight equal quarterly installments thereafter, subject to continued service as a director through the applicable vesting date.

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 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.

In connection with the appointment of Dr. Huang as our Chief Executive Officer, we entered into an employment agreement 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 $642,000. Commencing in 2021, Dr. Huang is also eligible to receive an annual performance bonus, with a target bonus of 65% of his base salary. Dr. Huang is also entitled to receive an annual award of $1,000,000 in our restricted stock units, which will vest in three equal installments on each of the first three anniversaries of the grant date, subject to continued service and achievement of any performance objectives established by our board of directors. In 2021, Dr. Huang was entitled to receive a one-time award of share options to purchase 300,000 ordinary shares at an exercise price equal to the fair market value on the grant date, which will vest in three equal installments on each of the first three anniversaries of their grant date, subject to continued service and achievement of any performance objectives established by our board of directors.

Pursuant to the employment agreement, if Dr. Huang's employment is terminated other than for "cause," (i) he is entitled to severance equal to 12 months of his base salary; and (ii) shares underlying restricted stock units and share options which are then eligible to vest during the 12-month period following the termination date will become immediately vested and exercisable, subject to execution by Dr. Huang of a severance agreement and general release of claims, with any remaining unvested restricted stock units and option shares to be forfeited.

In September 2019, we entered into an offer letter with Ms. Macomber, our current Vice President, Finance and our principal financial officer. The employment is "at will" and may be terminated at any time. Ms. Macomber is entitled to an annual base salary of $284,138 and is eligible to receive an annual performance bonus. Ms. Macomber participates in our performance-based share option and restricted stock unit schemes. Share options awards vest in equal installments on each of the first five anniversaries of the grant date and restricted stock units vest in equal installments on each of the first three anniversaries of the grant date.

We have entered into indemnification agreements with each of our directors and executive officers. 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 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, 2021, options covering 9,529,158 ordinary shares with a weighted-average exercise price of $2.90 per share were outstanding, and 4,732,466 ordinary shares remained available for the future option grants. During the period from November 29, 2019 through December 9, 2019, the Company granted to certain employees of the Company options to purchase ordinary shares of the Company pursuant to the Company's Share Option Scheme with an exercise price of $1.50 per ordinary share. As a result of the Company's filing of a registration statement with the U.S. Securities and Exchange Commission in connection with its initial public offering, certain listing rules of the Hong Kong Stock Exchange to which Genscript are subject became applicable. These Hong Kong Stock Exchange listing rules provided that during the period commencing six months prior to the filing of such registration statement through the listing date of the Company's American Depositary Shares, the exercise price of any granted stock options could be no lower than the $23.00 per ADS (each ADS representing two ordinary shares of the Company) public offering price in the initial public offering. Accordingly, in order to comply with this Hong Kong listing rule, the Company applied an adjustment to the affected share options, and the exercise price of each such option was adjusted to $11.50 per ordinary share. In connection with this adjustment, the Company agreed to pay each employee holding affected stock options an amount in cash representing the difference between the adjusted exercise price over the original exercise price upon exercising of such options.

Administration. Our board of directors administers our Share Option Scheme and has the power to, among other things, determine the eligible persons to whom, and the times at which, options will be granted, to determine the terms and conditions of each option (including the number of shares subject to the option, the exercise price of the option, if any, and when the option will vest and become exercisable), to accelerate the time at which an option may vest or be exercised, and to construe and interpret the terms of our Share Option Scheme and options granted thereunder. Certain grants to directors and employees of Genscript are subject to the approval of Genscript's independent directors and/or Genscript's shareholders.

Options. The exercise price of options granted under the Share Option Scheme is no less than the fair market value of an ordinary share on the date of grant. Subject to the provisions of the Share Option Scheme, the board of directors determines the other terms of options, including any vesting and exercisability requirements, the method of payment of the option exercise price, the option expiration date, and the period following termination of service during which options may remain exercisable.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a share split or reverse share split, appropriate adjustments will be made to the number of shares covered by, and the exercise price of, each outstanding option granted under the Share Option Scheme.

Plan Amendment or Termination. Subject to Hong Kong Stock Exchange listing rules applicable to Genscript and certain amendments requiring approval of Genscript shareholders, the board of directors may amend the Share Option Scheme at any time. An amendment that adversely affects the terms of options previously granted or agreed to be granted must generally be approved by at least three-fourths in nominal value of all shares then subject to options granted under the Share Option Scheme. The Share Option Scheme will terminate on December 21, 2027 and may be terminated prior to that date by the board of directors.

Restricted Share Unit Incentive Plan 2020 Restricted Shares Plan

On May 26, 2020, our shareholders approved our 2020 Restricted Shares Plan, or the RSU Scheme, under which, subject to the approval of our board of directors, we may grant restricted shares and restricted share units to eligible participants. The material terms of the RSU Scheme are set forth below.

The RSU Scheme provides for the grant of restricted shares and restricted share units (referred to as awards). Awards may be granted to our employees, consultants and directors, as well as to employees, consultants and directors of Genscript's other subsidiaries, subject to applicable law.

The maximum aggregate number of shares that may be issued pursuant to all awards granted under the RSU Scheme is 11,000,000 shares. As of December 31, 2021, restricted share units covering 2,601,187 ordinary shares were outstanding, and 8,049,597 ordinary shares remained available for future grant under the RSU Scheme.

Administration. Our board of directors or the compensation committee thereof (the administrator) administers our RSU Scheme and has the power to, among other things, determine the eligible persons to whom, and the times at which, awards will be granted, to determine the terms and conditions of each award (including the number of shares subject to the award, and when the award will vest), to accelerate the time at which an award may vest, and to construe and interpret the terms of our RSU Scheme and awards granted thereunder.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a share split or reverse share split, appropriate adjustments will be made to the aggregate number and type of shares that may be issued; the terms and conditions of any outstanding awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and the grant or exercise price per share for any outstanding awards.

Amendment or Termination. The administrator may terminate, amend or modify the RSU Scheme; provided, however, that (a) to the extent necessary and desirable to comply with applicable laws or stock exchange rules, the Company must obtain shareholder approval of any amendment in such a manner and to such a degree as required, unless the Company decides to follow home country practice, and (b) unless the Company decides to follow home country practice, shareholder approval is required for any amendment to the RSU Scheme that (i) increases the number of shares available under the RSU Scheme, (ii) permits the compensation committee to extend the term of the RSU Scheme, or (iii) results in a material increase in benefits or a change in eligibility requirements. Generally, no termination, amendment, or modification of the RSU Scheme may adversely affect in any material way any award previously granted pursuant to the RSU Scheme without the prior written consent of the participant.

C. Board Practices

Board of Directors

Our board of directors consists of seven directors. 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 Darren Xiaohui Ji, Corazon D. Sanders, Yau Wai Man Philip and Patrick Casey, representing four of our seven 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.

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. We are a "controlled company" as defined under the Nasdaq Stock Market Rules.

We have relied and will continue to rely on the "controlled company" exemption, and we are not required to have a majority of independent directors, our compensation committee and our nominating and corporate governance committee are not required to consist entirely of independent directors and such committees are not required to 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.

Duties of Directors

Under Cayman Islands law, our directors have a fiduciary duty to act honestly and in good faith with a view to our best interests. Our directors also have a duty to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended and restated memorandum and articles of association. A shareholder has the right to seek damages if a duty owed by our directors is breached.

The functions and powers of our board of directors include, among others:

- conducting and managing the business of our company;
- representing our company in contracts and deals;
- appointing attorneys for our company;
- selecting and removing senior management;
- providing employee benefits and pensions;
- managing our company's finance and bank accounts;
- evaluating the performance and determining the compensation level of chief executive officer;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- exercising any other powers conferred by the shareholders meetings or under our amended and restated memorandum and articles of association.

Terms of Directors and Executive Officers

Our directors may be elected by a resolution of our board of directors, or by an ordinary resolution of our shareholders, pursuant to our amended and restated memorandum and articles of association. Each director is currently elected to the board for a one-year term, to serve until the election and qualification of successor directors at the annual meeting of shareholders, or until the director's earlier removal, resignation or death. In accordance with our amended and restated memorandum and articles of association, our board of directors is divided into three classes, each of which consists, as nearly as possible, of one-third of the total number of directors constituting our entire board and which serve staggered three-year terms. At each annual meeting of shareholders, the successors to

directors whose terms then expire are elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class I, which consists of Ye Wang, Darren Xiaohui Ji and Ying Huang, and their term expires at our annual meeting of shareholders in 2024;
- Class II, which consists of Patrick Casey and Yau Wai Man Philip, and their term expires at our annual meeting of shareholders in 2022; and
- Class III, which consists of Li Zhu and Corazon D. Sanders, and their term expires at our annual meeting of shareholders in 2023.

Our amended and restated memorandum and articles of association provides that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control.

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 has established an audit committee, a compensation committee and a nominating and corporate governance committee. We have adopted a charter for each of the committees. Each committee's members and functions are described below.

Audit Committee

Our audit committee consists of Darren Xiaohui Ji, Corazon D. Sanders and Yau Wai Man Philip. Mr. Yau is the chairperson of our audit committee. Mr. Yau satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC. Each of Dr. Ji, Dr. Sanders and Mr. Yau satisfies the requirements for an "independent director" within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq and meets the criteria for independence set forth in Rule 10A-3 of the Exchange Act.

The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. Our audit committee is responsible for, among other things:

- selecting the independent auditor;
- pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;
- annually reviewing the independent auditor's report describing the auditing firm's internal quality control procedures, any material issues raised by the most recent internal quality control review, or peer review, of the independent auditors and all relationships between the independent auditor and our company;
- review responsibilities, budget, compensation and staffing of our internal audit function;
- reviewing with the independent auditor any audit problems or difficulties and management's response;
- reviewing and, if material, approving all related party transactions on an ongoing basis;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;

- reviewing and discussing with management and the independent auditors major issues regarding accounting principles and financial statement presentations;
- reviewing reports prepared by management or the independent auditors relating to significant financial reporting issues and judgments;
- discussing earnings press releases with management, as well as financial information and earnings guidance provided to analysts and rating agencies;
- reviewing with management and the independent auditors the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on our financial statements;
- discussing policies with respect to risk assessment and risk management with management and internal auditors;
- timely reviewing reports from the independent auditor regarding all critical accounting policies and practices to be used by our company, all alternative treatments of financial information within IFRS that have been discussed with management and all other material written communications between the independent auditor and management;
- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- such other matters that are specifically delegated to our audit committee by our board of directors from time to time; and
- meeting separately, periodically, with management, internal auditors and the independent auditor.

Compensation Committee

Our compensation committee consists of Darren Xiaohui Ji, Corazon D. Sanders and Ye Wang. Dr. Ji is the chairperson of our compensation committee. Each of Dr. Ji and Dr. Sanders 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 is responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation policies;
- reviewing and evaluating the performance of our directors and relevant senior officers and determining the compensation of relevant senior officers;
- reviewing and approving our senior officers' employment agreements with us;
- setting performance targets for relevant senior officers with respect to our incentive compensation plan and equity-based compensation plans;
- administering our equity-based compensation plans in accordance with the terms thereof; and
- such other matters that are specifically delegated to the compensation committee by our board of directors from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Ye Wang, Yau Wai Man Philip and Patrick Casey.

Ms. Wang is the chairperson of our nominating and corporate governance committee.

The nominating and corporate governance committee is 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.

Board Diversity

The table below provides certain information regarding the diversity of our board of directors as of the date of this Annual Report.

Board Diversity Matrix				
Total Number of Directors	7			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	5	0	0
Part II: Number of Directors Who Identify in Any of the Categories Below:				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	2	4	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	0	1	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+	0			
Persons with Disabilities	0			

D. Employees

As of December 31, 2021, we had 1,071 employees, 129 of whom hold Ph.D. and/or M.D. degrees. Of these 1,071 employees, 371 are engaged in research and development activities and 121 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,	
	2021	2020
Function:		
General and administrative	121	76
Research and development	371	388
Sales and marketing	60	24
Others	519	394
Total	1,071	882
Geography:		
United States	475	295
Asia-Pacific	582	579
Europe	14	8
Total	1,071	882

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 6.B Directors, Senior Management and Employees—Compensation" and "Item 7.A Major Shareholders and Related Party Transactions—Major Shareholders."

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

We had 308,456,852 ordinary shares outstanding as of December 31, 2021. Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2020:

- Each of our directors and executive officers;
- All of our directors and executive officers as a group; and
- Each person known to us to beneficially own more than 5% of our ordinary shares.

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 December 31, 2021, 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
5% or Greater Shareholders:		
Genscript Biotech Corporation(1)	174,497,556	56.6%
Hillhouse Investment Management, Ltd. (2)	33,609,850	10.9%
AquaPoint L.P.(3)	30,320,000	9.83%
Fangliang Zhang, Ph.D.(4)	33,816,490	10.96%
Executive Officers and Directors:		
Ying Huang, Ph.D.(5)	5,308	*
Lori Macomber, M.S.	—	—
Ye (Sally) Wang, M.S. (6)(7)	16	*
Darren Xiaohui Ji, M.D., Ph.D. (8)	14,696	*
Corazon D. Sanders, Ph.D (9)	16,144	*
Yau Wai Man Philip, CPA (10)	16,144	*
Li Zhu, Ph.D (11)	716	*
Patrick Casey, Ph.D	—	—
All Current Executive Officers and Directors as a Group (8 persons)	53,024	*

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

1) Consists of (i) 169,680,000 ordinary shares held by Genscript Biotech Corporation before our initial public offering, (ii) 1,043,478 ordinary shares issued to Genscript Biotech Corporation in the concurrent private placement, which are offset by 725,922 ordinary shares underlying ADSs that Genscript distributed to its shareholders to effect the assured entitlement distribution pursuant to the rules of the Hong Kong Stock Exchange, and (iii) 4,500,000 ordinary shares underlying 2,250,000 ADSs that Genscript Biotech Corporation purchased in connection with Legend Biotech's follow-on offering completed in December 2021. 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 2,800,000 ordinary shares held by funds managed by HHLR Fund, L.P. ("HHLR") and 30,809,850 ordinary shares (including 10,000,000 ordinary shares underlying warrants) held by funds managed by Hillhouse Investment Management, Ltd. ("HIM"). HHLR and HIM are under common

control and share certain policies, personnel and resources. The address for each of HHLR and HIM is Office #122, Windward 3 Building, Regatta Office Park, West Bay Road, Grand Cayman, Cayman Islands, KY1-9006.

3) 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, Cayman Islands.

4) Consists of (i) the shares described in footnote (3), and (ii) 3,496,490 ordinary shares as of December 31, 2021 due to exercise of share options, over which Dr. Zhang has voting power pursuant to an irrevocable proxy with the holders of such options, including shares (i) subject to options exercised but not sold as of December 31, 2021, (ii) subject to vested but unexercised options as of December 31, 2021 and (iii) subject to options scheduled to vest within 60 days thereafter. Dr. Zhang is shareholder of Genscript Biotech Corporation, a publicly traded company on the Hong Kong Stock Exchange, but does not have voting or dispositive power over the shares held by Genscript Biotech Corporation.

5) Consists of 2,654 ADSs directly held by Dr. Huang.

6) Ms. Wang directly holds 32.9% of AquaPoint L.P., whose general partner is Genscript Corporation, the largest holder of our majority shareholder, Genscript Biotech Corporation. Ms. Wang does not hold any voting or dispositive power over the ordinary shares held by AquaPoint L.P. Ms. Wang also directly holds 26,152 shares of Genscript and vested employee stock options to acquire 44,762,194 shares of Genscript.

7) Consists of 8,696 ordinary shares directly held by Dr. Ji. Also includes options to acquire 6,000 ordinary shares exercisable within 60 days of December 31, 2021, of which Dr. Ji has dispositive power but not voting power over.

8) Consists of 8,696 ordinary shares directly held by Dr. Sanders. Also includes options to acquire 6,000 ordinary shares exercisable within 60 days of December 31, 2021, of which Dr. Sanders has dispositive power but not voting power over.

9) Consists of 8,696 ordinary shares directly held by Mr. Yau. Also includes options to acquire 6,000 ordinary shares exercisable within 60 days of December 31, 2021, of which Mr. Yao has dispositive power but not voting power over.

10) Consists of 358 ADSs directly held by Dr. Zhu.

None of our principal shareholders has voting rights different than our other shareholders.

As of December 31, 2021, we estimate that 106,948,851 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held in the United States by two holders of record. The actual number of holders is greater than these numbers of record holders and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2021 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 Majority Shareholder Genscript

Genscript is our majority shareholder, owning approximately 56.6% of our outstanding ordinary shares as of March 1, 2022. Below are a summary of the other transactions we are party to with Genscript. As we continue to grow and execute on our business strategy, we anticipate that from time to time we will likely continue to enter into similar and other transactions with Genscript where we can take advantage of the resources and expertise that

Genscript can provide. Any future transaction we enter into with Genscript would be evaluated at an arms' length basis and approved in accordance with our related person transaction policy described below.

Purchase of ADSs from Legend Biotech

We consummated a public offering of 8,615,575 ADSs (reflecting a partial exercise of the over-allotment option by the underwriters to purchase an additional 1,115,575 ADSs) at a price to the public of $40.00 per ADS that closed on December 20, 2021. In that public offering, Genscript purchased 2,250,000 of our offered ADSs at the public offering price of $40 per ADS.

Exclusive Licensing of Patents to Nanjing Probio Biotech Co., Ltd.

We entered into the Exclusive License Agreement dated as of August 18, 2021 with Nanjing Probio Biotech Co., Ltd (Probio), a related party controlled by Genscript, pursuant to which Legend granted to Probio and its affiliates an exclusive license under specified patents and related know-how in exchange for Probio's payment to Legend of $1.5 million and its agreement to provide, within two years of the date of the agreement, $1.5 million in the form of CDMO services to Legend.

Funding of Certain Legal Fees

During the year ended December 31, 2021, we funded $177,156 of legal fees incurred by Genscript in connection with our securities offering activities.

IT Department and Human Resources Service Level Agreements

Legend Biotech USA Inc., Legend Biotech Ireland Limited and Nanjing Legend Biotech Co., Ltd. are each party to information technology support services agreements with a subsidiary of Genscript. We expect to pay this subsidiary of Genscript approximately $150,000 during 2022 in consideration of its performance of infrastructure related support services to us under these agreements. We expect to terminate these agreements on or before June 30, 2022. In addition, a subsidiary of Genscript provided certain application-related support services to Nanjing Legend Biotech Co., Ltd. under an agreement that expired at the end of 2021. We and Genscript are in discussions to extend that agreement for another year and, if extended, we expect to pay Genscript approximately $150,000 under the extended agreement during 2022.

In February 2020, we entered into the human resources service level agreement, or the Human Resources Agreement, with Genscript. Pursuant to that agreement, Genscript provided human resources services to us, such as managing long-term incentives globally and payroll services for Ireland. That agreement terminated during September 2021.

Facilities

Piscataway. In February 2018, we entered into a lease agreement with Genscript USA Holdings, Inc., a subsidiary of Genscript, under which we lease an approximately 22,000 square foot facility in Piscataway, New Jersey at a cost of $60,000 per month. In January 2020, we entered into an additional lease agreement. The lease term is from January 1, 2020 to December 31, 2021. Although the lease has expired, we continue to occupy the premises, and we and Genscript are in discussions regarding extension of the lease. The cost of the lease is expected to be approximately $600,000 for 2022.

Animal Facility Lease and Services Agreements. We are party to an animal facility lease agreement with Nanjing Genscript Biotechnology Co., Ltd., a subsidiary of Genscript, or Genscript Nanjing. Under the agreement, we lease a 1,000 square meter animal facility in Nanjing, China, at a cost of approximately RMB 51,000 per month ($7,994 per month, based on the conversion rate of RMB 6.38 to $1.00, which was the exchange rate on December 31, 2021) (value-added tax, or VAT, included). The lease expires in June 2025. In addition, we entered into an Animal Technical Service Agreement with Genscript Nanjing during April 2021, pursuant to which Genscript Nanjing provides facility operation, animal procurement, quarantine, animal feeding and care, and animal testing

compliance services to us. While that agreement terminated in September 2021, we and Genscript are in discussions regarding its extension. We expect that the extended agreement will cover substantially the same services, that we will pay Genscript approximately $1.5 million per year in services fees under the agreement, and that the agreement will have a scheduled expiration date during December 2024.

Dublin. In 2018, we entered into a lease agreement with Tango Medic SLU, under which we lease an approximately 8,300 square foot facility in Dublin, Ireland at a cost of approximately 13,000 Euro (€) per month. The term of this lease is from August 2018 to August 2028. Genscript has guaranteed our obligations under this lease.

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 $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 30, 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 "Item 6.B. Directors, Senior Management and Employees — Compensation— Compensation of Directors and Executive Officers." and "Item 6.B Directors, Senior Management and Employees—Compensation—Employment Agreements and Indemnification Agreements."

Employment Agreements and Indemnification Agreements

We have entered employment agreements with each of our executive officers, and into indemnification agreements with each of our executive officers and directors. For more information see "Item 6.B. Directors, Senior Management and Employees— Compensation— Employment Agreements and Indemnification Agreements."

Policies and Procedures for Related Person Transactions

On May 27, 2020, we adopted 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.

C. Interests of Experts and Counsel

Not Applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See "Item 18 Financial Statements."

Legal and Administrative 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.

In light of the investigation by the Customs Anti-Smuggling Department of Zhenjiang (the "Authority") in the People's Republic of China (the "PRC") of Genscript, and Dr. Fangliang Zhang, former Chairman of the Board of Directors and Chief Executive Officer of the Company and former Chairman and Chief Executive Officer of Genscript, as previously disclosed, the Audit Committee of our Board of Directors engaged external counsel to conduct an internal review of the Company's import and export transactions since our initial public offering (the "IPO") in June 2020 to confirm our compliance with import and export regulations under the laws of the PRC.

This review identified no apparent issues with respect to transactions conducted by us since our IPO. However, transactions prior to July 2020 were handled by Genscript on our behalf, which limits our ability to review such transactions. We understand that Genscript has performed a targeted review of these transactions with the assistance of its external counsel based on feedback from its communication with the Authority. In the course of its inspection of Genscript, the Authority identified nine import transactions, which Genscript handled on our behalf prior to the IPO, with respect to which Genscript has indicated there may be minor non-compliance issues concerning import declarations. Genscript believes that it is the target of the Authority's inquiries with respect to these import declaration matters, which are distinct from the matters that have been the focus of the Authority's investigation, and the Authority has not contacted us with respect to such import declaration matters.

Further, Genscript has not conducted a comprehensive internal review of all transactions it handled on our behalf prior to the IPO. Accordingly, our ability to ascertain the risk of our exposure to the Authority's investigation is limited and there is risk that we may become a subject of the Authority's investigation in the future, and thereafter subject to proceedings, penalties and restrictions on our activities.

In May 2021, Dr. Zhang and the four employees of Genscript, along with two PRC subsidiaries of Genscript, were notified by the Authority that the investigation was complete, and that their respective matter had been handed over to the Zhenjiang Municipal People's Procuratorate, or the Procuratorate, for examination and possible prosecution. In July 2021, the Procuratorate returned the case to the Authority for supplementary investigation. As of the date of this Annual Report on Form 20-F, the supplementary investigation is completed and the Authority has handed the case back to the Procuratorate. Whether or when the Procuratorate will pursue pressing any charges against GenScript, Dr. Zhang or Genscript employees remains undecided. To the best of our knowledge, no charges have been filed to date against Dr. Zhang, Genscript or us and the Authority has not notified us that we are a target of the Authority's investigation.

As of March 15, 2022, no charges have been filed in PRC against us or any of our current or former officers or directors, and to our knowledge, we are not a target of the Authority's investigation.

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. 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 "Item 12.D. Description of Securities Other than Equity Securities—American Depositary Shares." Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

B. Significant Changes

Not applicable.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ADSs are listed under the symbol "LEGN" for trading on the Nasdaq Global Select Market.

B. Plan of Distribution

Not Applicable.

C. Markets

Our ADSs have been listed under the symbol "LEGN" for trading on the Nasdaq Global Select Market since June 5, 2020.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not Applicable.

F. Expenses of the Issue

Not Applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not Applicable.

B. Memorandum and Articles of Association

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 Act (as amended) of the Cayman Islands, which we refer to as the Companies Act below and the common law of the Cayman Islands. We incorporate by reference into this Annual Report the description of our Third Amended and Restated Memorandum and Articles of Association contained in our Registration Statement on Form F-1 (File No. 333-238232), as amended, initially filed with the SEC on May 29, 2020. Our shareholders adopted our Third Amended and Restated Memorandum and Articles of Association by a special resolution on May 26, 2020, which became effective upon completion of our initial public offering of ordinary shares represented by our ADSs.

For summaries of material provisions of our amended and restated memorandum and articles of association, and of the Companies Act, insofar as they relate to the material terms of our ordinary shares, please refer to Exhibit 2.5 filed with this Annual Report on Form 20-F.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" or elsewhere in this Annual Report.

D. Exchange Controls

See "Item 4.B. Information On The Company—Business Overview— Government Regulation—PRC Regulation — Other PRC National- and Provincial-Level Laws and Regulations—Regulations Relating to Foreign Exchange." and "Item 4.B. Information on the Company—Business Overview—Government Regulation—PRC Regulation—Other PRC National- and Provincial-Level Laws and Regulations—Regulations Relating to Dividend Distributions."

E. 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. 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 Annual Report, 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) Act (2021 Revision), 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 (such as the effects of Section 451(b) of the Code conforming the timing of certain income accruals to financial statements) 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, 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 ADSs, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from our initial public offering and other fundraising activities in our business. Based on our operating history and the projected composition of our income and valuation of our assets, including goodwill, we do not believe we were a PFIC for our taxable year ending December 31, 2021. 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, including the current taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2021, and expresses no opinion with regard to our expectations regarding our PFIC status for the current or future taxable years.

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 Select 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 "Item 8.A. Consolidated Statements and Other Financial Information—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 "Item 10.E. Additional Information—Taxation—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 Select 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 "Item 10.E. Additional Information—Taxation—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 U.S. Holder 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 ownership and disposition of 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 "Item 10.E. Additional Information—Taxation—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 $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. In addition to these requirements, U.S. holders may be required to annually file FinCEN Report 114 (Report of Foreign Bank and Financial Accounts) with the U.S. Department of Treasury. U.S. holders are thus encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of the ADSs.

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 or non-PRC individuals, 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 ordinary 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 ordinary 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 Item 3.D. "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."

F. Dividends and Paying Agents

Not Applicable.

G. Statement by Experts

Not Applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act and are required to file reports and other information with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system.

We are a "foreign private issuer" as such term is defined in Rule 405 under the Securities Act, and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, we do not file the same reports that a U.S. domestic issuer would file with the SEC.

We also make available on our website's investor relations page, free of charge, our annual report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. The address for our investor relations page is www.*investors.legendbiotech.com*. The information contained on our website is not incorporated by reference in this Annual Report on Form 20-F.

I. Subsidiary Information

Not Applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash is held in readily available checking accounts and time deposits. 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 cash balance.

Pursuant to our collaboration and license agreement with Janssen, the advances we receive from Janssen accrue interest at the rate of LIBOR plus 2.5%. Accordingly, changes in LIBOR could result in fluctuations in our cash flows. For example, based on the $119.7 million aggregate principal amount of advances outstanding from Janssen as of December 31, 2021, a 0.5% (fifty basis point) per annum increase in LIBOR would result in an additional $0.6 million per year in interest payable by the Company.

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, 2020 and 2021.

We also do not believe that we are exposed to any material foreign currency exchange rate risk.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not Applicable.

B. Warrants and Rights

In connection with the PIPE Offering in May 2021, as described below in "Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds", we agreed to issue and sell to an institutional investor, concurrently with the PIPE Offering, a warrant exercisable for up to an aggregate of 10,000,000 ordinary shares. The warrant is exercisable, in whole or in part, at an exercise price of $20 per ordinary share, equivalent to a price of $40 per ADS, it became exercisable on May 19, 2021 and it will remain exercisable until the two-year anniversary of that date. The 10,000,000 ordinary shares issuable upon exercise of the warrant were registered pursuant to our Registration Statement on Form F-3, effective July 13, 2021. As of December 31, 2021, the warrant had not been exercised in whole or part.

C. Other Securities

Not Applicable.

D. American Depositary Shares

JPMorgan Chase Bank, N.A., or JPMorgan, as depositary for our ADSs, registers and delivers the ADSs. Each ADS represents an ownership interest in a designated number of shares which we deposit with the custodian, as agent of the depositary. Each ADS represents two ordinary shares. 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). The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

A 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 sets out the ADR holder rights as well as rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Payments from the Depositary to Us

Our depositary has agreed to share with us certain fees payable to the depositary by holders of ADSs. We anticipate that the fees shared with us by the depositary, after deduction of applicable U.S. taxes, will be substantially similar to those shared with us during fiscal year 2020, or approximately US$0.9 million.

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 a 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.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Material Modifications to the Rights of Security Holders

None.

E. Use of Proceeds

Initial Public Offering

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File No. 333-238232), in relation to our initial public offering, which was declared effective by the SEC on June 4, 2020. In June 2020, we completed our initial public offering in which we issued and sold an aggregate of 21,188,750 ADSs (reflecting the full exercise of the over-allotment option by the underwriters to purchase an additional 2,763,750 ADSs). We incurred aggregate underwriting discounts of approximately $34.1 million and offering expenses of approximately $3.1 million, resulting in net proceeds to us of approximately $450.1 million. No payments were made directly or indirectly to any directors, officers, general partners of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates. The offering commenced on June 5, 2020 and did not terminate before all of the securities registered in the registration statement were sold. Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC were the representatives of the underwriters for our initial public offering.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and time deposits and investments. As of December 31, 2021, there has been no material change in the planned use of the remaining proceeds from our IPO from those disclosed in the Prospectus on Form 424B4 (File No. 333-238232) filed with the SEC on June 8, 2020. The net proceeds from our IPO will be used, together with our cash and cash equivalents, short-term and long-term investments, to fund continued advancement of our product pipeline, with the balance to be used to fund working capital and other general corporate purposes, which may include licensing, acquiring or investing in complementary businesses, technologies, products or assets.

PIPE Offering and Warrant

The following "Use of Proceeds" information relates to a subscription agreement entered into during May 2021 between us and an institutional investor relating to our offering and sale of 20,809,850 ordinary shares in a private placement at a purchase price of $14.41625 per ordinary share, equivalent to a price of $28.8325 per ADS. We refer to that private placement as the PIPE Offering. Pursuant to the subscription agreement, we also agreed to issue and sell to this investor, concurrently with the PIPE Offering, a warrant exercisable for up to an aggregate of 10,000,000 ordinary shares. The warrant is exercisable, in whole or in part, at an exercise price of $20 per ordinary share, equivalent to a price of $40 per ADS, it became exercisable on May 19, 2021 and it will remain exercisable until the two-year anniversary of that date. Furthermore, this investor was granted customary registration rights with respect to the ordinary shares the investor acquired in the PIPE Offering and the ordinary shares issuable upon exercise of the warrant. The 10,000,000 ordinary shares issuable upon exercise of the warrant were registered pursuant to our Registration Statement on Form F-3, effective July 13, 2021. As of December 31, 2021, the warrant had not been exercised in whole or part.

We received net proceeds of $300 million from the PIPE Offering. We intend to use the net proceeds from the PIPE Offering and warrant exercises, together with our existing cash and cash equivalents, to fund the clinical development of cilta-cel, fund the construction of our manufacturing facilities, fund the commercial launch of cilta-cel and fund the development of our pipeline programs, as well as for working capital and other general corporate purposes.

December 2021 Public Offering

The following "Use of Proceeds" information relates to our shelf registration statement on Form F-3 (File No. 333-257609), which was filed and automatically effective on July 1, 2021, as supplemented by a prospectus supplement dated December 16, 2021, regarding our public offering of 8,615,575 ADSs (reflecting a partial exercise of the over-allotment option by the underwriters to purchase an additional 1,115,575 ADSs), at a price to the public of $40.00 per ADS, that closed on December 20, 2021. We incurred aggregate underwriting discounts of approximately $20.7 million and capitalized offering expenses of approximately $0.5 million, resulting in net proceeds to us of approximately $323.4 million. No payments were made directly or indirectly to any directors, officers, general partners of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the clinical development of cilta-cel, fund the construction of our manufacturing facilities, fund the commercial launch of cilta-cel and fund the development of our pipeline programs, as well as for working capital and other general corporate purposes.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

In the Original 20-F, we reported that our management, with the participation of our Chief Executive Officer, Chief Financial Officer and Vice President, Finance, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period December 31, 2021 (the "Evaluation Date"),, as required by Rule 13a-15(b) under the Exchange Act. Based on such evaluation, those officers had concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective.

Subsequent to that evaluation and in connection with the preparation of the Restatement, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, re-evaluated the Company's disclosure controls and procedures and concluded that, as of December 31, 2021, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness discussed below.

B. Management's Annual Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f).

In the Original 20-F, we reported that management, with the participation of the Chief Executive Officer, Chief Financial Officer and the Vice President, Finance, had assessed the effectiveness of internal control over financial reporting as of December 31, 2021. Management's assessment was based on the framework in "Internal Control – Integrated Framework (2013)", or 2013 framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on that assessment on March 31, 2022, when the Original 20-F was filed, management had concluded that our internal controls over financial reporting were effective. Subsequently, as a result of the material weakness described below, management revised its assessment and concluded that, as of December 31, 2021, our internal controls over financial reporting were not effective.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material weakness as of December 31, 2021

Under the standards established by the PCAOB, a material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented or detected on a timely basis. In connection

with the restatement discussed in Note 2.2 of the Consolidated Financial Statements included under "Item 18. Financial Statements", management identified a material weakness relating to the lack of adequate review and monitoring controls over complex arrangements, specifically, its sole collaboration and license agreement. See "Remediation of Material Weakness in Internal Control Over Financial Reporting" below under "—Changes in Internal Control Over Financial Reporting" for further information on the steps we are taking to remediate the material weakness.

C. Attestation Report of Independent Registered Public Accounting Firm

Our independent registered public accounting firm, Ernst & Young Hua Ming LLP, has issued an adverse report on the operating effectiveness of our internal control over financial reporting as of December 31, 2021, as stated in its report, which is included under "Item 18. Financial Statements" on page F-4.

D. Changes in Internal Control Over Financial Reporting

Remediation of Material Weakness in Internal Control Over Financial Reporting

Following the identification of the material weakness described above, and with the oversight of the Audit Committee, management is committed to implementing remediation efforts to address this material weakness. The remediation efforts, summarized below, which are either implemented or in process, are intended to both address the identified material weakness and strengthen our overall financial control environment. In this regard, our initiatives include:

- Implementing additional responsive review and monitoring controls for complex agreements, including the collaboration and license agreement, including additional review by the Chief Financial Officer and other senior finance staff over critical accounting judgments and estimates, reporting, and disclosures;
- Expanding the capabilities of existing financial reporting personnel through specific continuous training and education in the application of IFRS standards, with a focus on complex agreements, including the collaboration and license agreement; and
- Hiring additional financial reporting personnel with appropriate IFRS accounting experiences

To support the execution of this remediation plan, the Company has also engaged additional external resources to aid and supplement the Company's existing internal resources.

We believe the foregoing efforts, when fully implemented and operational, will effectively remediate the material weakness described above and strengthen our internal control over financial reporting. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address these control deficiencies or modify the remediation plan described above. We cannot assure you, however, when we will remediate such weakness, nor can we be certain of whether additional actions will be required.

Action taken as a result of the COVID-19 pandemic:

As a result of the COVID-19 pandemic, we have implemented work-from-home arrangements in accordance with guidance from public health authorities, local shelter-in-place orders, and other governmental restrictions in the United States and certain international locations during the year ended December 31, 2021. We have reviewed our financial reporting process and business continuity plans in order to mitigate the impact to our control environment, operating procedures, and data.

Except as described herein there have been no changes in our internal control over financial reporting that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Yau Wai Man Philip, an independent director (under the standards set forth in Nasdaq Stock Market Rule 5605(a)(2) and Rule 10A-3 under the Exchange Act) and member of our audit committee, is an audit committee financial expert.

ITEM 16B. CODE OF ETHICS

We adopted a Code of Business Conduct and Ethics applicable to our directors, officers and employees in accordance with applicable federal securities laws and Nasdaq rules. We have filed our Code of Business Conduct and Ethics as an exhibit to our registration statement on Form F-1 (File Number 333- 238232), as amended, initially filed with the Commission on May 13, 2020. Our Code of Business Conduct and Ethics is available on our website at *https://investors.legendbiotech.com*. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 20-F.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by Ernst & Young Hua Ming LLP for the periods indicated. We did not pay any other fees to Ernst & Young Hua Ming LLP during the periods indicated below. Ernst & Young Hua Ming LLP has served as our independent auditor since 2020. During our initial public offering, Ernst & Young Hua Ming LLP audited our consolidated statements of financial position as of December 31, 2018 and 2019. Prior to the completion of our initial public offering in 2020, we were audited as a subsidiary of Genscript.

	For the Years Ended December 31 (in US$ thousands)	
	2021	2020
Audit Fees(1)	2,250	2,150
Audit-related Fees (2)	67	16
Tax Fees(3)	—	—
All Other Fees(4)	—	—
Total	2,317	2,166

Notes:

(1) "Audit Fees" means the aggregate fees billed or to be billed for each of the fiscal years listed for professional services rendered by Ernst & Young Hua Ming LLP, our principal auditor, for the audit of our annual financial statements, as well as assistance with and review of documents filed with the SEC and other statutory and regulatory filings.

(2) "Audit-related Fees" represents the aggregate fees billed in each of the fiscal years listed for the assurance and related services rendered by our principal auditor that are reasonably related to the performance of the audit or review of our financial statements and not reported under "Audit Fees".

(3) "Tax Fees" means the aggregate fees billed in each of the fiscal years for professional services rendered by Ernst & Young Hua Ming LLP for the tax consultation.

(4) "All Other Fees" represents the aggregate fees billed in each of the fiscal years listed for services rendered by our principal auditor other than services reported under "Audit Fees," "Audit-related Fees" and "Tax Fees."

Audit Committee Pre-approved Policies and Procedures

Currently, all audit services to be provided by our independent registered public accountant, Ernst & Young Hua Ming LLP, must be approved by our audit committee.

During the year ended December 31, 2021, services relating to all non-audit related fees provided to us by Ernst & Young Hua Ming LLP were approved by our audit committee in accordance with the de minimis exception to the pre-approval requirement provided by paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

On December 20, 2021, the Company completed an underwritten public offering of 7,500,000 American depositary shares ("ADSs"), each representing two ordinary shares, at a public offering price of $40.00 per ADS. Genscript Biotech Corporation, the Company's majority shareholder, purchased 2,250,000 of the ADSs at the public offering price in this offering.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

The Nasdaq Stock Market listing rules include certain accommodations in the corporate governance requirements that allow foreign private issuers, such as us, to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. Currently, we do not plan to rely on home country practice with respect to any corporate governance matter.

We are a "controlled company" as defined under the Nasdaq Stock Market Rules. 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.

We have relied and will continue to rely on the "controlled company" exemption, and we are not required to, and at times may 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, our stockholders will not have the same protections afforded to shareholders of companies that are subject to all of the stock exchange rules. Currently, a majority of our directors are independent, but our compensation committee and our nominating and corporate governance committees do not consist entirely of independent directors. The foreign private issuer and controlled company exemptions do not modify the independence requirements for the audit committee.

ITEM 16H. MINE SAFETY DISCLOSURE

Not Applicable.

ITEM 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

See "Item 18. Financial Statements"

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements of Legend Biotech Corporation and its subsidiaries are included at the end of this Annual Report on Form 20-F.

ITEM 19. EXHIBITS

Exhibit Index
(Incorporated by Reference)

Exhibit Number	Description of Documents
1.1***	Third Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect (incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
2.1***	Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
2.2***	Form of Deposit Agreement between the Registrant and JP Morgan Chase Bank, N.A., as depositary (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
2.3***	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.2 on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
2.4***	Investors' Rights Agreement, dated March 30, 2020, by and among the Registrant and certain stockholders of the Registrant named therein (incorporated herein by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
2.5***	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act (incorporated herein by reference to Exhibit 2.5 to the Registrant's Form 20-F (File No. 001-39307), filed with the SEC on March 31, 2022)
2.6 ***	Subscription Agreement, dated as of May 13, 2021, by and between LGN Holdings Limited and the Registrant (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-3 (File No. 333-257625), filed with the SEC on July 2, 2021)
2.7***	Warrant to Purchase Ordinary Shares of the Registrant (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-3 (File No. 333-257625), filed with the SEC on July 2, 2021)
4.1***	Collaboration and License Agreement among Legend Biotech USA, Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc., dated December 21, 2017, as amended (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
4.2***	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)

4.3+***	Offer Letter to Ying Huang as Chief Executive Officer, dated as of December 24, 2020 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Report on Form 6-K (File No. 001-39307), filed with the SEC on December 30, 2020)
4.4+***	Share Option Scheme (including proxy form, notice of grant, notice of exercise and share purchase agreement and investment representation statement) (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
4.5***	Lease Agreement between Legend Biotech USA, Inc. and Genscript USA Holding, Inc., dated February 8, 2018 (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
4.6+***	2020 Restricted Shares Plan (including form of Restricted Share Unit Award Agreement), as amended August 28, 2020 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-239478), filed with the SEC on September 4, 2020)
4.7***^	Interim Supply Agreement, dated as of February 28, 2022, between Legend Biotech USA Inc. and Janssen Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.7 to the Registrant's Form 20-F (File No. 001-39307), filed with the SEC on March 31, 2022)
4.8^***	Collaborative Research and License Agreement between Legend Biotech USA, Inc. and Noile-Immune Biotech, inc., dated April 27, 2020 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 19, 2020).
8.1***	List of Principal Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 8.1 to the Registrant's Form 20-F (File No. 001-39307), filed with the SEC on March 31, 2022)
11.1***	Code of Business Conduct and Ethics of the Registrant (incorporated herein by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-238232), filed with the SEC on May 29, 2020)
12.1*	Principal Executive Officer Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Principal Financial Officer Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Principal Executive Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2**	Principal Financial Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of Ernst & Young Hua Ming LLP, an independent registered public accounting firm.
101*	The following materials from Legend Biotech Corp.'s Report on Form 20.F formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) the Consolidated Statements of Profit or Loss and Other Comprehensive Income, (ii) the Consolidated Statements of Financial Position, (iii) the Consolidated Statements of Changes in Equity, (iv) the Consolidated Statements of Cash Flows, (v) Notes to the Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed with this Amendment No. 1 to the Annual Report on Form 20-F.
** Furnished with this Amendment No. 1 to the Annual Report on Form 20-F.
***Previously filed.
+ Indicates management contract or compensatory plan

^ 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

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F on its behalf.

Legend Biotech Corporation

/s/ Ying Huang
Name: Ying Huang
Title: Chief Executive Officer

Date: February 17, 2023

LEGEND BIOTECH CORPORATION

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS (AS RESTATED)

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, 2021 and 2020, the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 31, 2022, except for the effect of the material weakness, as to which the date is February 17, 2023, expressed an adverse opinion thereon.

Restatement of December 31, 2021 Financial Statements

As discussed in Note 2.2 to the consolidated financial statements, the Company's December 31, 2021 consolidated financial statements have been restated to correct misstatements.

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 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. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition for the Collaboration and License Agreement

Description of the matter	As discussed in Notes 2, 3 and 5 to the consolidated financial statements, revenue recognition for the collaboration and license agreement required the Company to make a number of significant judgements, including the identification of the performance obligation(s) and the estimation of the transaction price. As discussed in Note 2.2 to the consolidated financial statements, the Company restated the consolidated financial statements to correctly account for its collaboration and license agreement. Auditing management's identification of the performance obligation(s) and the estimation of the transaction price was especially challenging due to the complex and highly judgmental nature of evaluating the terms of the related agreement. These judgments made on the application of the revenue recognition criteria have a material effect on the amount of the Company's revenue recognized in the financial reporting period.
How we addressed the matter in our audit	To test the Company's accounting for revenue from the collaboration and license agreement, we performed audit procedures that included, among others, assessing the Company's identification of performance obligation(s) by evaluating the stated terms of the related agreement in order to understand the nature of whether the promises were capable of being distinct and distinct in the context of the contract, reviewing the estimates and assumptions used to determine the transaction price, testing the mathematical accuracy of Company's calculations of revenue and the associated timing of revenue recognized in the financial reporting period, assessing the Company's revenue recognition accounting policies, and comparing amounts recognized for consistency with the Company's accounting policies and underlying documentation.

/s/ Ernst & Young Hua Ming LLP

We served as the Company's auditor from 2020 to 2022.
Shanghai, the People's Republic of China

March 31, 2022, except for the effects on the consolidated financial statements of the correction of an error as described in Note 2.2, as to which the date is February 17, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Legend Biotech Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Legend Biotech Corporation's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Legend Biotech Corporation (the "Company") has not maintained effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

In our report dated March 31, 2022, we expressed an unqualified opinion that the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria. Management has subsequently identified a deficiency in controls related to the lack of adequate review and monitoring controls over complex arrangements, specifically, its sole collaboration and license agreement, and has further concluded that such deficiency represented a material weakness as of December 31, 2021. As a result, management has revised its assessment, as presented in the accompanying "Management's Annual Report on Internal Control over Financial Reporting", to conclude that the Company's internal control over financial reporting was not effective as of December 31, 2021. Accordingly, our present opinion on the effectiveness of December 31, 2021's internal control over financial reporting as of December 31, 2021, as expressed herein, is different from that expressed in our previous report.

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 company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness in controls related to the lack of adequate review and monitoring controls over complex arrangements, specifically, its sole collaboration and license agreement**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2021 and 2020, the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the December 31, 2021 consolidated financial statements, and this report does not affect our report dated March 31, 2022, except for the error correction discussed in Note 2.2 as to which the date is February 17, 2023, which expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young Hua Ming LLP
Shanghai, the People's Republic of China

March 31, 2022, except for the effect of the material weakness described in the second paragraph above, as to which the date is February 17, 2023

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

	Notes	2021	2020	2019
		US$'000, except per share data (as restated)	US$'000, except per share data (as restated)	US$'000, except per share data (as restated)
REVENUE	5	68,826	75,000	59,980
Other income and gains	5	3,059	6,119	7,459
Research and development expenses		(313,346)	(232,160)	(161,943)
Administrative expenses		(46,961)	(23,134)	(6,751)
Selling and distribution expenses		(102,542)	(49,571)	(25,620)
Other expenses		(9,132)	(346)	(221)
Fair value loss of warrant liability		(6,200)	—	—
Fair value loss of convertible redeemable preferred shares		—	(79,984)	—
Finance costs	7	(900)	(4,209)	(223)
LOSS BEFORE TAX	6	(407,196)	(308,285)	(127,319)
Income tax credit	8	3,614	41,912	25,729
LOSS FOR THE YEAR		(403,582)	(266,373)	(101,590)
Attributable to:				
Ordinary equity holders of the parent		(403,582)	(266,373)	(101,590)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	9			
Basic		(1.43)	(1.13)	(0.51)
Diluted		(1.43)	(1.13)	(0.51)
OTHER COMPREHENSIVE INCOME/(LOSS)				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences:				
Exchange differences on translation of foreign operations		5,215	4,078	(1,268)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		5,215	4,078	(1,268)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX		5,215	4,078	(1,268)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(398,367)	(262,295)	(102,858)
Attributable to:				
Ordinary equity holders of the parent		(398,367)	(262,295)	(102,858)

The accompanying notes are an integral part of the consolidated financial statements.

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
AS AT DECEMBER 31, 2021 AND 2020

	Notes	December 31, 2021 (as restated)	December 31, 2020 (as restated)	January 1, 2020 (as restated)
		US$'000	US$'000	US$'000
NON-CURRENT ASSETS				
Property, plant and equipment	10	102,506	72,342	45,188
Advance payments for property, plant and equipment		2,168	224	665
Right-of-use assets	13	38,283	39,542	27,790
Time deposits	19	4,705	—	—
Intangible assets	11	4,684	2,852	519
Other non-current assets	12	17,269	13,189	6,449
Total non-current assets		169,615	128,149	80,611
CURRENT ASSETS				
Inventories	15	1,749	1,800	1,157
Trade receivables	16	50,410	75,000	30,000
Prepayments, other receivables and other assets	17	13,758	10,452	21,671
Financial assets measured at amortized cost	18	29,937	—	—
Lease receivables		94	619	—
Pledged deposits	19	1,444	384	256
Time deposits	19	163,520	50,000	75,559
Cash and cash equivalents	19	688,938	455,689	83,364
Total current assets		949,850	593,944	212,007
Total assets		1,119,465	722,093	292,618
CURRENT LIABILITIES				
Trade and notes payables	20	7,043	5,238	9,586
Other payables and accruals	21	123,558	99,787	70,854
Government grants	24	304	283	—
Lease liabilities	13	911	1,464	1,027
Tax payable	8	9,488	8,795	12,782
Warrant liability	23	87,900	—	—
Total current liabilities		229,204	115,567	94,249
NON-CURRENT LIABILITIES				
Interest-bearing loans and borrowings	25	120,462	—	—
Lease liabilities	13	1,593	1,909	5,058
Government grants	24	1,866	2,051	—
Deferred tax liabilities	22	—	4,241	41,988
Other non-current liabilities		396	554	—
Total non-current liabilities		124,317	8,755	47,046
Total liabilities		353,521	124,322	141,295
EQUITY				
Share capital	26	31	27	20
Reserves	29	765,913	597,744	151,303
Total ordinary shareholders' equity		765,944	597,771	151,323
Total equity		765,944	597,771	151,323
Total liabilities and equity		1,119,465	722,093	292,618

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, 2021, 2020 AND 2019

	Attributable to equity holders of the parent					
	Share capital	Share premium*	Share-based compensation reserves*	Foreign currency translation reserve* (as restated)	Retained earnings/ (accumulated losses)* (as restated)	Total Equity (as restated)
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
As at January 1, 2019	**20**	**3,908** *	**704** *	**(3,161)** *	**251,438** *	**252,909**
Loss for the year	—	—	—	—	(101,590)	(101,590)
Other comprehensive income:						
Exchange differences on translation of foreign operations	—	—	—	(1,268)	—	(1,268)
Total comprehensive loss for the year	**—**	**—**	**—**	**(1,268)**	**(101,590)**	**(102,858)**
Equity-settled share-based compensation expense	—	—	1,272	—	—	1,272
As at December 31, 2019	**20**	**3,908** *	**1,976** *	**(4,429)** *	**149,848** *	**151,323**
Loss for the year	—	—	—	—	(266,373)	(266,373)
Other comprehensive loss:						
Exchange differences on translation of foreign operations	—	—	—	4,078	—	4,078
Total comprehensive loss for the year	**—**	**—**	**—**	**4,078**	**(266,373)**	**(262,295)**
Conversion of convertible redeemable preferred shares to ordinary shares	2	240,432	—	—	—	240,434
Issuance of ordinary shares for initial public offering, net of issuance costs	4	450,081	—	—	—	450,085
Issuance of ordinary shares relating to private placement by GenScript	—	12,000	—	—	—	12,000
Exercise of share options	1	1,885	(422)	—	—	1,464
Equity-settled share-based compensation expense	—	—	4,760	—	—	4,760
As at December 31, 2020	**27**	**708,306** *	**6,314** *	**(351)** *	**(116,525)** *	**597,771**

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

	Attributable to equity holders of the parent					
	Share capital	Share premium*	Share-based compensation reserves*	Foreign currency translation reserve* (as restated)	Retained earnings/ (accumulated losses)* (as restated)	Total Equity (as restated)
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
As at December 31, 2020	**27**	**708,306**	* **6,314**	* **(351)**	* **(116,525)**	* **597,771**
Loss for the year	—	—	—	—	(403,582)	(403,582)
Other comprehensive income:						
Exchange differences on translation of foreign operations	—	—	—	5,215	—	5,215
Total comprehensive loss for the year	**—**	**—**	**—**	**5,215**	**(403,582)**	**(398,367)**
Issuance of ordinary shares relating to private placement for an institutional investor	2	218,298	—	—	—	218,300
Issuance of ordinary shares for follow-on public offering, net of issuance costs	2	323,438	—	—	—	323,440
Exercise of share options	—	6,089	(1,447)	—	—	4,642
Reclassification of vested restricted stock units	—	5,323	(5,323)	—	—	—
Equity-settled share-based compensation expense	—	—	20,158	—	—	20,158
As at December 31, 2021	**31**	**1,261,454**	* **19,702**	* **4,864**	* **(520,107)**	* **765,944**

* These reserve accounts comprise the consolidated reserves of US$765.9 million, US$597.7 million and US$151.3 million in the consolidated statements of financial position as at December 31, 2021, 2020 and 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, 2021, 2020 AND 2019

	Notes	2021 (as restated)	2020 (as restated)	2019 (as restated)
		US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss before tax		(407,196)	(308,285)	(127,319)
Adjustments for:				
Finance income	5	(971)	(2,930)	(4,581)
Finance costs	7	900	4,209	223
Depreciation of property, plant and equipment	10	8,139	6,234	3,163
Loss on disposal of property, plant and equipment	6	974	55	—
Amortization of intangible assets	11	1,379	192	63
Depreciation of right-of-use assets	13	4,399	3,507	2,036
Fair value loss of warrant liability	23	6,200	—	—
Fair value loss of convertible redeemable preferred shares		—	79,984	—
Fair value gains on financial assets measured at fair value change through profit or loss	5	—	(47)	(474)
Foreign currency exchange loss/(gain), net		4,867	(66)	(584)
Equity-settled share-based compensation expense		20,158	4,760	1,272
Deferred government grant	24	(295)	(114)	—
		(361,446)	(212,501)	(126,201)
Decrease/(increase) in trade receivables		24,590	(45,000)	21,229
(Increase)/decrease in prepayments, other receivables and other assets		(2,966)	3,366	(5,178)
Increase in other non-current assets		(1,175)	(3,973)	—
Decrease/(increase) in inventories		51	(643)	(22)
Government grant received	24	80	2,452	—
Increase/(decrease) in trade and notes payables		1,805	(4,348)	2,011
Increase in other payables and accruals		140,747	26,932	31,727
(Decrease)/increase in other non-current liabilities		(158)	554	—
Increase in pledged deposits, net		(1,060)	(128)	—
Cash used in operations		(199,532)	(233,289)	(76,434)
Income tax paid		—	(278)	(15,432)
Finance income received		652	3,366	9,024
Interest on loan from related party		—	—	(24)
Income tax received		557	7,391	—
Interest on lease payments		(142)	(195)	(199)
Net cash flow used in operating activities		(198,465)	(223,005)	(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, 2021, 2020 AND 2019

	Note	2021 (as restated) US$'000	2020 (as restated) US$'000	2019 (as restated) US$'000
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property, plant and equipment		(42,197)	(26,254)	(26,773)
Purchase of intangible assets		(3,207)	(4,029)	(534)
Prepayment to collaborator for collaboration right-of-use assets		(1,708)	(19,493)	(11,863)
Purchase of financial assets measured at fair value through profit or loss		(50,000)	(22,682)	(314,840)
Cash received from withdrawal of financial assets measured at fair value through profit or loss		50,081	22,682	320,854
Cash receipts of investment income		—	47	—
Cash advances to related parties	32	—	—	(13,006)
Collection of cash advances to related parties	32	—	—	62,996
Proceeds from disposal of property, plant and equipment		4	1	74
Addition in time deposits		(298,107)	(50,000)	(75,559)
Decrease in time deposits		180,000	75,559	—
Addition in pledged deposits		—	—	(256)
Decrease in pledged deposits		—	—	255
Purchase of financial assets measured at amortized cost		(29,849)	—	—
Net cash flows used in investing activities		(194,983)	(24,169)	(58,652)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from cash advances from related parties	32	—	—	38,945
Repayment of cash advances from related parties	32	—	(4)	(19,223)
Proceeds from loans from related parties	32	—	—	2,867
Repayments of loans from related parties	32	—	—	(2,867)
Proceeds from convertible redeemable preferred shares		—	160,450	—
Proceeds from issuance of ordinary shares for initial public offering, net of issuance costs		—	450,085	—
Proceeds from issuance of ordinary shares relating to private placement by GenScript		—	12,000	—
Proceeds from issuance of ordinary shares for follow on public offering, net of issuance costs		323,440	—	—
Proceeds from issuance of ordinary shares and warrant relating to private placement for an institutional investor		300,000	—	—
Proceeds from exercise of share options		4,642	1,464	—
Payments of expenses for issuance of convertible redeemable preferred shares		—	(2,514)	—
Principal portion of lease payments		(1,419)	(2,602)	(5,056)
Net cash flows from financing activities		626,663	618,879	14,666

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

	Note	2021 (as restated)	2020 (as restated)	2019 (as restated)
		US$'000	US$'000	US$'000
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		233,215	371,705	(127,051)
Effect of foreign exchange rate changes, net		34	620	249
Cash and cash equivalents at beginning of year	19	455,689	83,364	210,166
CASH AND CASH EQUIVALENTS AT END OF YEAR	19	688,938	455,689	83,364
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances		858,607	506,073	159,179
Less: Pledged deposits		1,444	384	256
Time deposits		168,225	50,000	75,559
Cash and cash equivalents as stated in the statement of financial position	19	688,938	455,689	83,364
Cash and cash equivalents as stated in the statement of cash flows		688,938	455,689	83,364

The accompanying notes are an integral part of the consolidated financial statements.

1. CORPORATE INFORMATION

Legend Biotech Corporation (the "Company") was incorporated on May 27, 2015 as an exempted company in the Cayman Islands with limited liability under the Companies Law of the Cayman Islands. The registered office address of the Company is PO Box 10240, Harbour Place, 103 South Church Street, George Town, Grant Cayman KY1-1002, Cayman Islands.

The Company is an investment holding company. The Company's subsidiaries are principally engaged in research and development of biological products.

In the opinion of the Directors, the ultimate holding company of the Company is Genscript Corporation ("Genscript 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	US$	80,000,000	100	—	Investment holding
Legend Biotech HK Limited ("Legend HK")	Hong Kong June 3, 2015	US$	80,000,000	—	100	Investment holding
Nanjing Legend Biotechnology Co., Ltd. ("Legend Nanjing")	PRC* November 17, 2014	US$	162,500,000	—	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 Belgium B.V. ("Legend Belgium")	Belgium June 23, 2021	US$	2,423,693	—	100	Manufacture and sale of life science research products and services
Hainan Chuanji Biotechnology Co., Ltd. ("Hainan Chuanji")	PRC October 25, 2021		—	—	100	Life science research and development

* The People's Republic of China (the "PRC" or "China"), including the Hong Kong Special Administrative Region of China ("Hong Kong").

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 ("IFRSs") as issued by the International Accounting Standards Board (the "IASB"), which comprise all standards and interpretations.

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 each of the three years ended December 31, 2021. 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.

2.2 RESTATEMENT OF PREVIOUSLY ISSUED CONSOLIDATED FINANCIAL STATEMENTS

The Group has restated its Consolidated Statements of Financial Position at December 31, 2021 and 2020, Consolidated Statements of Profit or Loss and Other Comprehensive Income, Changes in Equity and Cash Flows for each of the fiscal years ended December 31, 2021, 2020 and 2019, included in the Annual Report on Form 20-F for the fiscal year ended December 31, 2021, which was originally filed with the U.S. Securities and Exchange Commission (the "SEC") on March 31, 2022 (the "Original 20-F").

The individual restatement matters that underlie the restatement adjustments are described below. The restatement adjustments also affect periods prior to the Original 20-F and such adjustments have been reflected in the restated opening stockholders' equity balances as of January 1, 2019.

Revenue Recognition Adjustments

As previously disclosed, in December 2017, the Group entered into a worldwide collaboration and license agreement with Janssen Biotech, Inc. ("Janssen") for the worldwide development and commercialization of cilta-cel (the "Janssen Agreement"). Historically, the Group has recognized revenue under the Janssen Agreement pursuant to two performance obligations: (i) the sale of the commercial license for cilta-cel (the "Commercial License") and (ii) service on the Joint Steering Committee (the "JSC") under the collaboration. The sale of the Commercial License was recognized as revenue at the time of sale and the revenue the Group recognized as a result of its service on the JSC was recognized over the term of the clinical development plan under the Janssen Agreement. The Group concluded that the transaction price, at inception of the Janssen Agreement, includes the fixed upfront fee of $350 million and $50 million of milestone payments that were highly probable of being achieved. All other potential milestone payments were considered variable consideration.

The Group has since determined the Janssen Agreement contains a contract with a customer (Janssen) in the scope of IFRS 15 for a right to use our intellectual property (in the form of a license) and technology transfer service that form a single performance obligation. These elements of the Janssen Agreement are representative of a

vendor-customer relationship as Janssen contracted with Legend to obtain a license of its intellectual property for LCAR-B38M and related technology transfer, which are an output of Legend's ordinary activities, in exchange for consideration. Janssen is not a customer for collaborative activities, including participation on the JSC, which are in the scope of other IFRS standards. Also, the Group determined that the original stand-alone selling price of the Commercial License performance obligation was understated.

The Group has revised its accounting treatment to recognize revenue for the $350 million upfront fee and $50 million milestone license revenue in 2018, the year in which the single performance obligation to deliver the license of intellectual property, including a technology transfer service, was satisfied. Subsequent development, manufacturing and regulatory milestones will be recognized in full in the period in which it is highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract will not occur, as they are associated with the performance obligation to deliver the license of intellectual property that was satisfied in 2018. The Group recognized revenue of $65 million, $75 million and $60 million for development milestones achieved in 2021, 2020 and 2019, respectively. The Group will recognize revenue for sales-based milestones when the milestone is achieved pursuant to the royalty recognition constraint.

In connection with the restatement, the Group has also corrected the corresponding contract liabilities of previously deferred license and collaboration revenue as a result of the change in performance obligations identified.

Collaboration Assets Adjustments

The Group has identified and corrected errors related to the accounting treatment of assets purchased by the Group or Janssen that are solely to be used by the collaboration and subject to the cost sharing terms and conditions in the Janssen Agreement ("Collaboration Assets"). Historically, the Group recorded Collaboration Assets it purchased from third party vendors, net of Janssen's share of these costs, as well as its share of the cost of Collaboration Assets purchased by Janssen as property, plant and equipment.

The Group has revised its accounting treatment to record its share of Collaborations Assets that are leased to and by the collaboration in accordance with IFRS 16, Leases to correctly reflect the assets associated with the collaboration.

If the Group's collaboration partner owns the asset, and on the basis of the terms and conditions of the collaboration agreement, there is a lease from the Group's collaboration partner to the collaboration, the Group recognises a right-of-use asset and lease liability for its share of the asset leased from the collaboration partner to the collaboration. This is usually the case when the collaboration, through the JSC and other governance committees, has the right to direct the use and obtains substantially all of the economic benefits from using the asset. Lease payments the Group makes prior to lease commencement are recorded as prepaid rent within other non-current assets and will be reclassified to a right-of-use asset upon lease commencement.

If the Group owns the asset, and on the basis of the terms and conditions of the collaboration agreement, there is a lease from the Group to the collaboration, the Group recognises a finance lease for the asset it leases to the collaboration. In such cases, the Group's share of the asset that is jointly controlled by the collaboration is recorded in property, plant and equipment, and a lease receivable is recognized for the collaboration partner's share of the asset.

Income Taxes

The Company recorded adjustments to income taxes to reflect the impact of the restatement adjustments, as well as additional income tax adjustments related to the accounting for the Janssen Agreement.

The tables below present the impact of the restatement on the Company's Consolidated Statements of Financial Position at December 31, 2021 and 2020, Consolidated Statements of Profit or Loss and Other Comprehensive Income for the years ended December 31, 2021, 2020 and 2019, the Company's Consolidated Statements of Changes in Equity for the years ended December 31, 2021, 2020, and 2019 and the Company's Consolidated Statement of Cash Flows for the years ended December 31, 2021, 2020, and 2019.

	Consolidated statement of profit or loss and other comprehensive income for the year ended December 31, 2021					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Revenue	89,792	(20,966)	—	—	(20,966)	68,826
Other income and gains	3,059	—	—	—	—	3,059
Research and development expenses	(313,346)	—	—	—	—	(313,346)
Administrative expenses	(46,939)	(22)	—	—	(22)	(46,961)
Selling and distribution expenses	(102,542)	—	—	—	—	(102,542)
Other expenses	(9,132)	—	—	—	—	(9,132)
Fair value loss of warrant liability	(6,200)	—	—	—	—	(6,200)
Finance costs	(900)	—	—	—	—	(900)
Loss before tax	(386,208)	(20,988)	—	—	(20,988)	(407,196)
Income tax (expense)/credit	(1)	—	—	3,615	3,615	3,614
Loss for the year	(386,209)	(20,988)	—	3,615	(17,373)	(403,582)
Attributable to: ordinary equity holders of the parent	(386,209)	(20,988)	—	3,615	(17,373)	(403,582)
Loss per share attributable to ordinary equity holders of the parent						
Basic	(1.37)	(0.07)	—	0.01	(0.06)	(1.43)
Diluted	(1.37)	(0.07)	—	0.01	(0.06)	(1.43)
Exchange differences:						
Exchange differences on translation of foreign operations	10,620	(5,897)	—	492	(5,405)	5,215
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods	10,620	(5,897)	—	492	(5,405)	5,215
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	10,620	(5,897)	—	492	(5,405)	5,215
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(375,589)	(26,885)	—	4,107	(22,778)	(398,367)
Attributable to:						
Ordinary equity holders of the parent	(375,589)	(26,885)	—	4,107	(22,778)	(398,367)

	Consolidated statements of financial position as at December 31, 2021					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
NON-CURRENT ASSETS						
Property, plant and equipment	145,724	—	(43,218)	—	(43,218)	102,506
Advance payments for property, plant and equipment	2,168	—	—	—	—	2,168
Right-of-use assets	7,186	—	31,097	—	31,097	38,283
Time deposits	4,705	—	—	—	—	4,705
Intangible assets	4,684	—	—	—	—	4,684
Other non-current assets	5,148	—	12,121	—	12,121	17,269
Total non-current assets	169,615	—	—	—	—	169,615
CURRENT ASSETS						
Inventories	1,749	—	—	—	—	1,749
Trade receivables	50,410	—	—	—	—	50,410
Prepayments, other receivables and other assets	12,754	—	—	1,004	1,004	13,758
Financial assets measured at amortized cost	29,937	—	—	—	—	29,937
Lease receivables	—	—	94		94	94
Pledged deposits	1,444	—	—	—	—	1,444
Time deposits	163,520	—	—	—	—	163,520
Cash and cash equivalents	688,938	—	—	—	—	688,938
Total current assets	948,752	—	94	1,004	1,098	949,850
Total assets	1,118,367	—	94	1,004	1,098	1,119,465
CURRENT LIABILITIES						
Trade and notes payables	7,043	—	—	—	—	7,043
Other payables and accruals	123,464	—	94	—	94	123,558
Government grants	304	—	—	—	—	304
Lease liabilities	911	—	—	—	—	911
Tax payable	—	—	—	9,488	9,488	9,488
Warrant liability	87,900	—	—	—	—	87,900
Contract liabilities, current	60,644	(60,644)	—	—	(60,644)	—
Total current liabilities	280,266	(60,644)	94	9,488	(51,062)	229,204
NON-CURRENT LIABILITIES						
Interest-bearing loans and borrowings	120,462	—	—	—	—	120,462
Contract liabilities, non-current	242,578	(242,578)	—	—	(242,578)	—
Lease liabilities	1,593	—	—	—	—	1,593
Government grants	1,866	—	—	—	—	1,866
Other non-current liabilities	396	—	—	—	—	396
Total non-current liabilities	366,895	(242,578)	—	—	(242,578)	124,317
Total liabilities	647,161	(303,222)	94	9,488	(293,640)	353,521
EQUITY						
Share capital	31	—	—	—	—	31
Reserves	471,175	303,222	—	(8,484)	294,738	765,913
Total ordinary shareholders' equity	471,206	303,222	—	(8,484)	294,738	765,944
Total equity	471,206	303,222	—	(8,484)	294,738	765,944
Total liabilities and equity	1,118,367	—	94	1,004	1,098	1,119,465

	Consolidated Statements of Changes in Equity as at December 31, 2021		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
As at December 31, 2021			
Share capital	31	—	31
Share premium	1,261,454	—	1,261,454
Share-based compensation reserves	19,702	—	19,702
Foreign currency translation reserve	6,987	(2,123)	4,864
Accumulated losses	(816,968)	296,861	(520,107)
Total equity	471,206	294,738	765,944

	Consolidated statements of cash flows during the year ended December 31, 2021		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax	(386,208)	(20,988)	(407,196)
Adjustments for:			
Finance income	(971)	—	(971)
Finance costs	900	—	900
(Reversal of)/provision for the impairment of trade receivables	(22)	22	—
Depreciation of property, plant and equipment	11,046	(2,907)	8,139
Loss on disposal of property, plant and equipment	974	—	974
Amortization of intangible assets	1,379	—	1,379
Depreciation of right-of-use assets	1,492	2,907	4,399
Fair value loss of warrant liability	6,200	—	6,200
Foreign currency exchange loss, net	4,867	—	4,867
Equity-settled share-based compensation expense	20,158	—	20,158
Deferred government grant	(295)	—	(295)
	(340,480)	(20,966)	(361,446)
Decrease in trade receivables	24,590	—	24,590
Increase in prepayments, other receivables and other assets	(2,966)	—	(2,966)
Increase in other non-current assets	(1,175)	—	(1,175)
Decrease in inventories	51	—	51
Government grant received	80	—	80
Increase in trade and notes payables	1,805	—	1,805
Increase/(decrease) in other payables and accruals	142,091	(1,344)	140,747
Decrease in other non-current liabilities	(158)	—	(158)
(Decrease)/increase in contract liabilities	(22,310)	22,310	—
Increase in pledged deposits, net	(1,060)	—	(1,060)
Cash used in operations	(199,532)	—	(199,532)
Finance income received	652	—	652
Income tax received	557	—	557
Interest on lease payments	(142)	—	(142)
Net cash flow used in operating activities	(198,465)	—	(198,465)

	Consolidated statements of cash flows during the year ended December 31, 2021		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment	(43,905)	1,708	(42,197)
Purchase of intangible assets	(3,207)	—	(3,207)
Prepayment to collaborator for collaboration right-of-use assets	—	(1,708)	(1,708)
Purchase of financial assets measured at fair value through profit or loss	(50,000)	—	(50,000)
Cash received from withdrawal of financial assets measured at fair value through profit or loss	50,081	—	50,081
Proceeds from disposal of property, plant and equipment	4	—	4
Addition in time deposits	(298,107)	—	(298,107)
Decrease in time deposits	180,000	—	180,000
Purchase of financial assets measured at amortized cost	(29,849)	—	(29,849)
Net cash flows used in investing activities	(194,983)	—	(194,983)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of ordinary shares for follow on public offering, net of issuance costs	323,440	—	323,440
Proceeds from issuance of ordinary shares and warrant relating to private placement for an institutional investor	300,000	—	300,000
Proceeds from exercise of share options	4,642	—	4,642
Principal portion of lease payments	(1,419)	—	(1,419)
Net cash flows from financing activities	626,663	—	626,663
NET INCREASE IN CASH AND CASH EQUIVALENTS	233,215	—	233,215
Effect of foreign exchange rate changes, net	34	—	34
Cash and cash equivalents at beginning of year	455,689	—	455,689
CASH AND CASH EQUIVALENTS AT END OF YEAR	688,938	—	688,938
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances	858,607	—	858,607
Less: Pledged deposits	1,444	—	1,444
Time deposits	168,225	—	168,225
Cash and cash equivalents as stated in the statement of financial position	688,938	—	688,938
Cash and cash equivalents as stated in the statement of cash flows	688,938	—	688,938

	Consolidated Statement of profit or loss and other comprehensive income for the year ended December 31, 2020					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Revenue	75,676	(676)	—	—	(676)	75,000
Other income and gains	6,119	—	—	—	—	6,119
Research and development expenses	(232,160)	—	—	—	—	(232,160)
Administrative expenses	(23,147)	13	—	—	13	(23,134)
Selling and distribution expenses	(49,571)	—	—	—	—	(49,571)
Other expenses	(346)	—	—	—	—	(346)
Fair value loss of convertible redeemable preferred shares	(79,984)	—	—	—	—	(79,984)
Finance costs	(4,209)	—	—	—	—	(4,209)
Loss before tax	(307,622)	(663)	—	—	(663)	(308,285)
Income tax credit	4,145	—	—	37,767	37,767	41,912
Loss for the year	(303,477)	(663)	—	37,767	37,104	(266,373)
Attributable to: ordinary equity holders of the parent	(303,477)	(663)	—	37,767	37,104	(266,373)
Loss per share attributable to ordinary equity holders of the parent						
Basic	(1.28)	—	—	0.15	0.15	(1.13)
Diluted	(1.28)	—	—	0.15	0.15	(1.13)
Exchange differences:						
Exchange differences on translation of foreign operations	(2,142)	6,702	—	(482)	6,220	4,078
Net other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods	(2,142)	6,702	—	(482)	6,220	4,078
OTHER COMPREHENSIVE (LOSS)/ INCOME FOR THE YEAR, NET OF TAX	(2,142)	6,702	—	(482)	6,220	4,078
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(305,619)	6,039	—	37,285	43,324	(262,295)
Attributable to:						
Ordinary equity holders of the parent	(305,619)	6,039	—	37,285	43,324	(262,295)

	Consolidated Statements of Financial Position as at December 31, 2020					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
NON-CURRENT ASSETS						
Property, plant and equipment	113,091	—	(40,749)	—	(40,749)	72,342
Advance payments for property, plant and equipment	224	—	—	—	—	224
Right-of-use assets	8,009	—	31,533	—	31,533	39,542
Intangible assets	2,852	—	—	—	—	2,852
Other non-current assets	3,973	—	9,216	—	9,216	13,189
Total non-current assets	128,149	—	—	—	—	128,149
CURRENT ASSETS						
Inventories	1,800	—	—	—	—	1,800
Trade receivables	74,978	22	—	—	22	75,000
Prepayments, other receivables and other assets	10,007	—	—	445	445	10,452
Lease receivables	—	—	619	—	619	619
pledged deposits	384	—	—	—	—	384
Time deposits	50,000	—	—	—	—	50,000
Cash and cash equivalents	455,689	—	—	—	—	455,689
Total current assets	592,858	22	619	445	1,086	593,944
Total assets	721,007	22	619	445	1,086	722,093
CURRENT LIABILITIES						
Trade payables	5,238	—	—	—	—	5,238
Other payables and accruals	99,168	—	619	—	619	99,787
Government grants	283	—	—	—	—	283
Lease liabilities	1,464	—	—	—	—	1,464
Tax payable	—	—	—	8,795	8,795	8,795
Contract liabilities, current	55,014	(55,014)	—	—	(55,014)	—
Total current liabilities	161,167	(55,014)	619	8,795	(45,600)	115,567
NON-CURRENT LIABILITIES						
Contract liabilities, non-current	275,071	(275,071)	—	—	(275,071)	—
Lease liabilities	1,909	—	—	—	—	1,909
Government grants	2,051	—	—	—	—	2,051
Deferred tax liabilities	—	—	—	4,241	4,241	4,241
Other non-current liabilities	554	—	—	—	—	554
Total non-current liabilities	279,585	(275,071)	—	4,241	(270,830)	8,755
Total liabilities	440,752	(330,085)	619	13,036	(316,430)	124,322
EQUITY						
Share capital	27	—	—	—	—	27
Reserves	280,228	330,107	—	(12,591)	317,516	597,744
Total ordinary shareholders' equity	280,255	330,107	—	(12,591)	317,516	597,771
Total equity	280,255	330,107	—	(12,591)	317,516	597,771
Total liabilities and equity	721,007	22	619	445	1,086	722,093

	Consolidated Statements of Changes in Equity as at December 31, 2020		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
As at December 31, 2020			
Share capital	27	—	27
Share premium	708,306	—	708,306
Share-based compensation reserves	6,314	—	6,314
Foreign currency translation reserve	(3,633)	3,282	(351)
Accumulated losses	(430,759)	314,234	(116,525)
Total equity	280,255	317,516	597,771

	Consolidated statements of cash flows for the year ended December 31, 2020		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax	(307,622)	(663)	(308,285)
Adjustments for:			
Finance income	(2,930)	—	(2,930)
Finance costs	4,209	—	4,209
Provision/(reversal of) for the impairment of trade receivables	13	(13)	—
Depreciation of property, plant and equipment	8,248	(2,014)	6,234
Loss on disposal of property, plant and equipment	55		55
Amortization of intangible assets	192	—	192
Depreciation of right-of-use assets	1,493	2,014	3,507
Fair value loss of convertible redeemable preferred shares	79,984	—	79,984
Fair value gains on financial assets measured at fair value change through profit or loss	(47)	—	(47)
Foreign currency exchange gain, net	(66)	—	(66)
Equity-settled share-based compensation expense	4,760	—	4,760
Deferred government grant	(114)	—	(114)
	(211,825)	(676)	(212,501)
Increase in trade receivables	(45,000)	—	(45,000)
Decrease in prepayments, other receivables and other assets	3,366	—	3,366
Increase in other non-current assets	(3,973)	—	(3,973)
Increase in inventories	(643)	—	(643)
Government grant received	2,452	—	2,452
Decrease in trade and notes payables	(4,348)	—	(4,348)
Increase in other payables and accruals	20,230	6,702	26,932
Increase in other non-current liabilities	554	—	554
Increase/(decrease) in contract liabilities	6,026	(6,026)	—
Increase in pledged deposits, net	(128)	—	(128)
Cash used in operations	(233,289)	—	(233,289)
Income tax paid	(278)	—	(278)
Finance income received	3,366	—	3,366
Income tax received	7,391	—	7,391
Interest on lease payments	(195)	—	(195)
Net cash flow used in operating activities	(223,005)	—	(223,005)

	Consolidated Statements of Cash Flows For the year ended December 31, 2020		
	As Previously Reported	Total Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment	(45,747)	19,493	(26,254)
Purchase of intangible assets	(4,029)	—	(4,029)
Prepayment to collaborator for collaboration right-of-use assets	—	(19,493)	(19,493)
Purchase of financial assets measured at fair value through profit or loss	(22,682)	—	(22,682)
Cash received from withdrawal of financial assets measured at fair value through profit or loss	22,682	—	22,682
Cash receipts of investment income	47	—	47
Proceeds from disposal of property, plant and equipment	1	—	1
Addition in time deposits	(50,000)	—	(50,000)
Decrease in time deposits	75,559	—	75,559
Net cash flows used in investing activities	(24,169)	—	(24,169)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of cash advances from related parties	(4)	—	(4)
Proceeds from convertible redeemable preferred shares	160,450	—	160,450
Proceeds from issuance of ordinary shares for initial public offering, net of issuance costs	450,085	—	450,085
Proceeds from issuance of ordinary shares relating to private placement by GenScript	12,000	—	12,000
Proceeds from exercise of share options	1,464	—	1,464
Payments of expenses for issuance of convertible redeemable preferred shares	(2,514)	—	(2,514)
Principal portion of lease payments	(2,602)	—	(2,602)
Net cash flows from financing activities	618,879	—	618,879
NET INCREASE IN CASH AND CASH EQUIVALENTS	371,705	—	371,705
Effect of foreign exchange rate changes, net	620	—	620
Cash and cash equivalents at beginning of year	83,364	—	83,364
CASH AND CASH EQUIVALENTS AT END OF YEAR	455,689	—	455,689
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances	506,073	—	506,073
Less: Pledged deposits	384	—	384
Time deposits	50,000	—	50,000
Cash and cash equivalents as stated in the statement of financial position	455,689	—	455,689
Cash and cash equivalents as stated in the statement of cash flows	455,689	—	455,689

	Consolidated statement of profit or loss and other comprehensive income for the year ended December 31, 2019					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Revenue	57,264	2,716	—	—	2,716	59,980
Other income and gains	7,125	334	—	—	334	7,459
Research and development expenses	(161,943)	—	—	—	—	(161,943)
Administrative expenses	(6,752)	1	—	—	1	(6,751)
Selling and distribution expenses	(25,620)	—	—	—	—	(25,620)
Other expenses	(221)	—	—	—	—	(221)
Finance costs	(223)	—	—	—	—	(223)
Loss before tax	(130,370)	3,051	—	—	3,051	(127,319)
Income tax (expense)/credit	(2,602)	—	—	28,331	28,331	25,729
Loss for the year	(132,972)	3,051	—	28,331	31,382	(101,590)
Attributable to: ordinary equity holders of the parent	(132,972)	3,051	—	28,331	31,382	(101,590)
Loss per share attributable to ordinary equity holders of the parent						
Basic	(0.66)	0.02	—	0.13	0.15	(0.51)
Diluted	(0.66)	0.02	—	0.13	0.15	(0.51)
Exchange differences:						
Exchange differences on translation of foreign operations	182	(1,584)	—	134	(1,450)	(1,268)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	182	(1,584)	—	134	(1,450)	(1,268)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	182	(1,584)	—	134	(1,450)	(1,268)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(132,790)	1,467	—	28,465	29,932	(102,858)
Attributable to:						
Ordinary equity holders of the parent	(132,790)	1,467	—	28,465	29,932	(102,858)

	Consolidated statements of financial position as at January 1, 2020					
		Adjustments by category				
	As Previously Reported	Revenue Recognition	Collaboration assets	Tax impacts	Total Adjustments	As Restated
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
NON-CURRENT ASSETS						
Property, plant and equipment	70,079	—	(24,891)	—	(24,891)	45,188
Advance payments for property, plant and equipment	665	—	—	—	—	665
Right-of-use assets	9,348	—	18,442	—	18,442	27,790
Intangible assets	519	—	—	—	—	519
Other non-current assets	—	—	6,449	—	6,449	6,449
Total non-current assets	80,611	—	—	—	—	80,611
CURRENT ASSETS						
Inventories	1,157	—	—	—	—	1,157
Trade receivables	29,991	9	—	—	9	30,000
Prepayments, other receivables and other assets	16,777	—	—	4,894	4,894	21,671
Pledged deposits	256	—	—	—	—	256
Time deposits	75,559	—	—	—	—	75,559
Cash and cash equivalents	83,364	—	—	—	—	83,364
Total current assets	207,104	9	—	4,894	4,903	212,007
Total assets	287,715	9	—	4,894	4,903	292,618
CURRENT LIABILITIES						
Trade payables	9,586	—	—	—	—	9,586
Other payables and accruals	70,854	—	—	—	—	70,854
Lease liabilities	1,027	—	—	—	—	1,027
Tax payable	—	—	—	12,782	12,782	12,782
Contract liabilities, current	46,294	(46,294)	—	—	(46,294)	—
Total current liabilities	127,761	(46,294)	—	12,782	(33,512)	94,249
NON-CURRENT LIABILITIES						
Contract liabilities, non-current	277,765	(277,765)	—	—	(277,765)	—
Lease liabilities	5,058	—	—	—	—	5,058
Deferred tax liabilities	—	—	—	41,988	41,988	41,988
Total non-current liabilities	282,823	(277,765)	—	41,988	(235,777)	47,046
Total liabilities	410,584	(324,059)	—	54,770	(269,289)	141,295
EQUITY						
Share capital	20	—	—	—	—	20
Reserves	(122,889)	324,068	—	(49,876)	274,192	151,303
Total ordinary shareholders' (deficit)/ equity	(122,869)	324,068	—	(49,876)	274,192	151,323
Total (deficit)/equity	(122,869)	324,068	—	(49,876)	274,192	151,323
Total liabilities and equity	287,715	9	—	4,894	4,903	292,618

	Consolidated Statements of Changes in Equity as at December 31, 2019		
	As Previously Reported	Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
As at December 31, 2019			
Share capital	20	—	20
Share premium	3,908	—	3,908
Share-based compensation reserves	1,976	—	1,976
Foreign currency translation reserve	(1,491)	(2,938)	(4,429)
(Accumulated losses)/retained earnings	(127,282)	277,130	149,848
Total (deficit)/equity	(122,869)	274,192	151,323

	Consolidated statements of cash flow for the year ended December 31, 2019		
	As Previously Reported	Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax	(130,370)	3,051	(127,319)
Adjustments for:			
Finance income	(4,581)	—	(4,581)
Finance costs	223	—	223
Provision/(reversal of) for the impairment of trade receivables	1	(1)	—
Depreciation of property, plant and equipment	4,001	(838)	3,163
Amortization of intangible assets	63	—	63
Depreciation of right-of-use assets	1,198	838	2,036
Fair value gains on financial assets measured at fair value change through profit or loss	(474)	—	(474)
Foreign currency exchange gain, net	(250)	(334)	(584)
Equity-settled share-based compensation expense	1,272	—	1,272
	(128,917)	2,716	(126,201)
(Increase)/decrease in trade receivables	(3,771)	25,000	21,229
Increase in prepayments, other receivables and other assets	(3,928)	(1,250)	(5,178)
Increase in inventories	(22)	—	(22)
Increase in trade and notes payables	2,011	—	2,011
Increase in other payables and accruals	31,727	—	31,727
Increase/(decrease) in contract liabilities	26,466	(26,466)	—
Cash used in operations	(76,434)	—	(76,434)
Income tax paid	(15,432)	—	(15,432)
Finance income received	9,024	—	9,024
Interest on loan from related party	(24)	—	(24)
Interest on lease payments	(199)	—	(199)
Net cash flow used in operating activities	(83,065)	—	(83,065)

	Consolidated Statements of Cash Flows For the year ended December 31, 2019		
	As Previously Reported	Restatement Impacts	As Restated
	US$'000	US$'000	US$'000
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment	(38,636)	11,863	(26,773)
Purchase of intangible assets	(534)	—	(534)
Prepayment to collaborator for collaboration right-of-use assets	—	(11,863)	(11,863)
Purchase of financial assets measured at fair value through profit or loss	(314,840)	—	(314,840)
Cash received from withdrawal of financial assets measured at fair value through profit or loss	320,854	—	320,854
Cash advances to related parties	(13,006)	—	(13,006)
Collection of cash advances to related parties	62,996	—	62,996
Proceeds from disposal of property, plant and equipment	74	—	74
Addition in time deposits	(75,559)	—	(75,559)
Addition in pledged deposits	(256)	—	(256)
Decrease in pledged deposits	255	—	255
Net cash flows used in investing activities	(58,652)	—	(58,652)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from cash advances from related parties	38,945	—	38,945
Repayment of cash advances from related parties	(19,223)	—	(19,223)
Proceeds from loans from related parties	2,867	—	2,867
Repayments of loans from related parties	(2,867)	—	(2,867)
Principal portion of lease payments	(5,056)	—	(5,056)
Net cash flows from financing activities	14,666	—	14,666
NET DECREASE IN CASH AND CASH EQUIVALENTS	(127,051)	—	(127,051)
Effect of foreign exchange rate changes, net	249	—	249
Cash and cash equivalents at beginning of year	210,166	—	210,166
CASH AND CASH EQUIVALENTS AT END OF YEAR	83,364	—	83,364
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances	159,179	—	159,179
Less: Pledged deposits	256	—	256
Time deposits	75,559	—	75,559
Cash and cash equivalents as stated in the statement of financial position	83,364	—	83,364
Cash and cash equivalents as stated in the statement of cash flows	83,364	—	83,364

2.3 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised IFRSs, for the first time for the current year's financial statements. The adoption of these revised IFRSs did not have any material impact on the financial position and financial performance of the Group.

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase *II*

2.4 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	Reference to the Conceptual *Framework*[1]
Amendments to IFRS 10 and IAS 28 (2011)	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
IFRS 17	*Insurance Contracts*[2]
Amendments to IFRS 17	*Insurance Contracts*[2, 4]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current* [2]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[2]
Amendments to IAS 8	*Definition of Accounting Estimates*[2]
Amendments to IAS 12	*Deferred Tax related to Assets and* Liabilities *arising from a Single Transaction*[2]
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended *Use*[1]
Amendments to IAS 37	Onerous Contracts - Cost of Fulfilling a *Contract*[1]
Annual Improvements to IFRSs 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41[1]

1 Effective for annual periods beginning on or after January 1, 2022
2 Effective for annual periods beginning on or after January 1, 2023
3 No mandatory effective date yet determined but available for adoption
4 As a consequence of the amendments to IFRS 17 issued in October 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023

The Group is currently assessing the impact of these standards. So far, the Group has expected that these standards will not have significant effect on the Group's financial performance and financial position.

2.5 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (AS RESTATED)

Fair value measurement

The Group measures its financial assets at fair value through profit or loss and warrant liability 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 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 recognized 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 recognized 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 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 recognized impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognized 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/amortization) had no impairment loss been recognized for the asset in prior years. A reversal of such an impairment loss is credited to 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 and other comprehensive income in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes 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	2.6%
Leasehold improvement	10% to 20%
Machinery and equipment	10% to 20%
Computer, fixtures and office equipment	20% to 33.3%
Transportation equipment	10%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss and other comprehensive income in the year the asset is derecognized 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 amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intangible assets are amortized on the straight-line basis over the following useful economic lives:

Software	3-10 years

Research and development costs

All research costs are charged to the statement of profit or loss and other comprehensive income as incurred.

Expenditures incurred on projects to develop new products is capitalized 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.

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 recognizes 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 recognized 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 re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, 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
Building improvement	2 to 18 years
Machinery and equipment	5 to 10 years
Office equipment	3 to 5 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 recognized 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 lease. The variable lease payments that do not depend on an index or a rate are recognized 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 re-measured 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.

(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases 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 are recognized 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 other income in the statement of profit or loss and other comprehensive income. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognized over the lease term on the same basis as rental income.

Leases of collaboration assets

The Group and its collaboration partner purchase assets to be used for their collaboration and share the associated costs in accordance with the terms and conditions of the Janssen Agreement. The Group accounts for leases to and by the collaboration by applying the guidance in IFRS 16 on joint arrangements by analogy.

If the Group’s collaboration partner owns the asset, and on the basis of the terms and conditions of the collaboration agreement, there is a lease from the Group’s collaboration partner to the collaboration, the Group recognises a right-of-use asset and lease liability for its share of the asset leased from the collaboration partner to the collaboration. This is usually the case when the collaboration, through the JSC and other governance committees, has the right to direct the use and obtains substantially all of the economic benefits from using the asset. Lease payments the Group makes prior to lease commencement are recorded as prepaid rent within other non-current assets and will be reclassified to a right-of-use asset upon lease commencement.

If the Group owns the asset, and on the basis of the terms and conditions of the collaboration agreement, there is a lease from the Group to the collaboration, the Group recognises a finance lease for the asset it leases to the collaboration. In such cases, the Group’s share of the asset that is jointly controlled by the collaboration is recorded in property, plant and equipment, and a lease receivable is recognized for the collaboration partner’s share of the asset.

The Group recognizes the full lease liability, rather than its share, for leases entered into on behalf of the collaboration if the Group has the primary responsibility for making the lease payments. This may be the case when the Group, as a lead operator of the collaboration, is the sole signatory to the lease. A finance sublease is subsequently recognised if the related right-of-use asset is subleased to the collaboration.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized 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 amortized 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. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows.

All regular way purchases and sales of financial assets are recognized 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.

Subsequent measurement

Financial assets measured at amortized cost (debt instruments)

Financial assets measured at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss and other comprehensive income when the asset is derecognized, modified or impaired.

Financial assets measured at fair value through profit or loss

Financial assets measured at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss and other comprehensive income.

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 derecognized (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 recognize the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognizes 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 recognizes 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 recognized 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 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 measured at amortized 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 recognizes 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 recognized 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 notes payables, other payables, warrant liability, interest-bearing loans and borrowings, and lease liabilities.

Subsequent measurement

Financial liabilities measured at amortized cost (Loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized 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 recognized in the statement of profit or loss and other comprehensive income when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized 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 amortization is included in finance costs in the statement of profit or loss and other comprehensive income.

Derecognition of financial liabilities

A financial liability is derecognized 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 recognized in the statement of profit or loss and other comprehensive income.

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 recognized amounts and there is an intention to settle on a net basis, or to realize the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined on the weighted average basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an

appropriate proportion of overheads. Net realizable 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 deposits, and assets similar in nature to cash, which are not restricted as to use.

Time deposits

Time deposits represent cash placed with banks with original maturities of more than three months when acquired. The time deposits are presented as a non-current asset if the collection of time deposits is expected more than one year.

Provisions

A provision is recognized when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognized for a provision is the present value at the end of the reporting period of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in the statement of profit or loss and other comprehensive income.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognized outside profit or loss is recognized outside profit or loss, either in other comprehensive income or directly in equity.

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 recognized 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 recognized for all deductible temporary differences, the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable

profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilized, 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 recognized 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 utilized.

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 utilized. Unrecognized deferred tax assets are reassessed at the end of each reporting period and are recognized 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 realized 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 realize 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.

Government grants

Government grants are recognized 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 recognized as income on a systematic basis over the periods that the costs, for 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 and comprehensive income over the expected useful life of the relevant asset by equal annual instalments.

Collaboration Arrangements

The Group enters into collaboration arrangements with pharmaceutical and biotechnology collaboration partners, under which the Group may grant licenses to a collaboration partner to further develop and commercialize one of the Group's drug candidates. The Group may also perform research, development, manufacturing and commercial activities under a collaboration arrangement. Consideration under these contracts may include an upfront payment, development and regulatory milestones, commercial sales milestones and other contingent payments, expense reimbursements, and profit-sharing.

For collaboration arrangements that contain multiple elements, at contract inception the Group determines whether elements of the collaboration are reflective of a vendor-customer relationship and therefore are within the scope of IFRS 15. Elements of the collaboration arrangements that involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards of such activities are not arrangements with a customer and are outside the scope of IFRS 15. For a distinct bundle of goods or services within the arrangement that is not with a customer, the recognition and measurement of that unit of

account shall be based on other authoritative accounting literature, or if there is no appropriate authoritative accounting literature, a reasonable, rational and consistently applied accounting policy election.

If the Group concludes that a collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, the Group presents payments from the collaboration partner as a reduction of expense, based on where the Group presents the underling expense. If the collaborator performs research and development, manufacturing or commercialization-related activities, the Group recognizes as expense (e.g. research and development expense or selling and distribution expense, as applicable) in the period when the collaborator incurs such expenses, the portion of the collaborator's expenses that the Group is obligated to reimburse.

Revenue recognition

Revenue from contracts with customers

The Group recognizes revenue in accordance with IFRS 15, *Revenue from Contracts with Customers* (IFRS 15). Under IFRS 15, revenue from contracts with customers is recognized 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. To determine revenue recognition for agreements that we determine are within the scope of IFRS 15, the Group performs the following five-steps: (i) identify the contract, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Once a contract is determined to be within the scope of IFRS 15, at contract inception the Group assesses the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. 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 determines the transaction price based on the amount of consideration the Group expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable or a combination of both. 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 recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved. The contracts generally do not include a significant financing component.

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: (i) The counterparty simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs; or (ii) The Group's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.

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.

Contracts may be amended to account for changes in contract specifications and requirements. Contract modifications exist when the amendment either creates new, or changes existing, enforceable rights and obligations. When contract modifications create new performance obligations and the increase in consideration approximates the

standalone selling price for goods and services related to such new performance obligations as adjusted for specific facts and circumstances of the contract, the modification is considered to be a separate contract.

If a contract modification is not accounted for as a separate contract, the Group accounts for the promised goods or services not yet transferred at the date of the contract modification (the remaining promised goods or services) prospectively, as if it were a termination of the existing contract and the creation of a new contract, if the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification. For a change in transaction price that occurs after a contract modification, the Group allocates the change in the transaction price to the performance obligations identified in the contract before the modification if, and to the extent that, the change in the transaction price is attributable to an amount of variable consideration promised before the modification.

The Group accounts for a contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. In such case, the effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (the adjustment to revenue is made on a cumulative catch-up basis).

(a) ***License and collaboration revenue***

License of Intellectual Property

For collaboration arrangements that include a grant of a license to the Group's intellectual property, the Group consider whether the license grant is distinct from the other performance obligations included in the arrangement. 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). We evaluated that the license is a single performance obligation in the Janssen Agreement, including a technology transfer service, which represents 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.

Milestone Payments

Milestone payments, which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur, represent a form of variable consideration when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, the Group evaluates whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. 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. There is considerable judgement involved in determining whether it is highly 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.

When the Company cannot conclude that it is highly probable that a significant revenue reversal of cumulative revenue under the contract will not occur, the Company constrains the related variable consideration resulting in its exclusion from the transaction price. 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.

Royalty Payments

The Company recognizes revenue for sales-based milestone payments promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

(a) the subsequent sale occurs; and

(b) the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied).

Janssen Agreement

The Group entered into a license and collaboration agreement with one customer (Janssen). The terms of the arrangement include: non-refundable upfront fees of US$350 million and 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, respectively. The Group has assessed that there is one distinct performance obligation, being the transfer of a license of intellectual property, including a technology transfer service. The Group considers this performance obligation is distinct from other collaborative activities as the license has stand-alone value without the Company being further involved in the research and development or other collaborative activities. 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 was allocated to the single performance obligation in the contract.

Upfront fees

Upfront payment is allocated to the single performance obligation in the Janssen Agreement. The upfront fees of US$350 million were included in the transaction price upon contract inception in 2017 and were recognized when the single performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The US$350 million upfront fees were fully received by the Group in 2018.

Milestone payments

Certain milestone payments were allocated to the single performance obligation in the Janssen Agreement to deliver the license of intellectual property. The initial two milestone payments of aggregate US$50 million were included in the transaction price at contract inception in 2017 and recognized when the single performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. Subsequently in 2019, an additional two milestone payments of US$60 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. In 2020, an additional milestone with a payment of US$75 million was achieved relating to the clinical development of cilta-cel. In 2021, three additional milestone payments amounting to US$65 million were achieved relating to the submission of a Marketing Authorization to the EMA, enrollment of a specified number of patients in the CARTITUDE-5 clinical trial and filing of a Drug approval application for a product by the Ministry of Health, Labour and Welfare in Japan.

As of December 31, 2021, pursuant to the license and collaboration agreement, the remaining future contractual milestone payments for the Group aggregated to US$1,100 million for the achievement of various development, regulatory, manufacturing and net trade sales milestones. More specifically, the future contractual milestones consist of US$125 million for the achievement of specified manufacturing milestones, US$60 million for the achievement of specified development milestones, US$705 million for the achievement of specified regulatory milestones and US$210 million for the achievement of specified net trade sales milestones. The Group’s development plans and research progresses might change from time to time, which would increase the uncertainties of achieving future contractual milestones. The Company does not believe US$280 million of the remaining US$1,100 million contractual milestone payments would be eligible to be received based on a subsequent change in development plan with the collaborator. Furthermore, the Company assessed that achievement of all the remaining

contractual milestones is 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.

Collaborative activities

In addition to the license *of intellectual property*, the Janssen Agreement includes joint development, manufacturing and commercial activities that are performed by the Group and its collaboration partner. These activities and the related consideration for these activities are outside the scope of IFRS 15 as the Group and its collaboration partner are both active participants in the activities and are exposed to significant risks and rewards of such activities.

Product Sales

Revenue from the sale of goods is recognized 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 recognized 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.

Share-based payments

The Group operates a share option scheme and a restricted stock unit scheme ("RUS 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 of share option is determined by an external valuer using a binomial model, and the fair value of each RSU is determined by reference to market price of the Group's shares at the respective grant date, further details of which are given in notes 27 and 28 to the consolidated financial statements.

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 the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to 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 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 recognized. 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 recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized 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 recognized for the award is recognized 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 and RSUs are reflected as additional share dilution in the computation of earnings per share.

Other employee benefits

Pension scheme

The employees of the Group's subsidiaries which operates in Mainland China and Hong Kong are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute certain percentage of its payroll costs to the central pension scheme. The contributions are charged to 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 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 recognized in the statement of profit or loss and comprehensive income.

Differences arising on settlement or translation of monetary items are recognized in the statement of profit or loss and comprehensive income 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 recognized 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 and comprehensive income. 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 recognized in other comprehensive income or profit or loss is also recognized 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 recognizes 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 exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognized 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 recognized in the statement of profit or loss and comprehensive income.

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.

Impact of covid-19

The COVID-19 situation is very fluid across the world where each country or the sites within a country could be impacted differently. For the year ended December 31, 2021, COVID-19 has had limited impact on the Group's operations.

There are still uncertainties of COVID-19's future impact on the Group's business, results of operations and financial condition, and the extent of the impact will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the development and progress of distribution of COVID-19 vaccines and other medical treatments, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. If the situation materially deteriorates, the Group's business, results of operations and financial condition could be materially and adversely affected. 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.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (AS RESTATED)

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 recognized 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, specifically the Janssen Agreement:

(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 the license is capable of being distinct. In assessing whether the license 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 the license on its own. The Group determined that the license of intellectual property and technology transfer service form a single performance obligation. The license of intellectual property and technology transfer are highly interdependent and are not separately identifiable from each other. The technology transfer is essential for the customer's ability to obtain the use of and benefit from the license. The promise to transfer the license, including a technology transfer service, is distinct within the context of the contract. The license of intellectual property, including a technology transfer service, is separately identifiable in the contract and is meant to be transferred separate from other collaborative activities. The license, including a technology transfer service, 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 and participation in the collaborative activities (e.g. joint development) is to assist in conducting clinical trials and obtaining regulatory approval of the technology, but does not modify the license and technology. In addition, the license, including the technology transfer service, is not highly interdependent or highly interrelated with the JSC and other collaborative activities, because the delivery of license and technology transfer service is not dependent on these activities to be provided in the future, and accordingly, it is not interdependent or interrelated with these activities.

In determining whether the license, including the technology transfer service, 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 and the technology transfer occurred, which is when the customer can use and benefit from the license. 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 entire transaction price to the license of intellectual property, as this is the sole performance obligation in the arrangement.

(ii) Determining the method to estimate variable consideration

Certain contracts includes milestone payments 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 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. There were no indicators of impairment for all periods presented.

Deferred tax assets

Deferred tax assets are recognized 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 utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. The outcome of their actual utilization may be different. As at December 31, 2021 and 2020, the Group recognized gross deferred tax assets (before offset with deferred tax labilities) of US$22.8 million and US$30.8 million, respectively, and the amount of unrecognized deferred tax assets for tax losses as at December 31, 2021 and 2020 was US$609.2 million and US$200.5 million, respectively. Further details are contained in note 22 to the consolidated financial statements.

Warrant liability

The fair value of the warrant liability is determined by using the binominal 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. The risk-free interest rate is based on treasury yield curve rates with a remaining term which approximates to the expected life of the warrant. Changes in these input variables would affect fair value of the warrant. Further details are contained in notes 23 and 34 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 recognized for all share-based awards is net of estimated 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, 2021, 2020 and 2019, the equity-settled share option expense was US$2.4 million, US$1.9 million and US$1.3 million respectively. Further details are contained in note 27 to the consolidated financial statements.

4. OPERATING SEGMENT INFORMATION (AS RESTATED)

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 as restated

	2021	2020	2019
	US$'000	US$'000	US$'000
United States of America	65,402	75,000	59,977
China	3,424	—	3
Total	68,826	75,000	59,980

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	December 31, 2021	December 31, 2020
	US$'000	US$'000
United States of America	103,648	78,022
China	50,800	43,953
Other	10,462	6,174
Total	164,910	128,149

The non-current asset information above is based on the locations of assets and excludes non-current time deposits.

Information about major customer

Revenue of US$65.4 million, US$75.0 million and US$60.0 million for the years ended December 31, 2021, 2020 and 2019, respectively, was derived from sales to a single customer. Revenue of US$3.4 million for the year ended December 31, 2021 was generated from the exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates and subsequent sales-based royalties for using the aforementioned licensing (note 32).

5. REVENUE, OTHER INCOME AND GAINS (AS RESTATED)

An analysis of revenue is as follows:

	2021	2020	2019
	US$'000	US$'000	US$'000
Revenue from contracts with customer			
Sales of goods	—	—	3
License and collaboration revenue			
- Licensing of intellectual property	65,402	75,000	59,977
Licensing and Royalties	3,424	—	—
	68,826	75,000	59,980

Revenue from sales of goods and licensing of intellectual property is recognized at a point in time. Revenue from licensing of intellectual property represents variable consideration relating to the milestone payments which were constrained in prior years but included in the transaction price when the milestones were highly probable being achieved. At inception of the Janssen Agreement, the amount allocated to licensing of intellectual property was US$400 million for both U.S. and non-U.S. territories, which was updated to US$600 million as at December 31, 2021.

Licensing and royalties related to an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates and related subsequent sales-based royalties.

	2021 US$'000	2020 US$'000	2019 US$'000
Other income and gains			
Other income:			
Finance income	971	2,930	4,581
Government grants*	1,736	3,072	1,682
Others	35	4	138
	2,742	6,006	6,401
Gains:			
Foreign currency exchange gain, net	—	66	584
Fair value gains on financial assets measured at fair value change through profit or loss	—	47	474
Others**	317	—	—
	317	113	1,058
	3,059	6,119	7,459

* 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.
** The amount mainly represents reimbursement of depositary fees that are related to the establishment and maintenance of the American Depository Receipts (ADR) program.

6. LOSS BEFORE TAX (AS RESTATED)

The Group's loss before tax is arrived at after charging:

	2021 US$'000	2020 US$'000	2019 US$'000
Loss on disposal of assets	974	55	—
IPO expenses	—	1,439	—
Follow-on expenses	400	—	—
Employee benefit expense (including directors' remuneration):			
Wages and salaries	105,751	70,682	37,038
Pension scheme contributions (defined contribution schemes)	2,257	640	1,166
Equity-settled share-based compensation expense	20,158	4,760	1,272

7. FINANCE COSTS

	2021 US$'000	2020 US$'000	2019 US$'000
Interest on lease liabilities	142	195	199
Interest on interest-bearing loans and borrowings (note 25)	758	—	—
Expenses for issuance of convertible redeemable preferred shares	—	4,014	—
Interest on an entrusted loan from a related party	—	—	24
Total	900	4,209	223

8. INCOME TAX (AS RESTATED)

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.

British Virgin Islands

Under the current laws of the British Virgin Islands ("BVI"), 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 the two-tiered profits tax rates regime. The first HK$2,000,000 (2020 and 2019: HK$2,000,000) of assessable profits were taxed at 8.25% (2020 and 2019: 8.25%) and the remaining assessable profits were taxed at 16.5% (2020 and 2019: 16.5%). 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% (2020 and 2019: 21%) and state tax at a rate of 9% (2020 and 2019: 9%) without including 2.5% NJ Surcharge due to the anticipated timing of utilization of the NJ NOL in New Jersey. The 2.5% NJ Surcharge will be expired as of December 31, 2023. 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% (2020 and 2019: 12.5%) on its taxable trading income. Any non-trading income is subject to CIT at a rate of 25% (2020 and 2019: 25%). Dividend withholding tax is imposed on distributions made by Irish companies at a rate of 25% (2020: 25% and 2019: 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, 2021, 2020 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.

Belgium

Under the current laws of Belgium, the subsidiary which operates in Belgium is subject to CIT at a rate of 25% on its taxable trading income. Dividend withholding tax is imposed on distributions made by Belgium companies at a rate of 30% with many exemptions provided.

Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the jurisdictions in which the Group operates.

	2021 US$'000	2020 US$'000	2019 US$'000
Current – United States of America	211	(4,548)	(2,933)
Current – Elsewhere	416	383	(4,787)
Deferred (note 22)	(4,241)	(37,747)	(18,009)
Total tax credit for the year	(3,614)	(41,912)	(25,729)

A reconciliation of the tax charge/(credit) 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/(credit) at the effective tax rates is as follows:

	2021 US$'000	%	2020 US$'000	%	2019 US$'000	%
Loss before tax	(407,196)		(308,285)		(127,319)	
At the statutory blended income tax rate of 28.1% (2020 and 2019: 28.1%)	(114,463)	28.1	(86,659)	28.1	(35,789)	28.1
Effect of tax rate differences in other countries and regions	15,027	(3.7)	35,062	(11.4)	5,528	(4.3)
Research and development credit	(954)	0.2	(15,643)	5.1	(3,324)	2.6
Effect of non-deductible expenses	2,298	(0.6)	383	(0.1)	1,532	(1.2)
Tax losses and deductible temporary differences not recognized	102,481	(25.2)	26,040	(8.4)	5,212	(4.1)
Option income tax benefit	(9,532)	2.3	(442)	0.1	—	—
Others	1,529	(0.4)	(653)	0.2	1,112	(0.9)
Tax credit at the Group's effective rate	(3,614)	0.9	(41,912)	13.6	(25,729)	20.2

The Group's provision for income tax related to uncertain tax position with penalty and interest accrued including in the tax payables for the years ended December 31, 2021, 2020 and 2019 was as follows:

	2021 US$'000	2020 US$'000	2019 US$'000
Balance as of December 31	9,488	8,795	12,782

The Group's uncertain tax positions arose from a temporary inconsistency between the tax filings and accounting book for collaboration revenue. The Group has recorded the tax provision based on the most likely amounts and included the amounts in the consolidated statements of financial position but has not made revisions to the tax filing.

9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (AS RESTATED)

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 281,703,291, 236,305,234 and 200,000,000 in issue during the years ended December 31, 2021, 2020 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, 2021, 2020 and 2019 in respect of a dilution as the impact of the outstanding share options, restricted stock units and warrant liability 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:

	2021 US$'000	2020 US$'000	2019 US$'000
Earnings			
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(403,582)	(266,373)	(101,590)

	Number of shares		
	2021	2020	2019
Shares			
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	281,703,291	236,305,234	200,000,000

10. PROPERTY, PLANT AND EQUIPMENT (AS RESTATED)

	Freehold land	Buildings	Leasehold improvement	Machinery and equipment	Computer, fixtures, and office equipment	Transportation equipment	Construction in progress	Total
	US'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2021								
At January 1, 2021								
Cost	2,889	11,210	11,887	25,841	3,281	44	27,811	82,963
Accumulated depreciation	—	(817)	(1,854)	(6,514)	(1,426)	(10)	—	(10,621)
Net carrying amount	2,889	10,393	10,033	19,327	1,855	34	27,811	72,342
At January 1, 2021, net of accumulated depreciation	2,889	10,393	10,033	19,327	1,855	34	27,811	72,342
Additions	—	—	—	1,603	7	—	37,269	38,879
Disposals	—	—	(859)	(177)	(77)	—	—	(1,113)
Depreciation provided during the year	—	(543)	(1,833)	(4,967)	(792)	(4)	—	(8,139)
Exchange realignment	—	—	123	358	10	1	45	537
Transfers	—	4,801	9,941	8,675	341	—	(23,758)	—
At December 31, 2021, net of accumulated depreciation	2,889	14,651	17,405	24,819	1,344	31	41,367	102,506
At December 31, 2021:								
Cost	2,889	16,011	20,908	35,251	2,977	45	41,367	119,448
Accumulated depreciation	—	(1,360)	(3,503)	(10,432)	(1,633)	(14)	—	(16,942)
Net carrying amount	2,889	14,651	17,405	24,819	1,344	31	41,367	102,506

	Freehold land	Buildings	Leasehold improvement	Machinery and equipment	Computer, fixtures, and office equipment	Transportation equipment	Construction in progress	Total
	US'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2020								
At January 1, 2020								
Cost	2,889	10,072	10,382	20,802	1,297	42	3,687	49,171
Accumulated depreciation	—	(330)	(770)	(2,537)	(340)	(6)	—	(3,983)
Net carrying amount	2,889	9,742	9,612	18,265	957	36	3,687	45,188
At January 1, 2020, net of accumulated depreciation	2,889	9,742	9,612	18,265	957	36	3,687	45,188
Additions	—	—	—	—	560	—	31,625	32,185
Disposals	—	—	—	(165)	—	—	—	(165)
Depreciation provided during the year	—	(487)	(1,019)	(3,638)	(1,086)	(4)	—	(6,234)
Exchange realignment	—	—	375	775	12	2	204	1,368
Transfers	—	1,138	1,065	4,090	1,412	—	(7,705)	—
At December 31, 2020, net of accumulated depreciation	2,889	10,393	10,033	19,327	1,855	34	27,811	72,342
At December 31, 2020:								
Cost	2,889	11,210	11,887	25,841	3,281	44	27,811	82,963
Accumulated depreciation	—	(817)	(1,854)	(6,514)	(1,426)	(10)	—	(10,621)
Net carrying amount	2,889	10,393	10,033	19,327	1,855	34	27,811	72,342

11. INTANGIBLE ASSETS

	Software US$'000
December 31, 2021	
At January 1, 2021	
Cost	3,186
Accumulated amortization	(334)
Net carrying amount	2,852
At January 1, 2021, net of accumulated amortization	2,852
Additions	3,207
Amortization provided during the year	(1,379)
Exchange realignment	4
At December 31, 2021, net of accumulated amortization	4,684
At December 31, 2021	
Cost	6,402
Accumulated amortization	(1,718)
Net carrying amount	4,684
December 31, 2020	
At January 1, 2020	
Cost	598
Accumulated amortization	(79)
Net carrying amount	519
At January 1, 2020, net of accumulated amortization	519
Additions	2,583
Amortization provided during the year	(192)
Exchange realignment	(58)
At December 31, 2020, net of accumulated amortization	2,852
At December 31, 2020	
Cost	3,186
Accumulated amortization	(334)
Net carrying amount	2,852

12. OTHER NON-CURRENT ASSETS (AS RESTATED)

	December 31, 2021 US$'000	December 31, 2020 US$'000
Value-added Tax ("VAT") recoverable	4,080	3,542
Prepaid expenses	1,068	431
Collaboration Assets-Prepaid Lease	12,121	9,216
	17,269	13,189

13. LEASES (AS RESTATED)

The Group as a lessee

The Group has lease contracts for leasehold 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 leasehold land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these leasehold land. Other buildings and rooms generally have lease terms of 12 months or less from the commencement date and do not contain a purchase option. The group applies the short-term lease recognition exemption to its short-term leases. Collaboration assets represent the Group's share of assets leased to the collaboration from Janssen, which purchased the assets on behalf of the collaboration, in connection with the Janssen Agreement. Collaboration assets under construction that will be leased to the collaboration from Janssen when placed into service are classified as Collaboration Assets – Prepaid Lease in note 12 to the financial statements.

(a) Right-of-use assets

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Leasehold land	4,862	4,851
Lease buildings	2,324	3,158
Collaboration assets	31,097	31,533
	38,283	39,542

The carrying amounts of the Group's right-of-use assets and the movements during the year are as follows:

	Non-Collaboration Assets Leased		Collaboration Assets Leased			
	Leasehold land	Buildings	Buildings	Machinery And equipment	Computer and office equipment	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2021						
Right-of-use assets at January 1, 2021	4,851	3,158	21,311	10,201	21	39,542
Additions	—	678	7	2,517	—	3,202
Disposals	—	(59)	—	(53)	—	(112)
Exchange realignment	112	(62)	—	—	—	50
Depreciation of right-of-use assets	(101)	(1,391)	(1,411)	(1,491)	(5)	(4,399)
Right-of-use assets at December 31, 2021	4,862	2,324	19,907	11,174	16	38,283
December 31, 2020						
Right-of-use assets at January 1, 2020	4,630	4,718	11,639	6,787	16	27,790
Additions	—	491	10,726	4,369	10	15,596
Lease modifications	—	(928)	—	—	—	(928)
Exchange realignment	318	273	—	—	—	591
Depreciation of right-of-use assets	(97)	(1,396)	(1,054)	(955)	(5)	(3,507)
Right-of-use assets at December 31, 2020	4,851	3,158	21,311	10,201	21	39,542

(b) Lease liabilities

Lease liabilities are as indicated below:

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term.

	2021 US$'000	2020 US$'000
Carrying amount at January 1	3,373	6,085
Additions	678	491
Lease modifications	—	(928)
Disposals	(68)	—
Accretion of interest recognized during the year	142	195
Payments	(1,561)	(2,797)
Exchange realignment	(60)	327
Carrying amount at December 31	2,504	3,373
Analyzed into:		
Current portion	911	1,464
Non-current portion	1,593	1,909
	2,504	3,373

(c) The amounts recognized in profit or loss in relation to leases are as follows:

	2021 US$'000	2020 US$'000
Interest on lease liabilities	142	195
Depreciation charge of right-of-use assets	4,399	3,507
Expense relating to short-term leases	182	69
Total amount recognized in profit or loss	4,723	3,771

The maturity analysis of lease liabilities is disclosed in note 35 to the financial statements. The total cash outflow for leases is disclosed in note 30 (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. For these operating leases, rental income recognized by the Group for the year ended December 31, 2021 was US$13,000 (2020: 4,000). The Group also leases assets it owns to the collaboration in accordance with the Janssen Agreement. These are finance leases for which the Group did not recognize any finance income for the year ended December 31, 2021 and 2020 because the Group's collaboration partner pre-paid these lease payments.

At December 31, 2021 and 2020, the undiscounted minimum lease payments receivables by the Group in future periods under non-cancellable finance leases and operating leases with its tenants are as follows:

	2021 US$'000	2020 US$'000
Finance leases:		
Within one year	94	619
Operating leases:		
Within one year	13	4

14. CONVERTIBLE REDEEMABLE PREFERRED SHARES

On March 30, 2020 and on April 16, 2020, the Company issued a total of 20,591,629 Series A convertible redeemable preferred shares (the "Series A Preference Shares") to independent third parties, at the price of US$7.792 per share for an aggregate purchase consideration of US$160.5 million.

The key terms of the Series A Preference Shares are summarized as follows:

(1) Dividends rights

Each Series A Preference Shares holder is entitled to dividends at the rate of 8% of the Series A original issue price per annum per share shall accrue on such Series A Preference Shares. Such dividends (i) will be declared by the board of directors and paid to the holders of Series A Preference Shares each fiscal quarter, or (ii) if not declared and, with respect to any fiscal quarter, paid to the holders of Series A Preference Shares within thirty days after such fiscal quarter, such undeclared and unpaid dividends will accrue day to day from the last day of such fiscal quarter, will be cumulative and compound annually, and will only be paid upon a redemption or liquidation event or converted into ordinary shares upon an initial public offering.

(2) Conversion rights

Optional conversion

Each Series A Preference Share is convertible, at the option of the holder, at any time after the date of issuance of such Series A Preference Share, into such number of fully paid and non-assessable ordinary shares as is determined by dividing the Series A original issue price, by a conversion price equal to the lower of (i) the conversion price at the time in effect for such Series A Preference Share and (ii) the price per share that equals the lowest net price per ordinary share received by the Company in a public offering that is not a Qualified IPO.

Automatic conversion

Each Series A Preference Share will be automatically converted upon the closing of a Qualified IPO into a number of ordinary shares as is determined by dividing the Series A original issue price by a conversion price is equal to the lower of (i) the conversion price at the time in effect for such Series A Preference Share and (ii) the price per share that equals 90% of the lowest net price per ordinary share received by the Company in the Qualified IPO.

(3) Redemption rights

At any time on or after the occurrence of a Trigger Event (as defined below), each investor may require the Company to redeem the Series A Preference Shares issued to the investor and require the Company to immediately pay the investor an amount equal to the redemption price, plus 8% annualized. A "Trigger Event" means the occurrence of one or more of the following events: (A) as of September 30, 2021, the Company has not consummated a qualified IPO, (B) the Company consummates a non-Qualified IPO, (C) the License Agreement (i) is terminated as a result of a material breach by any party thereto or (ii) is amended in such a way that with (or without) the passage of time would reasonably be expected to adversely affect the value of the Company or the Series A Preference Shares in any material respect and (D) there occurs or it is discovered that there is a material adverse issue with respect to the patents, know-how and all other intellectual property owned or controlled by the Company or its affiliates and licensed to a customer under a license and collaboration agreement, which is not capable of being cured within a reasonable period.

(4) Liquidation

Upon any liquidation, dissolution or winding up of the Company (collectively, a "Liquidation Event"), before any distribution or payment shall be made to the holders of any Ordinary Shares, the holders of Series A Preference Shares will be entitled to be paid out of the assets of the Company legally available for distribution for each Series A Preference Share, an amount per Series A Preference Share equal to the sum of (i) the Series A Original Issue Price,

plus (ii) any accrued but unpaid Dividends on each Series A Preference Share. If, upon any such Liquidation Event, the assets of the Company will be insufficient to make payment in full to all holders of Series A Preference Shares, then such assets (or consideration) will be distributed among the holders of Series A Preference Shares at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

All Series A Preferred Shares were converted into ordinary shares of the Company and all accrued but unpaid dividends were settled in the form of ordinary shares upon qualified IPO in June 2020. A fair value loss of $80.0 million was recorded in the fiscal year ended December 31, 2020 due to change in fair value upon conversion.

15. INVENTORIES

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Raw materials and consumables	1,749	1,800

16. TRADE RECEIVABLES (AS RESTATED)

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Trade receivables	50,410	75,000

The Group's trading terms with its customers are mainly on credit. The credit period is 45 to 60 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 US$50.0 million (or 99.2%) and US$75.0 million (or 100%), respectively, of trade receivables were due from one single customer, Janssen, under a license and collaboration agreement as at December 31, 2021 and 2020. As at December 31, 2021, the remaining US$0.4 million of trade receivables were about royalties due from Nanjing Probio Biotech Co., Ltd. (note 32).

As at December 31, 2021 and 2020, the expected credit loss is insignificant.

17. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS (AS RESTATED)

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Interest receivable	230	80
Other receivables	837	264
Income tax refund	4,712	4,712
VAT recoverable	2,264	1,941
Prepayments	5,715	3,455
	13,758	10,452

As at December 31, 2021 and 2020, amounts due from the Group's related parties that are repayable on demand, which were included in the Group's other receivables, were US$262,000 and US$20,000, respectively (note 32). As at December 31, 2021 and 2020, amounts prepaid to the Group's related parties were US$1,199,000 and nil, respectively (note 32).

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 as at December 31, 2021 and 2020 is insignificant.

18. FINANCIAL ASSETS MEASURED AT AMORTIZED COST

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Financial assets measured at amortized cost	29,937	—

Financial assets measured at amortized cost was related to commercial paper issued by a financial institution with principal amount of US$30.0 million, discounted bid yield of 0.5% per annum and one year maturity date as June 1, 2022.

19. CASH AND CASH EQUIVALENTS, TIME DEPOSITS AND PLEDGED DEPOSITS

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Cash and bank balances	858,607	506,073
Less: Pledged deposits	(1,444)	(384)
Time deposits	(168,225)	(50,000)
Cash and cash equivalents	688,938	455,689
Denominated in USD	681,025	451,165
Denominated in RMB	5,875	4,335
Denominated in EUR	2,038	189
Cash and cash equivalents	688,938	455,689

The cash and bank balances of the Group denominated in Renminbi ("RMB") amounted to US$5.9 million and US$4.3 million in the consolidated statements of financial position as at December 31, 2021 and 2020, 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 authorized to conduct foreign exchange business.

The pledged deposit as at December 31, 2021 was pledged for issuing a letter of guarantee to a supplier of the Group and for credit card facilities. The pledged deposit as at December 31, 2020 was pledged for issuing bank acceptance notes to suppliers of the Group and credit card facilities.

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.

20. TRADE AND NOTES PAYABLES

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Trade payables	7,043	4,911
Notes payable	—	327
	7,043	5,238

The trade payables are non-interest-bearing and are normally settled on 30-day terms.

As at December 31, 2021 and 2020, amounts due to the Group's related parties, included in the Group's trade payables, were US$2.4 million and US$2.1 million, respectively (note 32).

21. OTHER PAYABLES AND ACCRUALS (AS RESTATED)

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Accrued payroll	19,207	13,609
Accrued expense	81,364	56,863
Other payables	16,867	25,760
Payable for Collaboration Assets	5,605	3,399
Other tax payables	515	156
	123,558	99,787

Other payables are non-interest-bearing and repayable on demand.

As at December 31, 2021 and 2020, amounts due to the Group's related parties, included in the Group's other payables, were US$3.3 million and US$3.7 million, respectively (note 32).

22. DEFERRED TAX (AS RESTATED)

The movements in deferred tax liabilities and assets during the years ended December 31, 2021 and 2020 are as follows:

Deferred tax liabilities

	Collaboration revenue	Difference allowance in excess of related depreciation	Right of use assets	Total
	US$'000	US$'000	US$'000	US$'000
At January 1, 2020	(42,317)	(5,387)	—	(47,704)
Deferred tax charged/(credited) to the statement of profit or loss during the year	14,106	(1,285)	(159)	12,662
Gross deferred tax liabilities at December 31, 2020	(28,211)	(6,672)	(159)	(35,042)
At January 1, 2021	(28,211)	(6,672)	(159)	(35,042)
Deferred tax charged/(credited) to the statement of profit or loss during the year	14,086	(1,964)	159	12,281
Gross deferred tax liabilities at December 31, 2021	(14,125)	(8,636)	—	(22,761)

Deferred tax assets

	Losses available for offsetting against future taxable profits	Difference in intangible assets amortization	Accrued expense	Lease liabilities	R&D credit	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
At January 1, 2020	216	4,845	—	—	655	5,716
Deferred tax charged to the statement of profit or loss during the year	14,865	497	608	165	8,950	25,085
Gross deferred tax assets at December 31, 2020	15,081	5,342	608	165	9,605	30,801
At January 1, 2021	15,081	5,342	608	165	9,605	30,801
Deferred tax charged to the statement of profit or loss during the year	5,367	(4,286)	649	(165)	(9,605)	(8,040)
Gross deferred tax assets at December 31, 2021	20,448	1,056	1,257	—	—	22,761

For presentation purposes, certain deferred tax assets and liabilities have been offset in the statement of financial position. The following is an analysis of the deferred tax balances of the Group for financial reporting purposes:

	2021	2020
	US$'000	US$'000
Net deferred tax liabilities recognised in the consolidated statement of financial position	—	4,241

The Group has tax losses arising in Hong Kong of US$38,000 in 2021 (2020: US$25,000) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

The Group has tax losses arising in Mainland China of US$91.8million in 2021 (2020: US$60.0 million) 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 Ireland of US$82.9 million in 2021 (2020 US$71.3 million) 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 America of US$226.6 million in 2021 (2020: nil) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

The Group has tax losses arising in Belgium of US$0.5 million in 2021 (2020: 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 utilized.

Deferred tax assets have not been recognized in respect of the following items:

	2021 US$'000	2020 US$'000
Deductible temporary differences	15,420	12,842
Tax losses	609,200	200,523
	624,620	213,365

Deferred income tax assets are recognized 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, 2021 and 2020, the subsidiaries 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.

At December 31, 2021 and 2020, the subsidiary in US had no distributable retained earnings.

23. WARRANT LIABILITY

On May 13, 2021, the Company entered into a subscription agreement with an institutional investor relating to the offer and sale of 20,809,850 ordinary shares of the Company, par value US$0.0001 per share, in a private placement at a purchase price of US$14.41625 per ordinary share (the "PIPE Offering"). The total proceeds from the PIPE Offering is US$300.0million. Pursuant to the subscription agreement, the Company also agreed to issue and sell concurrently with the PIPE offering a warrant (the "Warrant") exercisable for up to an aggregate of 10,000,000 ordinary shares (such transaction together with the PIPE Offering, the "Transactions"). The Transactions were completed on May 21, 2021(the "Closing Date"). The Warrant is exercisable, in whole or in part, at an exercise price of US$20.00 per ordinary share, at any time prior to the two-year anniversary of the Closing Date.

The Warrant is accounted for as a financial liability because the Warrant may be net share settleable at the holder's option. The fair value of the warrant liability is assessed at US$81.7 million and is recognized upon closing of the Transactions. As of December 31, 2021, the fair value of the Warrant was assessed at US$87.9 million. A fair value loss of US$6.2 million was recorded in profit or loss for the year ended December 31, 2021 due to change of the fair value. Management considered that there is no significant change of the Company's own credit risk that drives the fair value change of the warrant liability during the year ended December 31, 2021.

The movement of the warrant liability is set out as below:

	Total
	US$'000
At January 1, 2021	—
Issuance of the warrant liability	81,700
Fair value loss of the warrant liability	6,200
At December 31, 2021	87,900

24. GOVERNMENT GRANTS

	2021	2020
	US$'000	US$'000
Deferred government grants	2,170	2,334
Current	304	283
Non-current	1,866	2,051

The grants were related to the subsidies received from local government authorities for the purpose of compensation for the expenditure on certain facilities and were credited to a deferred income account. The grants were released to other income and gains over the expected useful lives of the relevant assets. The group also received certain financial subsidies from local government authorities to support local business. There were no unfulfilled conditions and other contingencies attached to these government grants. These government grants were recognized in other income and gains upon receipt.

25. INTEREST-BEARING LOANS AND BORROWINGS

	Effective interest rate	Maturity	December 31, 2021
	%		US$'000
Non-current			
Loans from a collaborator	3.03	No specific maturity date	120,462

Pursuant to the license and collaboration agreement entered into with a collaborator, the Company is entitled to receive funding advances from the collaborator when certain operational conditions are met. As a result, the Company took an initial funding advance with principal amounting to US$17.3 million on June 18, 2021, a second funding advance with principal amounting to US$53.1 million on September 17, 2021, and a third funding advance with principal amounting to US$49.3 million on December 17, 2021, by reducing the same amount of other payables due to the collaborator, respectively (collectively, the "Funding Advances").

These Funding Advances are accounted for as interest-bearing borrowings funded by the collaborator, constituted by a principal amounting to US$119.7 million and applicable interests accrued amounting to US$0.8 million upon such principal. The respective interest rate of each borrowing is based on the average annual London Interbank Offered Rate (LIBOR) for U.S. Dollars as reported in the Wall Street Journal on the due date of the quarterly invoice or the next business date should the due date fall on a weekend or holiday, plus 250 basis points, calculated on the number of days from the date on which the Company applied such borrowings. For each of the three batches of funding advances, interest started to accrue from June 18, 2021, September 17, 2021 and December 17, 2021, respectively.

Pursuant to the terms of the license and collaboration agreement, the collaborator may recoup the aggregate amount of Funding Advances together with interest thereon from Company's share of pre-tax profits from the first profitable year of the collaboration program. The Company's management estimated the loan will not be recouped

by the collaborator within one year, nor does the Company expect to repay the funding advances within one year, and thus the loan was classified as a long-term liability.

26. SHARE CAPITAL AND SHARE PREMIUM

Shares

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Authorized:		
2,000,000,000 shares of US$0.0001 each	200	200
Issued and fully paid:		
308,456,852 (2020: 266,010,256) ordinary shares of US$0.0001 each	31	27

A summary of movements in the Company's share capital and share premium is as follows:

	Number of shares in issue	Share capital	Share premium	Total
		US$'000	US$'000	US$'000
At December 31, 2019 and January 1, 2020	200,000,000	20	3,908	3,928
Issuance of ordinary shares for conversion of preferred shares	20,907,282	2	240,432	240,434
Issuance of ordinary shares for initial public offering, net of issuance cost	42,377,500	4	450,081	450,085
Issuance of ordinary shares for private placement by GenScript	1,043,478	—	12,000	12,000
Exercise of share options	1,681,996	1	1,885	1,886
At December 31, 2020 and January 1, 2021	266,010,256	27	708,306	708,333
Issuance of ordinary shares relating to private placement for an institutional investor (note 23)	20,809,850	2	218,298	218,300
Issuance of ordinary shares for follow-on public offering, net of issuance cost (note)	17,231,150	2	323,438	323,440
Exercise of share options	4,056,380	—	6,089	6,089
Reclassification of vesting of restricted stock units	349,216	—	5,323	5,323
At December 31, 2021	308,456,852	31	1,261,454	1,261,485

Note: On December 20, 2021, the Company completed a follow-on public offering by issuing 17,231,150 ordinary shares, in aggregate, at US$20.00 per ordinary share and received net proceeds of US$323.4 million, after deduction of related issuance costs of US$21.2 million.

27. 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.

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:

	2021		2020		2019	
	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options
	US$ per share	'000	US$ per share	'000	US$ per share	'000
At January 1,	1.9353	14,241	0.9273	18,013	0.7782	14,311
Granted during the year	15.4774	595	15.6128	679	1.4973	3,757
Forfeited during the year	2.9987	(1,251)	0.9963	(2,769)	1.0909	(55)
Exercised during the year	1.3346	(4,056)	1.0131	(1,682)	—	—
At December 31,	2.8970	9,529	1.9353	14,241	0.9273	18,013
Exercisable at December 31	1.4334	2,828	1.0703	4,619	0.7852	2,484

The weighted average share price at the date of exercise for share options exercised during the year was US$18.4846 per share (2020: US$14.9131, 2019: No share options were exercised).

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

December 31, 2021

Number of options '000	Exercise price* US$ per share	Exercise period
4,054	0.5	2019/12/25 – 2027/12/25
1,849	1.0	2019/07/01 – 2028/08/29
382	1.0	2019/12/31 – 2028/12/30
1,822	1.5	2020/07/02 – 2029/07/01
332	11.5	2020/11/29 – 2029/11/28
90	11.5	2021/06/05 – 2030/06/04
385	16.3	2021/09/01 – 2030/08/31
20	13.6	2021/11/19 – 2030/11/18
430	14.1	2022/03/29 – 2031/03/28
165	19.0	2022/08/27 – 2031/08/26
9,529		

December 31, 2020

Number of options '000	Exercise price* US$ per share	Exercise period
5,393	0.5	2019/12/25 - 2027/12/25
4,317	1.0	2019/07/01 - 2028/08/29
540	1.0	2019/12/31 - 2028/12/30
2,868	1.5	2020/07/02 - 2029/07/01
444	11.5	2020/11/29 - 2029/11/28
90	11.5	2021/06/05 - 2030/06/04
569	16.3	2021/09/01 - 2030/08/31
20	13.6	2021/11/19 - 2030/11/18
14,241		

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. Pursuant to certain listing rules of the Hong Kong Stock Exchange to which members of the Genscript Group are subject to, the Company adjusted the exercise price of options granted during November 29, 2019 through December 9, 2019 to $11.50 per share. Concurrent with this adjustment, the Company agreed to pay each employee holding affected share options an amount in cash representing the difference between the adjusted exercise price over the original exercise price upon exercising the share options.

The fair value of the share options granted during the year ended December 31, 2021 was US$5.7 million (US$9.497 each) (2020: US$6.7 million, US$9.817 each; 2019: US$1.1 million, US$0.294 each). The Group recognized share option expense of US$2.4 million (2020: US$1.9 million, 2019: US$1.3 million) during the year ended December 31, 2021.

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:

	2021	2020	2019
Dividend yield (%)	—	—	—
Expected volatility (%)	73.2-76.4	73.0-87.2	66.4-80.3
Risk-free interest rate (%)	0.03-1.72	0.07-0.91	1.98-2.69
Expected life of options (year)	10	10	10

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. The weighted average share price was US$15.4774 used in the share option fair value valuation model during the year ended December 31, 2021.

As at December 31, 2021, the Company had 9,529,158 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 9,529,158 additional ordinary shares of the Company, an additional share capital of US$953 and a share premium of US$27.6 million (before issue expenses).

At the date of approval of these financial statements, the Company had 9,529,158 share options outstanding under the share option scheme, which represented approximately 3.1% of the Company's shares in issue as at that date.

28. RESTRICTED STOCK UNITS

The Company operates a restricted stock units scheme (the "RSU 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 May 26, 2020 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 target set by the board of directors.

The movement in the number of RSU outstanding for the year ended 31 December 2021 and 2020 was as follow:

	2021	
	Number of RSU	Weighted average grant date fair value
	'000	US$ per unit
Outstanding at January 1	1,113	15.3409
Granted during the year	2,133	15.0120
Vested during the year	(349)	15.2420
Forfeited during the year	(296)	14.4913
Outstanding at December 31	2,601	15.1808

	2020	
	Number of RSU	Weighted average grant date fair value
	'000	US$ per unit
Outstanding at January 1, 2020	—	—
Granted during the year	1,139	15.3639
Forfeited during the year	(26)	16.3350
Outstanding at December 31, 2020	1,113	15.3409

The weighted-average remaining contractual life for outstanding RSUs granted under the RSU Scheme was 8.16 years and 8.84 years as of December 31, 2021 and 2020, respectively.

The fair value of the awarded shares was calculated based on the market price of the Group's shares at the respective grant date.

The fair value of the RSU granted during the period was US$32.0 million (US$15.012 each), of which the Group recognized RSU expense of US$17.8 million during the year ended 31 December 2021.

The fair value of the RSU granted during the period was US$17.5 million (US$15.364 each), of which the Group recognized RSU expense of US$2.9 million during the year ended 31 December 2020.

At the date of approval of these financial statements, the Company had 2,601,187 RSUs outstanding under the restricted shares plan, which represented approximately 0.8% of the Company's shares in issue as at that date.

29. RESERVES (AS RESTATED)

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 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 reserve funds of the Company's PRC subsidiary, totaling US$71.9 million and US$31.9 million as at December 31, 2021 and 2020, respectively.

30. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS (AS RESTATED)

(a) Major non-cash transactions

For the year ended December 31, 2021, the Group had non-cash additions to interest-bearing loans and borrowings of US$119.7 million which was received through the deduction of other payables to a collaborator.

For the year ended December 31, 2021, the Group had non-cash fair value loss of US$6.2 million of warrant liability.

For the year ended December 31, 2021, the Group had non-cash prepayment of US$1.5 million in exchange of research and development service from Nanjing Probio Biotech Co., Ltd. and Jiangsu GenScript Probio Biotech Co., Ltd.

For the years ended December 31, 2021, 2020 and 2019, the Group had non-cash additions to right-of-use assets of US$0.7 million, US$0.5 million and US$2.2 million, and lease liabilities of US$0.7 million, US$0.5 million and US$2.2 million, in respect of lease arrangements for buildings, respectively.

For the years ended December 31, 2021, 2020 and 2019, the Group had non-cash additions to lease receivables of US$0.3 million, US$0.6 million and US$0.7 million, respectively, resulting from financial leases for the assets leased to the collaboration, and settled lease receivables of US$0.2 million, nil and US$0.7 million, respectively, through the deduction of other payable to the collaboration partner.

For the years ended December 31, 2021, 2020 and 2019, the Group had non-cash additions to other non-current assets included in the other payables and accruals for the assets leased from the collaboration partner of US$7.6 million, US$5.2 million and US$6.8 million, respectively, and had non-cash additions to property, plant and equipment included in other payables and accruals of US$6.7 million, US$8.6 million and US$2.2 million, respectively.

For the year ended December 31, 2020, the Group had non-cash additions to finance costs of US$1.5 million and other payable of US$1.5 million, in respect of expenses for convertible redeemable preferred shares.

For the year ended December 31, 2020, the Group had non-cash fair value loss of $80.0 million of convertible redeemable preferred shares.

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$4.4 million.

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$19.5 million and US$5.5 million, respectively.

(b) Changes in liabilities arising from financing activities

	Convertible redeemable preferred shares	Other payables to related parties	Lease liabilities
	US$'000	US$'000	US$'000
At January 1, 2021	—	—	3,373
Additions of lease liabilities	—	—	678
Changes from financing cash flows	—	—	(1,419)
Disposal	—	—	(68)
Interest expense	—	—	142
Interest paid classified as operating cash flows	—	—	(142)
Foreign exchange movement	—	—	(60)
At December 31, 2021	—	—	2,504
At January 1, 2020	—	4	6,085
Additions of lease liabilities	—	—	(437)
Changes from financing cash flows	160,450	(4)	(2,602)
Interest expense	—	—	195
Interest paid classified as operating cash flows	—	—	(195)
Fair value loss of the convertible redeemable preferred shares	79,984	—	—
Conversion to ordinary shares	(240,434)	—	—
Foreign exchange movement	—	—	327
At December 31, 2020	—	—	3,373
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 30(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:

	2021	2020	2019
	US$'000	US$'000	US$'000
Right-of-use assets			
Within operating activities	142	195	199
Within financing activities	1,419	2,602	5,056
Short-term leases	182	69	272
	1,743	2,866	5,527

31. COMMITMENTS AND CONTINENCIES (AS RESTATED)

(a) Capital commitments

The Group had the following capital commitments at the end of the year:

	2021 US$'000	2020 US$'000	2019 US$'000
Construction in progress	25,897	33,637	2,844

(b) Loss contingencies

In September 2021, a former employee elected to enter into arbitration against Legend Biotech USA Inc. ("Legend USA") with the American Arbitration Association, claiming such former employee was discriminated against due to her gender and wrong fully terminated in retaliation for engaging in alleged protected activity. The former employee demanded Legend USA to pay damages of approximately US$3.0 million for alleged lost pay, lost equity, damage to reputation, emotional distress and other related losses.

Management believes that the former employee's claims above are without merit and intends to defend vigorously. At the early stage of the process, management cannot predict the ultimate outcome of the above claims, whether in whole or in part, which may result in a loss, if any. Therefore, in the opinion of management and legal counsel, an estimate of the amount or arrange of reasonably possible losses cannot be made at this time. Accordingly, no provision for any liability has been made in the financial statements.

(c) Lease contingency

We are party to a lease with Janssen under which we expect to lease an approximately 106,000 square foot manufacturing facility from Janssen located in Raritan, New Jersey. That lease will become effective and recorded as a lease in a future date contingent on the FDA's approval of our or BLA for cilta-cel, which we referred to as the Facility Transition Date. For this facility, which we collaboratively operate with Janssen, we continue to invest in manufacturing, quality, information technology and distribution capabilities to support the launch of CARVYKTI™.

32. RELATED PARTY TRANSACTIONS

Company	Relationship
Nanjing GenScript Biotech Co., Ltd. (formerly named as Nanjing Jinsirui Biotechnology Co., Ltd.)	Company controlled by the ultimate holding company
Nanjing Bestzyme Bioengineering 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
Nanjing Probio Biotech Co., Ltd.	Company controlled by the ultimate holding company
Jiangsu GenScript Probio Biotech Co., Ltd.	Company controlled by the ultimate holding company
Genscript Netherlands	Company controlled by the ultimate holding company
Genscript Biotech Corporation (“GenScript”)	Company controlled by the ultimate holding company
Genscript (Nanjing) Co., Ltd. (formerly named as Jinsikang Technology (Nanjing) Co., Ltd.)	Company controlled by the ultimate holding company

(a) In addition to the transactions detailed elsewhere in the consolidated financial statements, the Group had the following transactions with related parties during the year :

(i) Licensing of patents to related parties:

	2021 US$’000	2020 US$’000	2019 US$’000
Nanjing Probio Biotech Co., Ltd.	3,019	—	—

The sale was generated from an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates.

(ii) Sales-based royalties from related parties:

	2021 US$’000	2020 US$’000	2019 US$’000
Nanjing Probio Biotech Co., Ltd.	405	—	—

The sale was generated from sales-based royalties related to the exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates.

(iii) Sales of materials to related parties:

	2021 US$’000	2020 US$’000	2019 US$’000
Nanjing Genscript Biotech Co., Ltd.	—	—	3

The terms of these services and materials were charged based on the prices agreed by both parties.

(iv) Other income to related parties:

	2021 US$’000	2020 US$’000	2019 US$’000
Nanjing GenScript Biotech Co., Ltd.	12	—	265

The other income was the income for sublease to Nanjing GenScript Biotech Co., Ltd. The price and terms are agreed by both parties

(v) Purchases from related parties:

	2021	2020	2019
	US$'000	US$'000	US$'000
Nanjing GenScript Biotech Co., Ltd.	9,615	4,162	4,480
Genscript USA Incorporated	786	424	296
Jiangsu GenScript Probio Biotech Co., Ltd	334	—	—
Jiangsu GenScript Biotech Co., Ltd	146	41	198
Nanjing Probio Biotech Co., Ltd.	21	—	—
Genscript Netherlands	6	—	—
Genscript Biotech (Netherlands) B.V.	—	7	—
Genscript USA Holdings Inc	—	—	4
	10,908	4,634	4,978

The transactions were made according to the price and terms agreed with related parties.

(vi) Management fee:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript USA Incorporated	—	95	198
Genscript (HongKong) Ltd	—	59	—
	—	154	198

The management fee was charged by related parties based on the cost of services provided.

(vii) Shared services:

During the years ended December 31, 2021, 2020 and 2019, Nanjing GenScript Biotech Co., Ltd. provided certain accounting, legal, IT and administrative shared services to the Group for a consideration of US$1.6 million, US$3.3 million and US$2.1 million, respectively. During the year ended December 31, 2021, Genscript USA Incorporated provided certain IT shared service to the Group for a consideration of US$3,000.

(viii) Compensation fee for termination of service agreement:

	2021	2020	2019
	US$'000	US$'000	US$'000
Jiangsu GenScript Biotech Co., Ltd.	2,666	—	—

In May 2021, pursuant to a settlement agreement between the Group and Jiangsu GenScript Biotech Co., Ltd., the Group incurred compensation charges for the termination of a service agreement related to the design and construction of a lab facility.

(ix) Cash advances from related parties:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	—	28,199
Nanjing GenScript Biotech Co., Ltd.	—	—	2,168
Genscript USA Incorporated	—	—	8,000
Genscript (Nanjing) Co., Ltd.	—	—	578
	—	—	38,945

(x) Repayment of cash advances from related parties:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	—	4,335
Nanjing GenScript Biotechnology Co., Ltd.	—	—	6,310
Genscript USA Incorporated	—	—	8,000
Genscript (Nanjing) Co., Ltd.	—	—	578
Genscript (HongKong) Ltd.	—	4	—
	—	4	19,223

(xi) Cash advances to related parties:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	—	13,006

(xii) Collection of cash advances to related parties:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	—	48,496
Genscript USA Incorporated	—	—	14,500
		—	62,996

The above cash advances from/to related parties were unsecured, interest free and repayable on demand.

(xiii) Entrusted loan from a related party:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript (Nanjing) Co., Ltd.	—	—	2,867

(xiv) Repayments of entrusted loan from a related party:

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript (Nanjing) Co., Ltd.	—	—	2,867

The above entrusted loan from a related party was unsecured, bearing an interest rate of 4.35% p.a. and was repaid in December 2019, with an interest expense of US$24,000 recognized in 2019.

(xv) Purchase of equipment

	2021	2020	2019
	US$'000	US$'000	US$'000
Nanjing GenScript Biotech Co., Ltd.	—	54	7

(xvi) Sale of equipment

	2021	2020	2019
	US$'000	US$'000	US$'000
Nanjing GenScript Biotech Co., Ltd.	—	—	13

The sale or purchase of equipment was made at their respective carrying values.

(xvii) Financing from follow-on public offering, net of issuance cost

	2021	2020	2019
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	84,600	—	—

Genscript Biotech Corporation purchased 4,500,000 ordinary shares, in the form of ADSs issued as part of the follow-on public offering on December 20, 2021, at the same price as these shares issued to the public(note 26).

(xviii) Lease contract guarantee

In 2018, Legend Ireland entered into a copy property lease agreement with a third party in Dublin with lease period from 2018 to August 2028. Genscript Biotech Corporation provided a guarantee on Legend Ireland's payment obligations under the lease agreement for nil consideration.

(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, 2021	December 31, 2020
	US$'000	US$'000
Trade receivables		
Nanjing Probio Biotech Co., Ltd.	409	—

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Other receivables		
Genscript USA Incorporated	19	6
Nanjing GenScript Biotech Co., Ltd.	243	14
	262	20

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Prepayment		
Jiangsu GenScript Probio Biotech Co., Ltd	925	—
Nanjing Probio Biotech Co., Ltd.	274	—
	1,199	—

(ii) Due to related parties.

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Trade payables		
Nanjing GenScript Biotech Co., Ltd.	2,301	1,547
Genscript USA Incorporated	46	555
Nanjing Probio Biotech Co., Ltd.	22	—
Jiangsu GenScript Biotech Co., Ltd	1	1
	2,370	2,103

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Other payables		
Nanjing GenScript Biotech Co., Ltd.	3,293	3,736
Genscript USA Incorporated	50	—
	3,343	3,736

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Lease liabilities		
Nanjing GenScript Biotech Co., Ltd.	286	351
Genscript USA Holdings Inc	—	582
	286	933

Except for lease liabilities with incremental borrowing rates between 2.00% and 8.89% repayable over 5 years, all other related party balances are unsecured and repayable on demand and interest free.

(c) Compensation of key management personnel of the Group:

	2021	2020	2019
	US$'000	US$'000	US$'000
Short-term employee benefits	1,942	1,733	1,036
Equity-settled share-based compensation expense	2,907	529	590
Termination payment	—	774	—
	4,849	3,036	1,626

33. FINANCIAL INSTRUMENTS BY CATEGORY (AS RESTATED)

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, 2021

Financial assets

	Financial assets at amortized cost
	US$'000
Trade receivables	50,410
Financial assets included in prepayments, other receivables and other assets (note 17)	1,067
Financial assets measured at amortized cost	29,937
Lease receivables	94
Time deposits	168,225
Pledged deposits	1,444
Cash and cash equivalents	688,938
	940,115

Financial liabilities

	Financial liabilities at amortized cost	Financial liabilities at fair value through profit and loss
	US$'000	US$'000
Trade and notes payables	7,043	—
Warrant liability	—	87,900
Financial liabilities included in other payables and accruals (note 21)	16,867	—
Interest-bearing loans and borrowings	120,462	—
Lease liabilities	2,504	—
	146,876	87,900

As at December 31, 2020

Financial assets

	Financial assets at amortized cost
	US$'000
Trade receivables	75,000
Financial assets included in prepayments, other receivables and other assets (note 17)	344
Lease receivables	619
Time deposits	50,000
Pledged deposits	384
Cash and cash equivalents	455,689
	582,036

Financial liabilities

	Financial liabilities at amortized cost
	US$'000
Trade and notes payables	5,238
Financial liabilities included in other payables and accruals (note 21)	25,760
Lease liabilities	3,373
	34,371

34. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

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 following table illustrates the fair value measurement hierarchy of the Group's financial instruments:

Liability measured at fair value:

As at December 31, 2021

	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
Warrant liability	—	87,900	—	87,900

The following table lists the inputs to the binominal model used for the fair value valuation of warrant liability:

	December 31, 2021
Underlying stock price	US$23.31
Volatility	70.5%
Risk free rate	0.58%
Dividend	0%

During the year ended December 31, 2021, 2020 and 2019, 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.

35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (AS RESTATED)

The Group's principal financial instruments comprise cash and cash equivalents, pledged deposits, time deposits, financial assets measured at amortized cost, prepayments, other receivables and other assets, and financial liabilities included in other payables and accruals. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade receivables and trade and notes payables, which arise directly from its operations.

The main risks arising from the Group's financial instruments are interest rate risk, 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 summarized below.

Interest rate risk

As at December 31, 2021, the Group's exposure to the risk of changes in interest rates primarily relates to the Group's Funding Advances with a floating interest rate as disclosed in note 25 to the consolidated financial statements. As at December 31, 2021, management considered that any reasonable changes in the interest rate would not have significant impact on the interest expense from the Funding Advances. Accordingly, no sensitivity analysis for interest rate risk is presented.

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 54% in 2021 (2020 and 2019: nil and 15%) 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, 2021, 2020 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$'000
Year ended December 31, 2021		
If US$ strengthens against RMB	5	1,215
If US$ weakens against RMB	(5)	(1,215)
If US$ strengthens against EUR	5	(3,086)
If US$ weakens against EUR	(5)	3,086
Year ended December 31, 2020		
If US$ strengthens against RMB	5	678
If US$ weakens against RMB	(5)	(678)
If US$ strengthens against EUR	5	(817)
If US$ weakens against EUR	(5)	817
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 recognized 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 measured at amortized cost 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 16 and 17 to the consolidated financial statements, respectively.

Since the Group trades only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by debtor. The Group had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 16 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, 2021

	Less than 1 years	Over 1 years	Total
	US$'000	US$'000	US$'000
Trade and notes payables	7,043	—	7,043
Other payables and accruals	16,867	—	16,867
Warrant liability	87,900	—	87,900
Interest-bearing loans and borrowings (note)	—	120,462	120,462
Lease liabilities	911	1,708	2,619
	112,721	122,170	234,891

As at December 31, 2020

	Less than 1 years	Over 1 years	Total
	US$'000	US$'000	US$'000
Trade and notes payables	5,238	—	5,238
Other payables and accruals	25,760	—	25,760
Lease liabilities	1,464	2,099	3,563
	32,462	2,099	34,561

Note: Pursuant to the terms of the license and collaboration agreement, the collaborator may recoup the aggregate amount of Funding Advances together with interest thereon from Company's share of pre-tax profits for the first profitable year of the collaboration program. The Company's management estimated the loan will not be recouped by the collaborator within one year.

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 maximize shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the reporting periods.

The Group monitors capital using a gearing ratio, which is total liabilities divided by total assets. The gearing ratios as at the end of each year were as follows:

	December 31, 2021	December 31, 2020
	US$'000	US$'000
Total liabilities	353,521	124,322
Total assets	1,119,465	722,093
Gearing ratio	32%	17%

36. APPROVAL OF THE CONSOLIDATED FINANCIAL STATEMENTS (AS RESTATED)

The consolidated financial statements were approved and authorized for issue by the board of directors on February 17, 2023.

Exhibit 12.1

Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Ying Huang, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 20-F/A (this "report") of Legend Biotech Corp. (the "Company").

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 17, 2023

/s/ Ying Huang

Name: Ying Huang
Title: Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 12.2

Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Lori Macomber, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 20-F/A (this "report") of Legend Biotech Corp. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 17, 2023

/s/ Lori Macomber

Name: Lori Macomber
Title: Chief Financial Officer
(*Principal Financial Officer*)

EXHIBIT 13.1

Certification by the Principal Executive Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this Amendment No. 1 to the Annual Report of Legend Biotech Corp. (the "Company") on Form 20-F/A for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ying Huang, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 17, 2023

/s/Ying Huang

Name: Ying Huang
Title: Chief Executive Officer
(*Principal Executive Officer*)

EXHIBIT 13.2

Certification by the Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with this Amendment No. 1 to the Annual Report of Legend Biotech Corp. (the "Company") on Form 20-F/A for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lori Macomber, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 17, 2023

/s/ Lori Macomber

Name: Lori Macomber
Title: Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Post-Effective Amendment No. 1 to the Registration Statement (Form S-8 No. 333-239478) pertaining to the Share Option Scheme and the 2020 Restricted Shares Plan of Legend Biotech Corporation,
(2) Registration Statement (Form F-3 No.333-257609) of Legend Biotech Corporation, and
(3) Registration Statement (Form F-3 No.333-257625) of Legend Biotech Corporation;

of our report dated March 31, 2022 (except for the effects on the consolidated financial statements of the correction of an error as described in Note 2.2, as to which the date is February 17, 2023) with respect to the consolidated financial statements of Legend Biotech Corporation, and our report dated March 31, 2022 (except for the effect of the material weakness described in the second paragraph of our report, as to which the date is February 17, 2023) with respect to the effectiveness of internal control over financial reporting of Legend Biotech Corporation included in this Amendment No. 1 to the Annual Report on Form 20-F for the year ended December 31, 2021.

/s/Ernst & Young Hua Ming LLP
Shanghai, the People's Republic of China
February 17, 2023