Genscript Biotech Corporation
金斯瑞生物科技股份有限公司 *
(Incorporated in the Cayman Islands with limited liability)
(Stock code: 1548)

OVERSEAS REGULATORY ANNOUNCEMENT
ANNUAL REPORT
FOR THE YEAR ENDED 31 DECEMBER 2020
BY A LISTED SUBSIDIARY — LEGEND BIOTECH CORPORATION

This announcement is made by the board of directors (the "**Board**") of GenScript Biotech Corporation (the "**Company**") pursuant to 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Legend Biotech Corporation ("**Legend**"), a non-wholly owned subsidiary of the Company, whose shares are listed by way of American Depositary Shares on the Nasdaq Global Select Market in the United States, has filed a Form 20-F with the United States Securities and Exchange Commission (the "**SEC**") in relation to the annual report of Legend for the year ended 31 December 2020 ("**Annual Report**"). For details, please refer to the attached Annual Report. The attached Annual Report is the full Form 20-F as published on the SEC's website available at https://www.sec.gov/Archives/edgar/data/0001801198/000156459021017439/0001564590-21-017439-index.htm.

Shareholders and potential investors of the Company are advised to pay attention to investment risks and exercise caution when they deal or contemplate dealing in the securities of the Company.

By order of the Board
Genscript Biotech Corporation
MENG Jiange
Chairman and Executive Director

Hong Kong, 6 April 2021

As at the date of this announcement, the executive Directors are Mr. Meng Jiange, Ms. Wang Ye and Dr. Zhu Li; the non-executive Directors are Dr. Wang Luquan, Mr. Pan Yuexin and Ms. Wang Jiafen; and the independent non-executive Directors are Mr. Guo Hongxin, Mr. Dai Zumian, Mr. Pan Jiuan and Dr. Wang Xuehai.

* *For identification purposes only*

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(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, 2020

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:
266,010,256 ordinary shares, par value $0.0001 per share, were issued and outstanding as of December 31, 2020

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

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, "we," "us," "our," the "Company" and "Legend Biotech" refer to Legend Biotech Corporation and its consolidated subsidiaries. References to "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 6.52 to $1.00, which is the exchange rate as of December 31, 2020 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, excluding, for the purpose of this Annual Report only, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan; "Greater China" does not exclude Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan;
- "ordinary shares" are to ordinary shares of our company, par value $0.0001 per share;
- "Renminbi" or "RMB" refers to the legal currency of the PRC;
- "Series A Preference Shares" are to the Series A preference shares, par value $0.0001 per share; and
- "US$," "U.S. dollars," "$," or "dollars" are to the legal currency of the United States.

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 Legend Biotech Corporation appearing in this Annual Report on Form 20-F are the property of Legend Biotech Corporation. 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 statements relating to:

- the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- our ability to achieve milestones under our collaboration with Janssen 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 and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;

- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- the effect of epidemics and pandemics, such as the COVID-19 pandemic, or other business disruptions on our business; 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

A. Selected Financial Data

The following selected consolidated statement of profit or loss data for the years ended December 31, 2020, 2019 and 2018 and the selected consolidated statement of financial position data as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. Our consolidated financial statements are prepared and presented in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. IFRS differ in certain significant respects from U.S. generally accepted accounting principles, or U.S. GAAP.

Our historical results for any period are not necessarily indicative of results to be expected for any future period. The selected consolidated financial data should be read in conjunction with, and are qualified in their entirety by reference to, our audited consolidated financial statements and related notes and "Item 5. Operating and Financial Review and Prospects" below.

Summary consolidated statement of profit or loss data

	Year Ended December 31,		
	2020	2019	2018
	(in thousands, except per share data)		
Revenue	$ 75,676	$ 57,264	$ 49,133
Other income and gains	6,119	7,125	13,901
Research and development expenses	(232,160)	(161,943)	(60,637)
Administrative expenses	(23,147)	(6,752)	(2,769)
Selling and distribution expenses	(49,571)	(25,620)	(1,160)
Other expenses	(346)	(221)	(2)
Fair value loss of convertible redeemable preferred shares	(79,984)	—	—
Finance costs	(4,209)	(223)	(82)
Loss before tax	(307,622)	(130,370)	(1,616)
Income tax credit/(expense)	4,145	(2,602)	(1,168)
Loss for the year	$ (303,477)	$ (132,972)	$ (2,784)
Attributable to:			
Equity holders of the parent	$ (303,477)	$ (132,972)	$ (2,784)
Loss per share attributable to ordinary equity holders of the parent			
Basic	$ (1.28)	$ (0.66)	$ (0.01)
Diluted	$ (1.28)	$ (0.66)	$ (0.01)

Summary consolidated statement of financial position data

	As of December 31, (in thousands)	
	2020	2019
Cash and cash equivalents	$ 455,689	$ 83,364
Working capital[(1)]	431,691	79,343
Total assets	721,007	287,715
Total liabilities	440,752	410,584
Share capital	27	20
Total ordinary shareholders' equity/(deficit)	280,255	(122,869)

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

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 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;

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;
- The difficulties associated with designing and implementing clinical trials;
- Our dependence on enrollment of patients in clinical trials for development of our product candidates;
- Risks associated with investigator-initiated clinical trials in which we do not have full control are conducted;
- Certain product opportunities may face limited market opportunities;
- Adverse side effects or other safety risks associated with our product candidates;
- Our ability to create manufacturing infrastructure or to operate manufacturing facilities effectively and cost efficiently;
- The difficulties in manufacture of complex biologics;
- Human and systemic risks associated with T cell therapy;

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;
- Dependence on information technology systems;
- Any failure to comply with various governmental laws and regulations may adversely affect our business;
- The effect of epidemics and pandemics, such as the COVID-19 pandemic, or other business disruptions on our business;
- Risks associated with any failure to implement and maintain effective internal controls over financial reporting.

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 stringent clinical trial regulations, pre-marketing regulatory requirements, pricing, reimbursement and cost-containment regulations, and rigorous ongoing regulation of approved products.
- The effect of price controls in certain jurisdictions on our revenue and commercialization;

Risks Related to the Commercialization of Our Product Candidates

- The dependence of our success on our ability to establish sales, marketing and distribution capabilities;
- The highly competitive and rapidly changing nature of the biopharmaceutical industry;
- The acceptance of new products in the medical community and marketplace;

- Potential product liability risks;

Risks Related to Our Intellectual Property

- Our ability to obtain, maintain and enforce intellectual property protection for our products and disparities in intellectual property rights throughout the world;
- Our ability to successfully defend ourselves in legal proceedings and protect our intellectual property, and the significant increase in legal expenses as a result of such proceedings;
- The 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;
- The adverse effect of an ongoing investigation involving our majority shareholder and former CEO and chairman;
- Monetary, economic, political, environmental, social, and trade disputes between the U.S. and China;

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, an emerging growth company and a foreign private issuer;

Risks Related to Our Securities

- Risks associated with owning our ADSs, including volatility in our trading price due to our business and financial performance.

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.

We are a clinical-stage biopharmaceutical company with a limited operating history and we have incurred significant net losses since our inception. Our net loss was $303.5 million for the year ended December 31, 2020. We have funded our operations to date primarily with capital contributions from Genscript and from upfront and milestone payments from Janssen.

While we had revenue of $75.7 million for the year ended December 31, 2020, this was attributable to our recognition of upfront and milestone payments we received from Janssen in connection with our collaboration and license agreement with Janssen, or the Janssen Agreement. We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of 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.

None of our product candidates have received marketing approval, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our

shareholders' deficit and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned research and development of cilta-cel for the treatment of MM;
- conduct preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including ongoing and planned development of additional therapies for the treatment of TCL, NHL, AML, gastric cancer, pancreatic cancer, ovarian cancer and HIV;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- hire additional clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States, China, Europe and other geographies; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

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

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

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

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

We are a clinical-stage biopharmaceutical company with a limited operating history. As an organization, we have not demonstrated an ability to successfully complete late-stage clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our short history as an operating company makes any assessment of our future success or viability

subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will be materially harmed.

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

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

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

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

Although these have been remediated, we may identify future material weaknesses in our internal control over financial reporting. If we identify any material weaknesses that we are unable to remedy, or if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our ADS price.

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

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

The material weaknesses that have been identified related to our lack of sufficient accounting and financial reporting personnel with requisite knowledge of and experience in application of IFRS and SEC rules, and lack of financial reporting policies and procedures that are commensurate with IFRS and SEC reporting and compliance requirements.

We have implemented a number of measures to improve our internal control over financial reporting to address the material weaknesses that have been identified. We have hired additional qualified financial and accounting staff with IFRS and SEC reporting experience to strengthen our financial reporting capability. We have designed an ongoing training program and provided continuous ongoing trainings and education to our accounting and financial reporting staff in the accounting and reporting requirements under IFRS, and SEC rules and regulations. We have improved our accounting and financial reporting policies, accounting manual, monthly closing process, and related financial reporting and disclosure procedures. We have also established an internal audit department to enhance internal controls and have engaged an independent advisory firm to assist us in assessing the design and effectiveness of our execution of internal controls in accordance with the compliance requirements under the Sarbanes-Oxley Act of 2002 and in improving our overall internal controls and established an audit committee with members who have an appropriate level of financial expertise to oversee our accounting and financial reporting processes as well as our external and internal audits. See "Item 15.C. Changes in internal control over financial reporting."

As of December 31, 2020, based on an assessment performed by our management on the performance of the remediation measures described above, we determined that the material weaknesses previously identified in our internal control over financial reporting had been remediated.

Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. It is possible that, had our independent registered public accounting firm conducted an audit of our internal control over financial reporting, such firm might have identified additional material weaknesses and deficiencies. We are subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act, or Section 404, required that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report for the fiscal year ending December 31, 2021. In addition, once we cease to be an "emerging growth company" as such term is defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse report if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, as a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

In addition, our internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our ADSs could decline and we could be subject to sanctions or investigations by the Nasdaq, SEC or other regulatory authorities.

Risks Related to the Development of Our Product Candidates

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

Our lead product candidate, cilta-cel, is in clinical development for the treatment of MM. 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 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 120 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. In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including NHL, AML and TCL, of which the first two are currently in investigator-initiated Phase 1 clinical trials in China. We are also developing 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 NMPA, the 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 our 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. We do not currently have any approved or commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to reengineer or abandon a particular product candidate. Because CAR-T cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

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

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

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

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, only 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 if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR-T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

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

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

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

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

- disagreement with the design, protocol or conduct of our clinical trials;

- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes of our facilities;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

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

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

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

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

A key element of our strategy is to use our expertise in tumor biology and cell programming and our proprietary and modular CAR-T cell programming technologies to develop what we believe are safer and more effective CAR-T cell therapies. Our initial focus is on the development of a pipeline of product candidates for the treatment of hematological cancers and the progression of these product candidates through clinical development. We also intend to develop follow-on, or next-generation, product candidates with additional elements of programming built into the programmed CAR-T cell product candidate to offer enhanced characteristics as compared to the earlier product generation, as well as developing additional cell therapy product candidates. However, we may not be able to develop product candidates that are safe and effective, or which compare favorably with other commercially available alternatives. Even if we are successful in continuing to build our pipeline and

developing next-generation product candidates or expanding into solid tumor indications, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, lack of anti-tumor activity, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

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

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

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

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

Some of our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications in the United States and clinical trial applications, or CTAs, in China and the European

Union. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities allowing clinical trials to begin.

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

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

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

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

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

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

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

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

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

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

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

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

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

Accordingly, there is risk to part of our strategy to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China that the NMPA may refuse to consider the data from the investigator-

initiated clinical trials of our product candidates due to concerns that (1) this does not follow the mainstream regulatory pathway of relying on registrational clinical trial, or that (2) the non-registrational clinical trials of our product candidates may not otherwise fully comply with the same requirements applicable to registrational clinical trials, as further explained below.

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

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

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

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

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

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, in our planned Phase 1 clinical trial for LB1901, we will seek to enroll patients with relapsed or refractory TCL, a rare and heterogeneous form of NHL. Even if we

obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenue without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

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

In clinical trials conducted by other companies involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures and speech impairment. Adverse events with the worst grades and attributed to CAR-T cells were severe and life threatening in some patients. The life threatening events were related to kidney dysfunction and neurotoxicity. Severe and life threatening toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three weeks, but several patients died in clinical trials involving CAR-T cells, including in our clinical trials. In 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 September 1, 2020, 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 fourteen deaths during the Phase 1b/2 CARTITUDE-1 trial: five due to disease progression, three due to unrelated adverse events, including two cases of acute myelogenous leukemia and one case of pneumonia, and six due to related adverse events, including sepsis and/or septic shock in two patients, CRS/HLH in one patient, neurotoxicity in one patient, respiratory failure in one patient and lung abscess in one patient.

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

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

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;

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

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

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

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

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

- the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit eligible patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, such as cytokine-induced toxicity and T cell aplasia, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA, the NMPA, the EMA, the PMDA or regulatory authorities in other countries or jurisdictions to approve 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.

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

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

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

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 developing our own manufacturing capability. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

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

We believe that our current, robust manufacturing processes are fit for commercial scale and we anticipate they will enable commercial supply at an economical cost. However, we have not yet established manufacturing capacity at sufficient commercial scale and may underestimate the cost and time required to do so, or overestimate

cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our product candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those product candidates are commercialized.

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

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

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

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

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

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

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

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

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

Patients with hematological cancers typically receive highly toxic chemotherapy as their initial treatments that can impact the viability of the T cells collected from the patient and may contribute to highly variable responses to CAR-T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed CAR-T cell product candidate and thereby these patients may have cancer cells with low or no expression of the target. As a result, our CAR-T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. Our lead product candidate, cilta-cel, may face this challenge. For example, MM patients could have received a BCMA-targeting antibody drug conjugate BCMA-ADC like GSK2857916, BCMA targeting T cell engagers like AMG-420 (Amgen) and CC-93269 (Bristol-Myers Squibb), or similar products or product candidates prior to receiving 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 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, 2020, we had approximately 882 full-time employees. As our development and commercialization plans and strategies to expand and develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel

to support our product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

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

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

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

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

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

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

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

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

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

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

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

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

Our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants may be vulnerable to a variety of disruptive elements, including cyber-attacks by malicious third parties (including the deployment of computer viruses, harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or a loss of, or damage to, our data or applications, or those of our third-party vendors and other collaborators, contractors and

consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed. In addition, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party vendors and other collaborators, contractors and consultants become subject to disruptions or security breaches, we may be exposed to material liability and have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

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

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

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 foreign 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. Drafts of some of these measures have now been published, including the draft rules on cross-border transfers published by the Cyberspace Administration of China in 2017, which may, upon enactment, require security review before transferring human health-related data out of China. 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 foreign 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. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

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

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

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR- like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and can include any of our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a

result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

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

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

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

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

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

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

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;

- interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether. 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.

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

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

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, which could require us to restate our operating results or result in our auditors issuing a qualified audit report. In order to maintain effective disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Developing, implementing and testing changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or

regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on the Nasdaq.

We 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 material breach of agreement and unforeseen material safety event. If the Janssen Agreement were to be terminated, we could encounter significant delays in 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.

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, and as of December 31, 2020, we have received four milestone payments from Janssen totaling $110.0 million. Janssen may not execute its obligations as planned or may refuse to honor their commitments under the Janssen Agreement. The non-performance of Janssen, early termination of the Janssen Agreement, or our inability to find new or replacement partners may negatively impact our revenue and research and development activities and funding therefor. Should any of these risks materialize, this would have an adverse effect on our business, prospects, financial condition and results of operations.

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

We have received and expect to continue to receive payments from Janssen when we satisfy certain pre-specified milestones in the Janssen Agreement. We currently depend to a large degree on these milestone payments from Janssen in order to fund our operations. We may enter into new collaboration agreements that also provide for milestone payments. The milestone payments in the Janssen Agreement are generally dependent on the accomplishment of various clinical, regulatory, sales and other product development objectives. The successful or timely achievement of many of these milestones is outside of our control, in part because some of these activities are being or will be conducted by Janssen. If we or Janssen fail to achieve the applicable milestones, we will not receive such milestone payments. A failure to receive any such milestone payment may cause us to:

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

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

We rely on Genscript to provide various services.

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

If Genscript fails to perform its obligations in accordance with the terms of these agreements, it could be difficult for us to operate our business, including compliance with SEC reporting requirements. Any failure by Genscript to effectively manage the services that they provide to us could harm our business, financial condition and results of operations. In addition, the termination of our relationships with Genscript could make it difficult for us to

operate our business. For instance, Genscript may terminate our human resources services agreement with them with one-month written notice.

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

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

We have entered into and may seek to enter into additional collaborations or partnerships with third parties for the development and potential commercialization of our product candidates. Should we seek to collaborate with a third party with respect to a prospective development program, we may not be able to locate a suitable partner or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing partners for the development and commercialization of our product candidates, such as the arrangement we have entered into related to the development and commercialization of 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 a product candidate.

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

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

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

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

In order to market and sell our products in China, the European Union, Japan and any other international jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval 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 candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

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

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a REMS program or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements of the FDA, the NMPA, the EMA, the PMDA and other regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP and other comparable regulations and standards, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We or our suppliers could be subject to periodic unannounced inspections by the FDA, the NMPA, the EMA, the PMDA or other regulatory authorities to monitor and ensure compliance with cGMP.

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

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

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

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

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

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement of profits, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, or other government supported healthcare in other jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable healthcare laws, including, without limitation, the U.S.

federal Anti-Kickback Statute and the U.S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and privacy and security regulation by the U.S. federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, 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 new 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 also contains 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 HIPPA 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 will 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 recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

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

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

There has been heightened governmental scrutiny in the United States, China, the European Union, Japan and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congressional leadership 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 the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we obtain marketing approval. For a detailed discussion of healthcare reform initiatives of importance to the pharmaceutical industry, see “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 eliminates the health insurer tax.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. In March 2020, the Supreme Court granted a writ of certiorari and agreed to review the judgement of the federal appeals court. Oral argument was held in the case in November 2020, and a decision is expected by the time the current Supreme Court term ends in June of 2021. Pending action by the Supreme Court and any remand of the action to a court below or further litigation that may follow, which could take an extended period of time, the ACA remains operational. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

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 from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. While the Consolidated Appropriations Act of 2021 extended the suspension through March 31, 2021, the American Rescue Plan Act of 2021 (ARPA) did not include any additional extensions, 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. 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. At the federal level, the Trump administration’s budget proposal for fiscal year 2021 included a $135 billion allowance over 10 years to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of drugs that contained additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and, at the same time, has implemented others under its existing authority. The FDA also 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. 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. In

response, the government agreed to delay the effective date and evaluate the rule adopted by the previous administration. In the interim, the status quo has been restored. The likelihood of implementation of, or willingness to defend, any of the other Trump administration reform initiatives is uncertain, particularly in light of the recent transition to the Biden administration. 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, particularly as a result of the recent presidential election. 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 the Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

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

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- hospitals and cancer treatment centers establishing the infrastructure required for the administration of redirected CAR-T cell therapies;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the effectiveness of launch preparation activities;

- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

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

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

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

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

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

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The

position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

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

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

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

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

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

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

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

Risks Related to Our Intellectual Property

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

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

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

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

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our

patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, recent changes in patent laws in the United States, may affect the scope, strength, validity and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

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

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

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

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

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

Third parties, including our competitors, may allege that our product candidates, including 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

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 Standing Committee of the NPC 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 will not pursue criminal or civil remedies against us 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 have 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. 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, 2020, (i) Dr. Zhang owns 18.4% of the issued and outstanding ordinary shares of Genscript, (ii) Genscript, in turn, beneficially owns 63.9% of our ordinary shares, and (iii) two out of six 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 foreign exchange, and a less efficient allocation of resources.

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

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

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

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

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

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in China against us or our management named in the Annual Report based on foreign laws. It may also be difficult for overseas regulators 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 overseas regulators 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 overseas securities regulator 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 overseas parties. While detailed interpretation of or implementing rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator 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 Measures for the Management of Scientific Data, or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded, at least in part, by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Currently, as the term “state secret” is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

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

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

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

and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside the PRC with "de facto management body" within the PRC is considered a "resident enterprise" and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, SAT issued a circular, known as SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China.

Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having

its “de facto management body” in China and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in the PRC.

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

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

Fluctuation in exchange rates could have a negative effect on our results of operations.

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 overseas and cross-border investment activity. If our PRC resident and enterprise shareholders fail to make any required applications and filings under such regulations, we may be unable to distribute profits to such shareholders and may become subject to liability under PRC law.

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

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

We may not be aware of the identities of all of our beneficial owners who are PRC residents. To our knowledge, some of our beneficial owners have not complied with SAFE registration requirements under SAFE Circular 37 and subsequent implementation rules on time or at all, sometimes due to reasons beyond their control. However, we do not have control over our beneficial owners and cannot compel them to comply with SAFE Circular 37 and subsequent implementation rules. Therefore, we cannot assure you that any required registration under SAFE Circular 37 and any amendment will be completed in a timely manner, or at all. The failure of our beneficial owners who are PRC residents to register or amend their foreign exchange registrations pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future beneficial owners of our company who are PRC residents to comply with the registration procedures set forth in SAFE Circular 37 and subsequent

implementation rules, may subject such beneficial owners or our PRC subsidiary to fines and legal sanctions. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiary and limit our PRC subsidiary's ability to distribute dividends to us.

These risks may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

We may also decide to finance our PRC subsidiary by means of capital contributions. According to the relevant PRC regulations on foreign-invested enterprises in China, these capital contributions are subject to registration with State Administration for Market Regulation or its local counterparts. In addition, the PRC government also restricts the convertibility of foreign currencies into RMB and use of the proceeds. On March 30, 2015, SAFE promulgated the Notice on Reforming the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or SAFE Circular 19, which took effect and replaced certain previous SAFE regulations from June 1, 2015. SAFE further promulgated the Circular on Reforming and Regulating Policies on the Management of Foreign Exchange Settlement of Capital Accounts, or SAFE Circular 16, effective on June 9, 2016, which, among other things, amends certain provisions of SAFE Circular 19. According to SAFE Circular 19 and SAFE Circular 16, the flow and use of the RMB capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope. Violations of the applicable circulars and rules may result in severe penalties, including substantial fines as set forth in the Foreign Exchange Administration Regulations. These circulars may limit our ability and speed to transfer 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 requirements for employee stock ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

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

Prior approval from the China Securities Regulatory Commission may be required for the listing and trading of our ADSs on Nasdaq.

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

However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel. If it is determined that the CSRC approval was required for our initial public offering, we may face sanctions by the CSRC or other PRC regulatory agencies for failure to seek the CSRC approval for that offering. These sanctions may include fines and penalties on our operations in the PRC although, to our knowledge, no definitive rules or interpretations have been issued to determine or quantify such fines or penalties, delays or restrictions on the repatriation of the proceeds from securities offerings into the PRC, restrictions on or prohibition of the payments or remittance of dividends by our PRC subsidiary, or other actions that may have a material adverse effect on our business and the trading price of the ADSs.

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

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

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

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises, issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors involved in "an industry related to national security" are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. 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 an overseas holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such Indirect Transfer to the relevant tax authority. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer other than transfer of shares of ADSs acquired and sold on public markets may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes.

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

The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, our investors are deprived of the benefits of such inspection. In addition, various legislative and regulatory developments related to U.S.-listed China-based companies due to lack of Public Company Accounting Oversight Board inspection and other developments due to political tensions between the United States and China may have a material adverse impact on our listing and trading in the U.S. and the trading prices of our ADSs.

Our independent registered public accounting firm that issues the audit report included in this Annual Report, as auditors of companies that are traded publicly in the United States and a firm registered with the PCAOB is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Because our auditors are located in the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditors are not currently inspected by the PCAOB. On December 7, 2018, the SEC and the PCAOB issued a joint statement highlighting continued challenges faced by the U.S. regulators in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. The joint statement reflects a heightened interest in this issue that U.S. regulators have focused on in recent years. On April 21, 2020, SEC Chairman Jay Clayton and PCAOB Chairman William D. Duhnke III, along with other senior SEC staff, released a joint statement highlighting the risks associated with investing in companies that are based in or have substantial operations in emerging markets, including China, reiterating past SEC and PCAOB statements on matters including the difficulty associated with inspecting accounting firms and audit work papers in China, higher risks of fraud in emerging markets and the difficulty of bringing and enforcing SEC, DOJ and other U.S. regulatory actions, including in instances of fraud, in emerging markets generally. However, it remains unclear whether the SEC and PCAOB will take any further actions to address the issue.

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

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

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which, if passed, would require the SEC to maintain a list of issuers for which the PCAOB is not able to inspect or investigate an auditor report issued by a foreign public accounting firm. On May 20, 2020, the U.S. Senate approved the Holding Foreign Companies Accountable Act, or the HFCA Act, and the HFCA Act was approved by the U.S. House of Representatives on December 2, 2020. It will be presented to the president of the United States for signing into law within the same month. The HFCA Act includes requirements for the SEC to identify issuers whose audit reports are prepared by auditors that the PCAOB is unable to inspect or investigate because of restrictions imposed by non-U.S. authorities. The HFCA Act would also require public companies on this SEC list to certify that they are not owned or controlled by a foreign government and make certain additional disclosures in their SEC filings. In addition, for issuers on the SEC list for three consecutive years, the SEC would be required to prohibit the securities of these companies from being traded on a U.S. national securities exchange, such as The Nasdaq Global Select Market, or in U.S. over-the-counter markets. Both pieces of proposed legislation would require issuers on the SEC list to make certain disclosures on foreign ownership and control of the issuer. Enactment of one or more of these bills or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of the ADSs could be adversely affected. In addition, enactment of these legislations may result in prohibitions on the trading of the ADSs on The Nasdaq Global Select Market or other U.S. exchange if our auditors fail to be inspected by the PCAOB for three consecutive years. It is unclear if these proposed legislations would be enacted. Furthermore, there has been recent media reports on deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. If any such deliberations were to materialize, the resulting legislation may have material and adverse impact on our stock performance and we could be delisted if we are unable to meet the PCAOB inspection requirement in time.

If additional remedial measures are imposed on the "big four" PRC-based accounting firms, including our independent registered public accounting firm, in administrative proceedings brought by the SEC alleging such firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, we could fail to timely file future financial statements in compliance with the requirements of the Securities Exchange Act of 1934, as amended.

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

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

against all four "big four" accounting firms. The audit committee is aware of the policy restriction and regularly communicated with our independent auditor to ensure compliance. If additional remedial measures are imposed on the China-based "big four" accounting firms, including our independent registered public accounting firm, in administrative proceedings brought by the SEC alleging the firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act. The settlement did not require the firms to admit to any violation of law and preserves the firms' legal defenses in the event the administrative proceeding is restarted.

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delisting of our ordinary shares from the Nasdaq Global Select Market or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of our ADSs in the U.S.

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

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

The latest version of the "negative list," namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2020), which became effective on July 23, 2020, provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies.

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. As of the date of this Annual Report, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" and the application of this regulation remains unclear. Legend Nanjing is engaged in the research and development of CAR-T cell therapies. We believe the CAR-T cell therapies, as they are currently being researched and developed by Legend Nanjing, do not involve the use of human stem cells or genetic diagnosis and treatment, and as such should not fall into the category of "human stem cell or gene diagnostic and therapeutic technologies." Moreover, relevant governmental authorities also confirmed the research and development of CAR-T cell therapies currently engaged in by Legend Nanjing complies with the requirements of foreign investment industrial policies. We have been advised by our PRC legal counsel, JunHe LLP, that Legend Nanjing has complied with PRC laws and regulations in all material respects for, and obtained all material governmental approvals and permits from PRC regulatory agencies for, the research and development of CAR-T cell therapies. However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to our view and the opinion of our PRC legal counsel above. If our CAR-T cell therapies or other technologies that are being researched and developed by Legend Nanjing are deemed by relevant PRC regulatory agencies as falling into the category of "human stem cell or gene diagnostic and therapeutic technologies," Legend Nanjing would be prohibited from engaging in the research or development of such technologies. In that event, we may have to stop investing in Legend Nanjing or consider restructuring Legend Nanjing as a PRC domestic entity and our variable interest entity. Legend Nanjing may also have to forfeit its income derived from the research and development of such technologies. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

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

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

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

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

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

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

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, 2021, 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 are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our ADSs may be less attractive to investors.

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

We qualify as a foreign private issuer and, as a result, we 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, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to the holders of our ADSs or ordinary shares.

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 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 one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

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.

We do not anticipate paying any cash dividends in the foreseeable future.

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 are not likely to receive dividends for the foreseeable future. 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. 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 rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our 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, 2020. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. 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, 2020, 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 have classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

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

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

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

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property

development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

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. 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, 2020, 2019 and 2018 amounted to $52.6, $46.8 and $27.1, respectively. These expenditures primarily consisted of property, plant and equipment and intangible 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 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 800 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.

In December 2019, we reported updated data from a Phase 1 clinical trial of LCAR-B38M CAR-T cells in China, in 74 patients with RRMM across four independent sites. Patients treated with LCAR-B38M CAR-T cells had 25 to 26 months of median follow-up and achieved an overall response rate, or ORR, of 88 percent, with a complete response, or CR, rate ranging from 74 to 82 percent, depending on the site. In the largest site of 57 patients, median overall survival, or mOS, was 36.1 months as of July 31, 2019.

The Phase 1b/2 registrational trial of cilta-cel in RRMM patients in the United States and Japan, which we refer to as CARTITUDE-1, has completed enrollment. In the United States, 97 patients were treated with cilta-cel in the combined Phase 1b/2 CARTITUDE-1 trial. As of September 1, 2020, the primary endpoint of ORR was achieved in 97 percent of patients which included stringent complete response, or sCR, rate of 67 percent, very good partial response rate, or VGPR, of 26 percent (VGPR or better, 93 percent) and partial response rate of 4 percent. Median time to first response was 1 month (range, 0.9-8.5) and responses were ongoing in 72 percent of patients. The median progression-free survival, or PFS, was not reached at median follow-up of 12.4 months (range, 1.5-24.9). The 12-month PFS and overall survival, or OS, rates were 77 percent (95% confidence interval (CI), 66-84) and 89 percent (95% CI, 80-94), respectively.

Cilta-cel has been granted breakthrough therapy designation by the U.S. Food and Drug Administration, or FDA, Priority Medicines, or PRIME, designation, enabling accelerated assessment, by the European Medicines Agency, or EMA, and breakthrough therapy designation by China Center for Drug Evaluation, or CDE. In January 2021, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA has accepted a request for an

accelerated assessment of the marketing authorization application, or MAA. We anticipate submitting for cilta-cel for the treatment of RRMM. 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. Rolling submission of the cilta-cel BLA to the FDA has been initiated in December 2020 and we anticipate a MAA, to be submitted to the EMA in the first half of 2021 for the treatment of RRMM.

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

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

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

Our lead product candidate, 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. We are developing cilta-cel as a potentially improved therapy for MM. MM is a highly aggressive disease representing approximately 10 percent of all hematologic malignancies and 20 percent of deaths of hematologic malignancies worldwide. In 2020, the American Cancer Society projects that 32,270 new cases of MM and 12,830 deaths will occur in the United States. Worldwide, there were an estimated 159,985 new cases of MM in 2018. Existing therapies include monoclonal antibodies, proteasome inhibitors and immunomodulatory agents, which generated aggregate sales of approximately $18 billion in 2018. Nevertheless, MM remains incurable and patients eventually relapse and become refractory to treatment. For example, mOS in patients who have received at least three prior lines of therapy and are refractory to both an immunomodulatory drug and a proteasome inhibitor is only 13 months. The reported ORR for approved therapies for the population of heavily pre-treated and refractory patients with MM is 30% or less. Therefore, we believe there is a high unmet need for a therapy that provides an improved efficacy profile for a prolonged period of time.

We believe that 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 have completed enrolling patients in a Phase 2 registrational trial of cilta-cel in RRMM patients in China, which we refer to as CARTIFAN-1, and conducting CARTITUDE-1 Phase 1b/2 registrational trial of cilta-cel in RRMM patients in the United States and Japan.

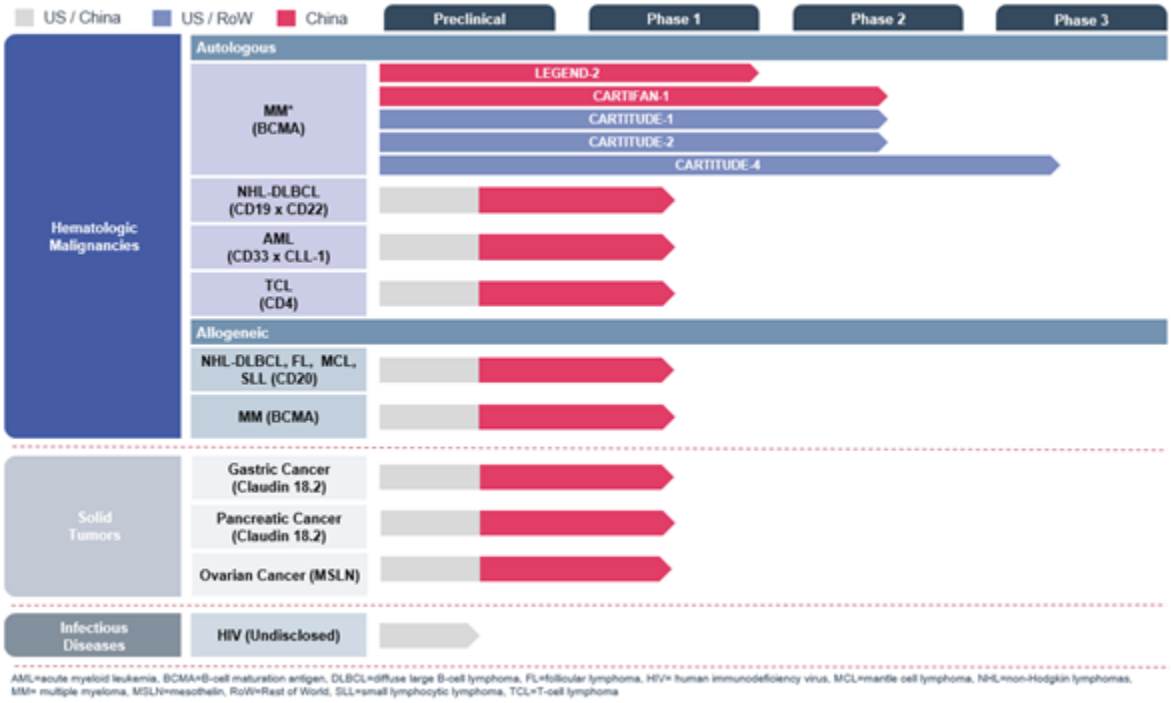
Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b and Phase 2 portions of the trial, the rolling submission of the cilta-cel BLA to the FDA has been initiated in December 2020 and

we anticipate a MAA to be submitted to the EMA in the first half of 2021. We also intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China, which we expect to submit in the second half of 2021, and the data from CARTITUDE-1 in support of a regulatory submission for approval in Japan, which we expect to be submitted in the second half of 2021.

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 120 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, 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.

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, and as of December 31, 2020, we have received four milestone payments totaling $110.0 million.

In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous product candidates targeting various cancers, including Non-Hodgkins Lymphoma, or NHL, Acute Myeloid Leukemia, or AML, and T cell Lymphoma, or TCL, 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 the treatment of MM, which are currently in investigator-initiated Phase 1 clinical trials in China. Allogeneic cells are cells from a donor. Furthermore, we have several product candidates in early preclinical and clinical development for the treatment of solid tumors as well as infectious diseases. Our pipeline of product candidates is summarized in the table below.



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

* In collaboration with Janssen, Pharmaceutical Companies of Johnson & Johnson

We are led by Ying Huang, Ph.D., our Chief Executive Officer and Chief Financial Officer, 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. Based on the results of CARTITUDE-1, a rolling submission of a BLA to the FDA has been initiated for cilta-cel for the treatment of RRMM in December 2020. 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 submissions for approval in the major markets of the United States, Europe, China and Japan. We also intend to establish a global commercial team to support all aspects of our product sales including market access, healthcare provider education, hospital certification, reimbursement, manufacturing and patient and provider support.
- **Expand our manufacturing capabilities.** We currently have manufacturing facilities in China and the United States supplying clinical materials for our trials. As we prepare to potentially commercialize our products, we intend to further expand the commercial-scale manufacturing capacities at these facilities

and establish a manufacturing facility in Europe. We expect these facilities will enable rapid scale-up capabilities and provide product supply at both a regional and global scale.

- **Establish ourselves as a preferred global partner.** Our global network and strategy facilitates accelerated clinical proof-of-concept for pipeline candidates. Further, through our strong presence in China, deep relationships with Chinese key opinion leaders, health policy experts, leading healthcare institutions, local world-class manufacturing and strong understanding of and experience with Chinese regulations, we are well positioned to be the partner of choice to help foreign companies navigate the lucrative yet complex Chinese market. We believe our global collaboration with Janssen, for the development and potential commercialization of 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 300 researchers who identify potential cellular targets and create and assess a broad portfolio of product candidates. Establishing this expertise has attracted the leading investigators and partners within China.

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 selecting a European site and facility for future supply for Europe.

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

Our Programs

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. As of September 1, 2020, the primary endpoint of ORR was achieved in 97 percent of patients which included sCR rate of 67 percent, VGPR of 26 percent (VGPR or better, 93 percent) and partial response rate of 4 percent. The median time to first response was 1 month (range, 0.9-8.5) and responses were ongoing in 72 percent (n=70) of patients. The median PFS was not reached at median follow-up of 12.4 months (range, 1.5-24.9). The 12-month PFS and OS rates of 77 percent (95% CI, 66-84) and 89 percent (95% CI, 80-94), respectively. The most common hematologic adverse events were neutropenia (96 percent; Grade 3/4 95 percent); anemia (81 percent; Grade 3/4 68 percent); thrombocytopenia (79 percent; Grade 3/4 60 percent); leukopenia (62 percent; Grade 3/4 61 percent); and lymphopenia (53 percent; Grade 3/4 50 percent). CRS of any grade was observed in 95 percent of patients, of which 95 percent were Grade 1/2, 3 percent were Grade 3, 1 percent was Grade 4 and 1 percent was Grade 5. Neurotoxicity of any grade was observed in 21 percent of patients, with Grade 3 or higher neurotoxicity observed in 10 percent of patients. Fourteen deaths were reported during the trial: five due to disease progression, three due to unrelated adverse events, including two cases of acute myelogenous leukemia and one case of pneumonia, and six due to related adverse events, including sepsis and/or septic shock in two patients, CRS/HLH in one patient, neurotoxicity in one patient, respiratory failure in one patient and lung abscess in one patient.

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. We anticipate submitting for cilta-cel for the treatment of RRMM. 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. Rolling submission of the cilta-cel BLA to the FDA has been initiated in December 2020 and we anticipate a MAA to be submitted to the EMA in the first half of 2021 for the treatment of RRMM.

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. Based on the results of CARTITUDE-1, including the efficacy observations from the Phase 1b/ 2portions of the trial, the rolling submission of the cilta-cel BLA to the FDA has been initiated in December 2020 and we anticipate a marketing authorization application to be submitted to the EMA in the first half of 2021. We also intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China, which we expect to submit in the second half of 2021, and the data from CARTITUDE-1 in support of a regulatory submission in Japan in 2021.

In 2017, we entered into a global collaboration with Janssen for 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, and as of December 31, 2020, we have received four milestone payments totaling $110.0 million.

Background on Multiple Myeloma

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

Most people in the United States who are diagnosed with MM are 65 years old or older, with less than one percent of cases diagnosed in people younger than 35 years old. With currently available treatments, MM has a five-year survival rate of approximately 52 percent. Treatment choices for MM vary with the aggressiveness of the disease and overall health of the patients.

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

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

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

BCMA

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

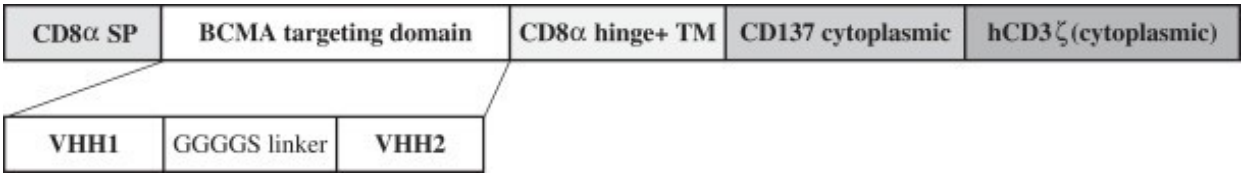
Tissue distribution of BCMA, as determined using quantitative analysis of transcription levels, show that BCMA is generally expressed only in lymphoid cells and not in other tissues in the body. The expression level of BCMA in plasmacytomas, or MM tumors, is hundreds to thousands of times higher than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

Published details of a third-party trial conducted by leading researchers at the U.S. National Institutes of Health report that treatment with anti-BCMA CAR-T cells yielded an ORR of 58 percent in a series of 24 RRMM patients and an ORR of 81 percent in a subset of 16 patients receiving the highest dose of 9 x 10^6 CAR-T cells/kg. These results provide preliminary evidence for the role that anti-BCMA CAR-T cells may play in the treatment of RRMM. We believe that there are opportunities to build upon these initial results in the development of next-generation CAR-T cell therapies.

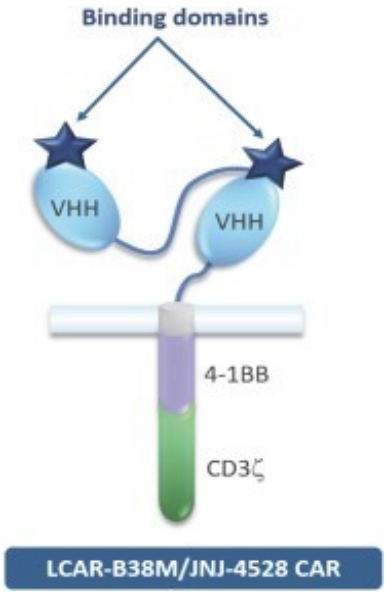
Our Solution, Cilta-cel

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

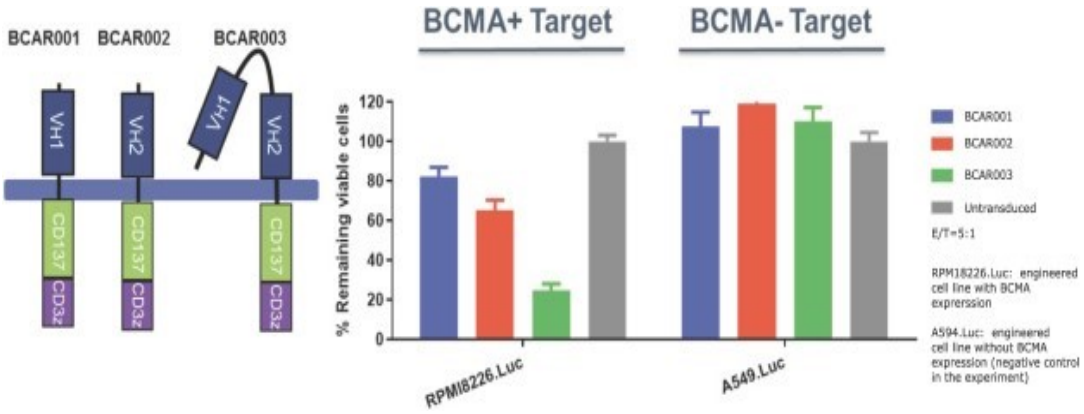
We believe cilta-cel has the potential to provide benefits to MM patients through the following mechanisms of action:

- 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)

In October 2015, an investigator-initiated Phase 1 trial of LCAR-B38M CAR-T cells was initiated at four independent sites in China, enrolling a total of 74 patients with RRMM. We reported updated data from the trial in December 2019 at the American Society of Hematology conference. The primary endpoint of the trial was the occurrence of treatment-related adverse events and the secondary endpoint was anti-myeloma responses to LCAR-B38M CAR-T cell treatment. Patients in the trial had failed a median of three prior lines of therapy, in the Xi'an site and a median of four prior lines of therapy, in the remaining three sites. The actual treatment protocol varied between sites, providing us with the opportunity to explore multiple treatment protocols within a single trial. The trial protocol was standardized to the extent possible across sites; however, some variation in methodologies may have occurred due to the flexible nature of this proof-of-concept, first-in-human study.

Patients in the trial were preconditioned with either cyclophosphamide, or cy, alone, or cy and fludarabine, or flu, together, which is a standard lymphodepletion, or reduction in the number of the patient's lymphocytes, regimen. The safety and efficacy results presented are based on uniform medical reviews of source hospital medical records by the investigators for all treated patients.

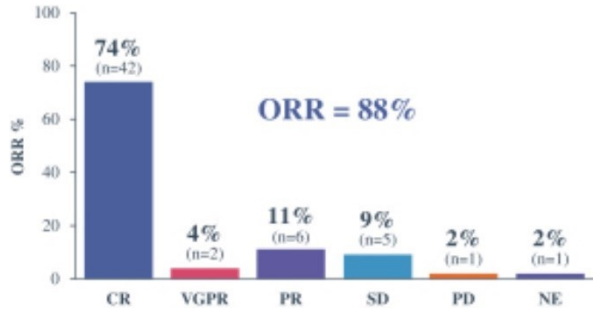
Clinical site	Number of patients	Preconditioning	LCAR-B38M infusion
Xi'an	57	Cy only	Split-dose
Changzheng	3	Cy + flu	Split-dose
Ruijin	5	Cy + flu	Split-dose
Jiangsu	9	Cy only	Single-dose

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

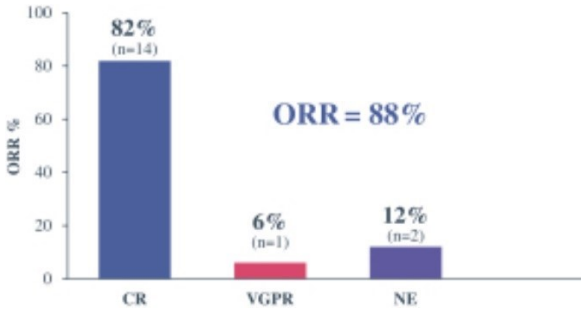
data on responses. The Ruijin, Jiangsu and Changzheng sites, which enrolled a total of 17 patients, have reported their data together in a separate analysis. Patients at the Xi'an site and the other three sites achieved an ORR and a CR rate shown below as of July 31, 2019 and October 31, 2019, respectively.

Efficacy results of the LEGEND-2 trial

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



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

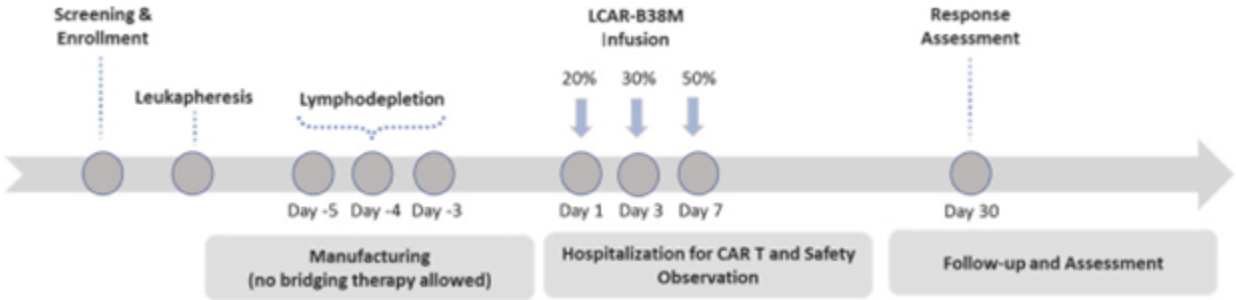


SD = stable disease
PD = progressive disease
NE = not evaluable

Patients at the Xi'an site had a median duration of response, or mDOR, of 27.0 months and, among the patients achieving a CR, the mDOR for CR was 29.1 months. The median time to achieving an initial response was one month at each of the four independent sites.

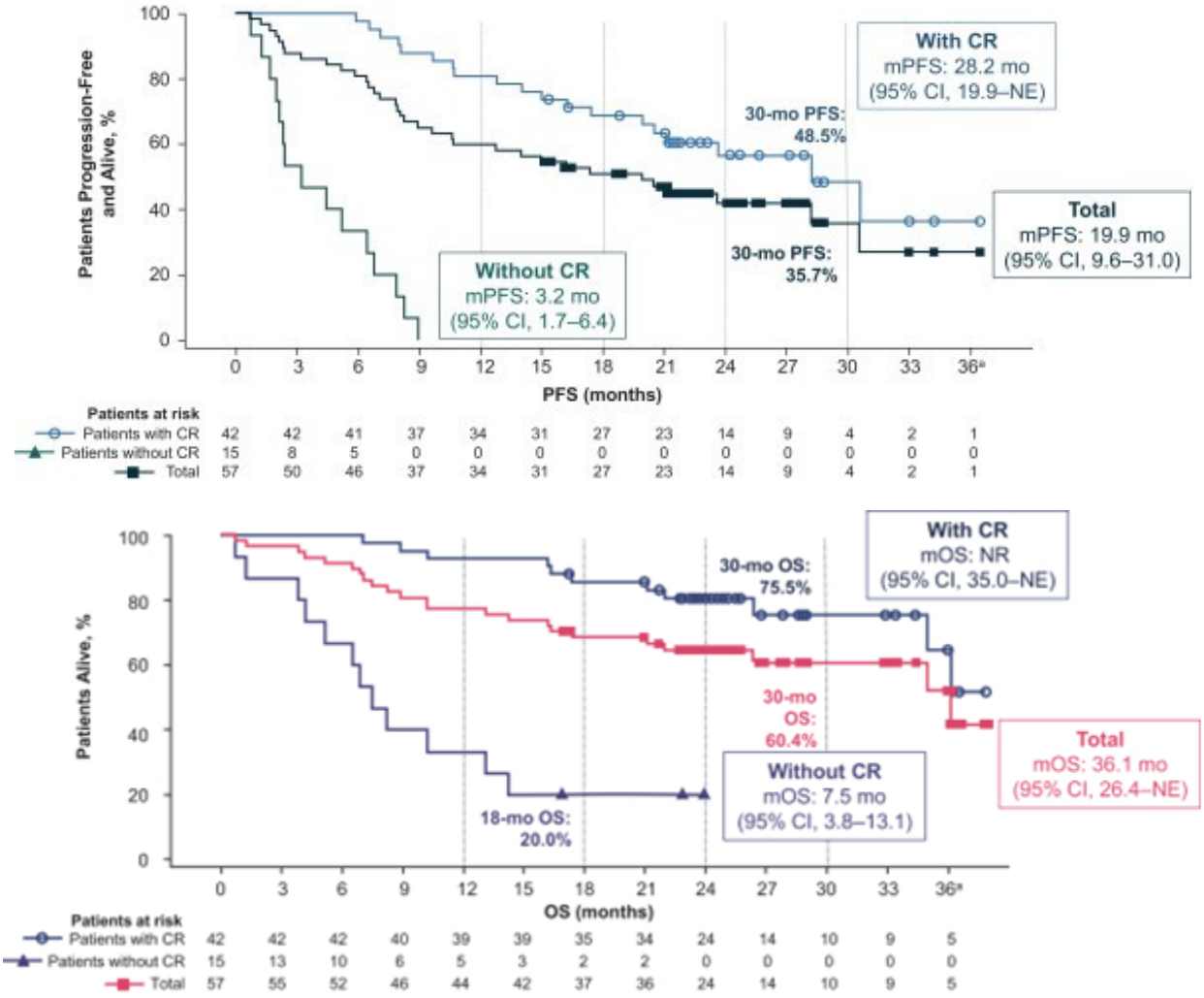
At the Xi'an site, all 57 patients treated had lymphodepletion three to five days before receiving LCAR-B38M CAR-T cells using cyclophosphamide alone. LCAR-B38M CAR-T cells were administered as three split infusions, as shown below, with the total number of CAR-T cells delivered to patients averaging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

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



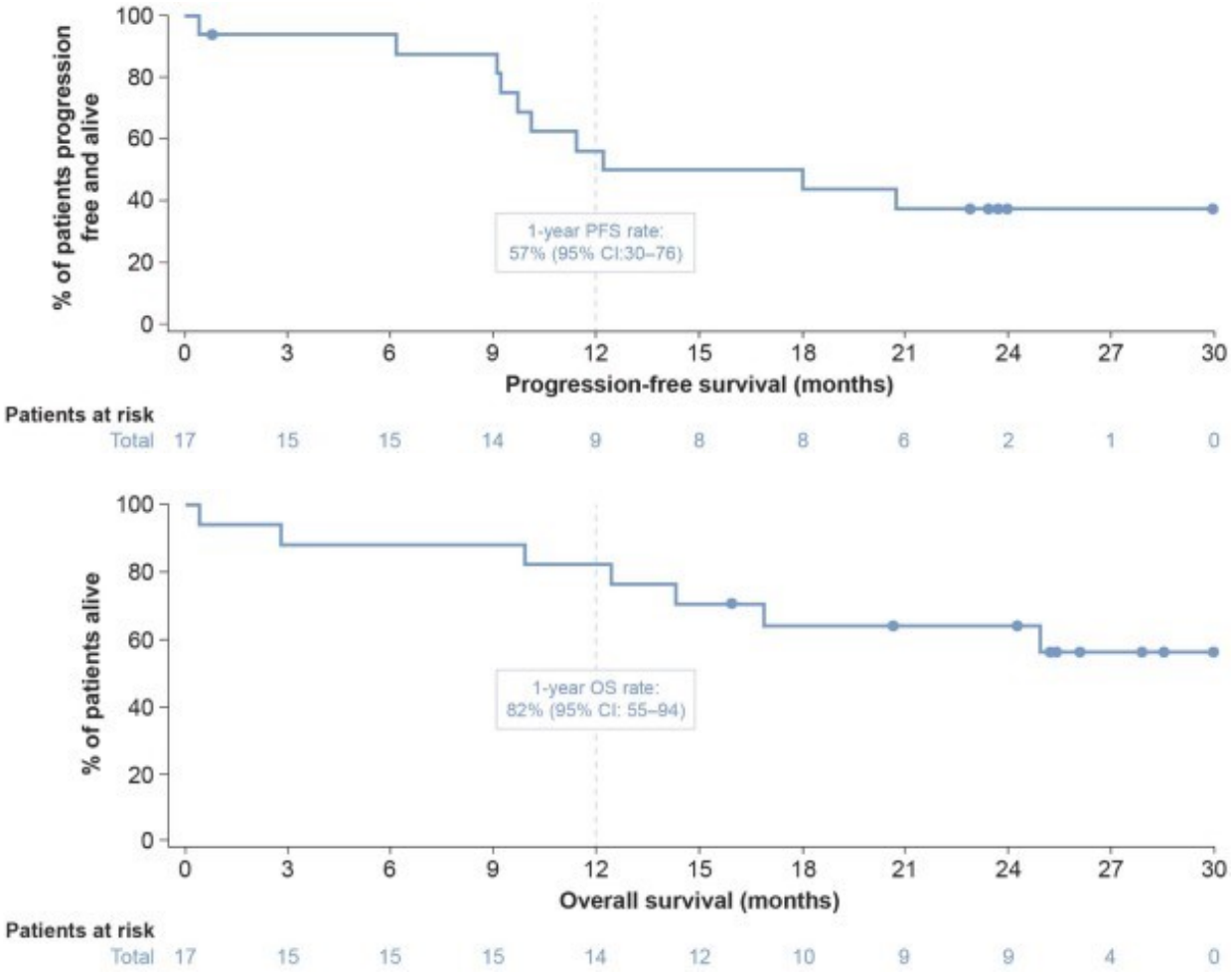
The overall survival of patients enrolled at the Xi'an site is shown in the chart below as of July 31, 2019. Patients from the Xi'an site who achieved a CR had a median progression free survival, or mPFS, of 28.2 months and an OS of 92.9 percent at 12 months and 75.5 percent at 30 months. Patients who did not achieve a CR had poorer survival with a mOS of 7.5 months.

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



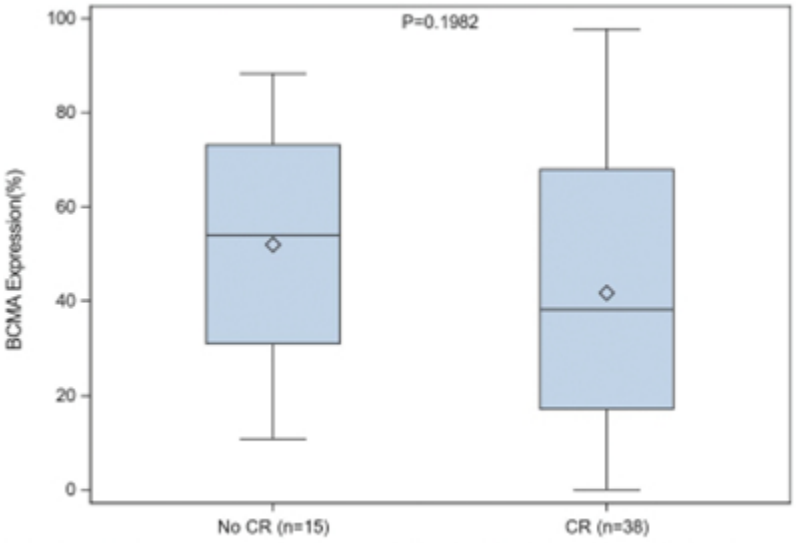
The 17 patients treated at the other three sites had similar outcomes, achieving an ORR of 88 percent and a CR rate of 82 percent as of October 31, 2019. The median progression free survival was 18 months and overall survival was 82 percent at 12 months and 64 percent at 24 months as of October 31, 2019.

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



There was no significant difference in response rates for patients treated at the Xi'an site based on the level of BCMA expressed by their tumors, as shown below.

Levels of BCMA expression did not correlate with clinical response in Xi'an site

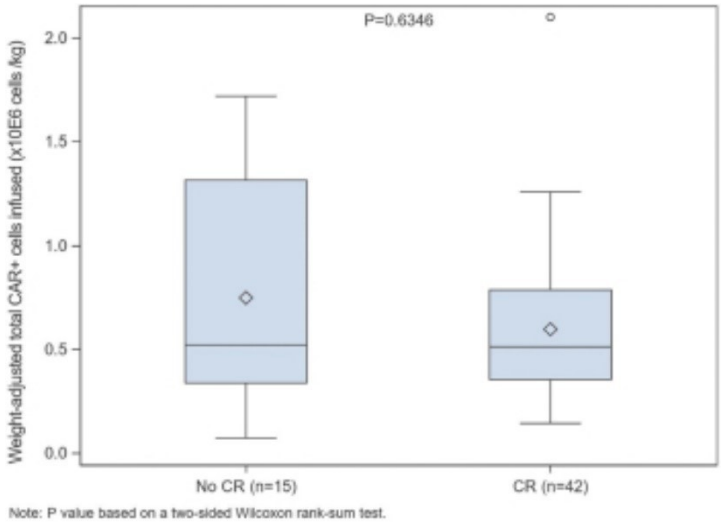


Note: Among 42 CR responders, 4 didn't have BCMA measurement. P value based on a two-sided Wilcoxon rank-sum test.

A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

There was also a lack of correlation between the number of CAR-T cells infused and response rates. In the LEGEND-2 trial, patients in Xi'an site received a median of 0.5 x 10^6 CAR+ viable T cells/kg (range 0.07 x 10^6 to 2.1x 10^6). In the other three sites combined, patients received a mean of 0.70 x 10^6 CAR+ viable T cells/kg. This response was achieved with a relatively low dose compared to other CAR-T product candidates in clinical trials.

No significant difference in response rate based on number of CAR-T cells infused



Note: P value based on a two-sided Wilcoxon rank-sum test.

Safety Results

As of July 31, 2019 for the Xi'an site and October 31, 2019 for the other three sites, adverse events were reported in all patients in LEGEND-2 with over 90 percent reporting fever and CRS. Over 82 percent of patients had Grade 1 or Grade 2 CRS which was managed with standard treatments such as administration of anti-IL-6R, vasopressor or oxygen therapy. In all but two cases CRS was resolved. In one case the patient died on day 13 as a result of CRS and tumor lysis syndrome, or TLS. This is an adverse event caused by rapid tumor lysis causing an accumulation of breakdown products such as uric acid, potassium and phosphorous in the blood, leading to the risk of multi-organ failure. A second patient, who was recovering from Grade 2 CRS, developed difficulty breathing and died at day 22 from a potential pulmonary embolism and acute coronary syndrome. In addition to CRS, thrombocytopenia and leukopenia were reported by 49 percent and 47 percent of patients, respectively.

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

	All grade		**Grade ≥3**	
	n=57	**n=17**	**n=57**	**n=17**
Hematologic AEs, n (%)				
Anemia	17(30)	—	10(18)	—
Thrombocytopenia	28(49)	—	13(23)	—
Leukopenia	27(47)	—	17(30)	—
Cytopenia	—	14(82)	—	10(59)
Tumor lysis syndrome	—	3(18)	—	0
CAR-T–associated AEs, n (%)				
CRS	51(90)	17(100)	4(7)	7(41)
Neurotoxicity	1(2)	0	0	0
Non-hematologic AEs, n (%)				
Pyrexia	52(91)	—	11(20)	—
Hypotension	12(21)		3(5)	—
Liver toxicity				
Elevated ALT	—	7(41)	—	0
Elevated AST	22(39)	16(94)	12(21)	5(29)
Elevated bilirubin	—	1(6)	—	1(6)

We have submitted data from the LEGEND-2 trial to the FDA and NMPA. While we do not intend to use the data from LEGEND-2 as direct evidence of efficacy or safety in our potential future regulatory approval submissions as LEGEND-2 was not a registrational trial, we may use the data from LEGEND-2 trial as indirect supportive evidence in future regulatory submissions. We anticipate receiving updated clinical data from investigators for the LEGEND-2 trial in 2021.

Ongoing Clinical Development

We obtained approval to conduct confirmatory clinical trial, CARTIFAN-1, through multiple centers in China in March 2018. Following the submission of an IND, which was cleared by the FDA in May 2018, we and Janssen are conducting the CARTITUDE-1, CARTITUDE-2 and CARTITUDE-4 trials.

CARTIFAN-1 (China)

We 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 intend to use the data from CARTIFAN-1 in support of a regulatory submission for approval in China in 2021.

CARTITUDE-1 (United States and Japan)

Together with Janssen, we 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 10^6 CAR+ viable T cells/kg (range 0.51 – 0.95 x 10^6). As of September 1, 2020, the primary endpoint of ORR was achieved in 97 percent of patients which included sCR rate of 67 percent, VGPR of 26 percent (VGPR or better, 93 percent) and partial response rate of 4 percent. Median time to first response was 1 month (range, 0.9-8.5) and responses were ongoing in 72 percent (n=70) of patients. The median PFS was not reached at median follow-up of 12.4 months (range, 1.5-24.9). The 12-month PFS and OS rates of 77 percent (95% CI, 66-84) and 89 percent (95% CI, 80-94), respectively.

Of 57 MRD evaluable patients, 93 percent were MRD negative at 10^{-5}. MRD refers to the presence and number of malignant B or T cells that may remain in a patient's body during and following treatment and can contribute to relapse and disease progression. MRD is measured by next-generation technologies and MRD negativity is defined as the absence of tumor plasma cells within bone marrow.

As of September 1, 2020, with a median follow-up of 12.4 months, the most common hematologic adverse events observed in the CARTITUDE-1 study were neutropenia (96 percent; Grade 3/4 95 percent); anemia (81 percent; Grade 3/4 68 percent); thrombocytopenia (79 percent; Grade 3/4 60 percent); leukopenia (62 percent; Grade 3/4 61 percent); and lymphopenia (53 percent; Grade 3/4 50 percent). CRS of any grade was observed in 95 percent of patients, with a median duration of four days (range, 1-97 days), and 99 percent of which resolved within 14 days of onset. Of the 92 patients with CRS, 95 percent were Grade 1/2, 3 percent were Grade 3, 1 percent was Grade 4 and 1 percent was Grade 5. The median onset of CRS was seven days (range, 1-12 days) post-infusion, with 89 percent of patients experiencing CRS onset at day four or later, which is supportive of potential outpatient administration for cilta-cel. 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. Of these, Immune effector Cell-Associated Neurotoxicity Syndrome, or ICANS, was observed in 16 patients and generally occurred concurrently with CRS; other neurotoxicities were observed in 12 patients and generally occurred after resolution of CRS and/or ICANS (eight patients experienced both ICANS and other neurotoxicities). ICANS events were resolved in all patients with a median time to recovery of four days (range, 1-12 days). Other neurotoxicities were resolved in six patients at a median time of 75 days (range, 2-160 days) and were not resolved in six patients (one with ongoing toxicity, one died from neurotoxicity and four died due to other causes). Fourteen deaths were reported during the trial: five due to disease progression, three due to unrelated adverse events, including two cases of acute myelogenous leukemia and one case of pneumonia, and six due to related adverse events, including sepsis and/or septic shock in two patients, CRS/HLH in one patient, neurotoxicity in one patient, respiratory failure in one patient and lung abscess in one patient.

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.

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 2020 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 2021. 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 has been initiated in December 2020 and we anticipate a marketing authorization application to be submitted to the EMA in

the first half of 2021. We also intend to use the data from CARTITUDE-1 in support of a regulatory submission for approval in Japan, which we expect to be submitted in the second half of 2021.

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

We and Janssen began enrolling patients in November 2019 in a 120-patient, 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 initially consists of five cohorts:

- 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

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 2021.

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.

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 expect to initiate 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.

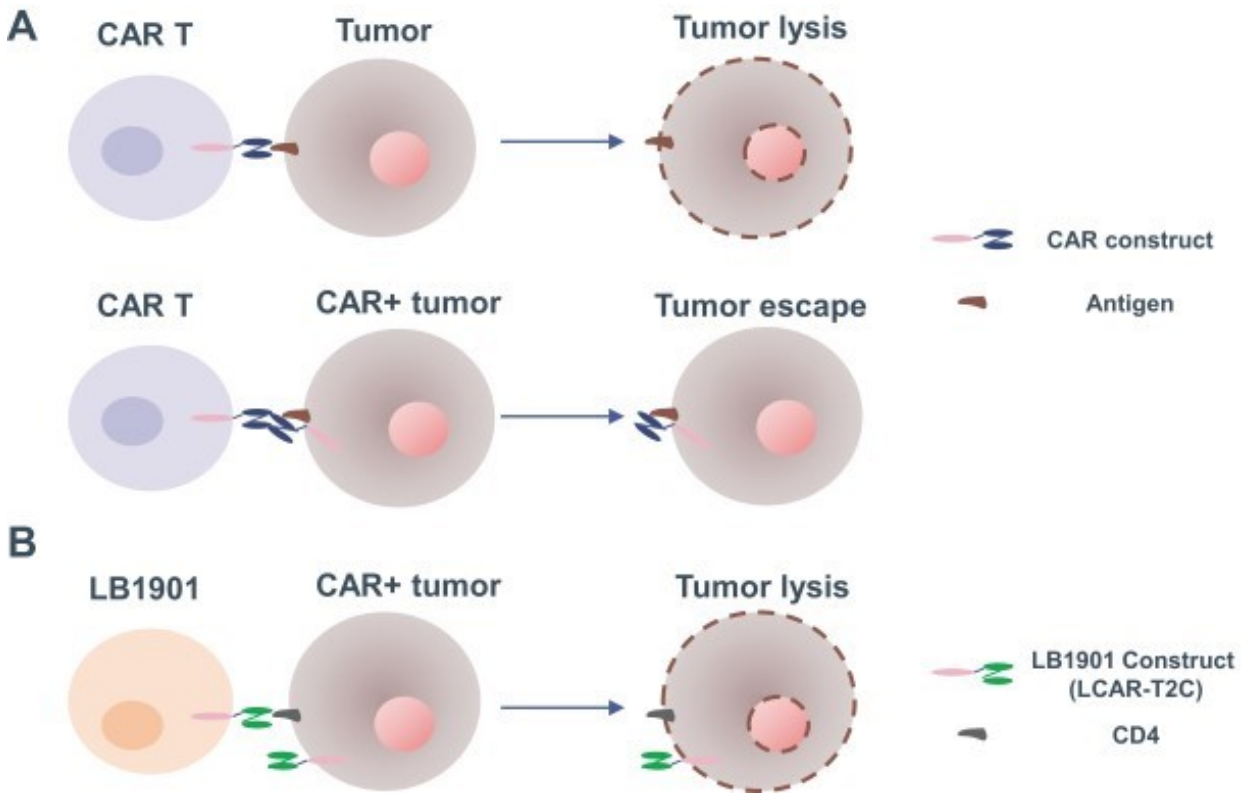
Our Solution: LB1901

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.

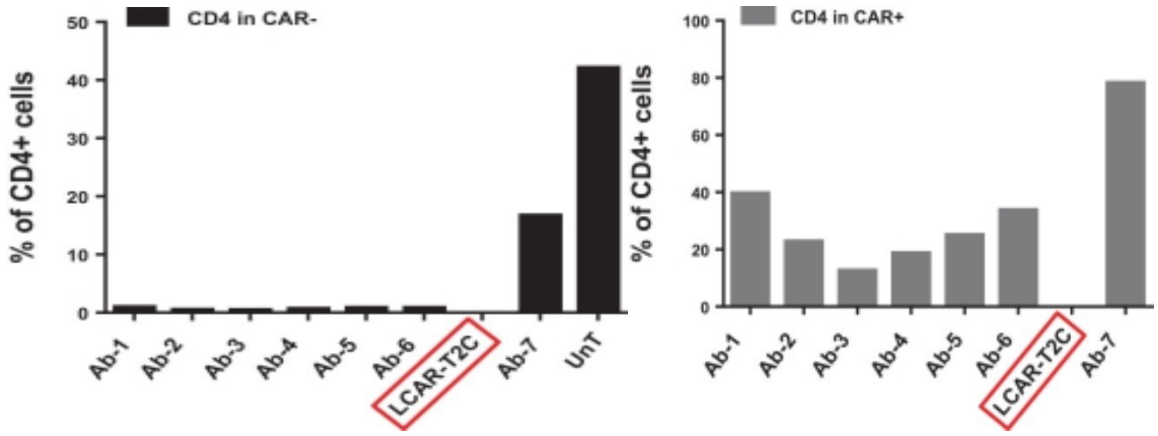
LB1901 was selected to avoid resistance due to inadvertent transduction of the CAR construct into tumor cells



Preclinical Data

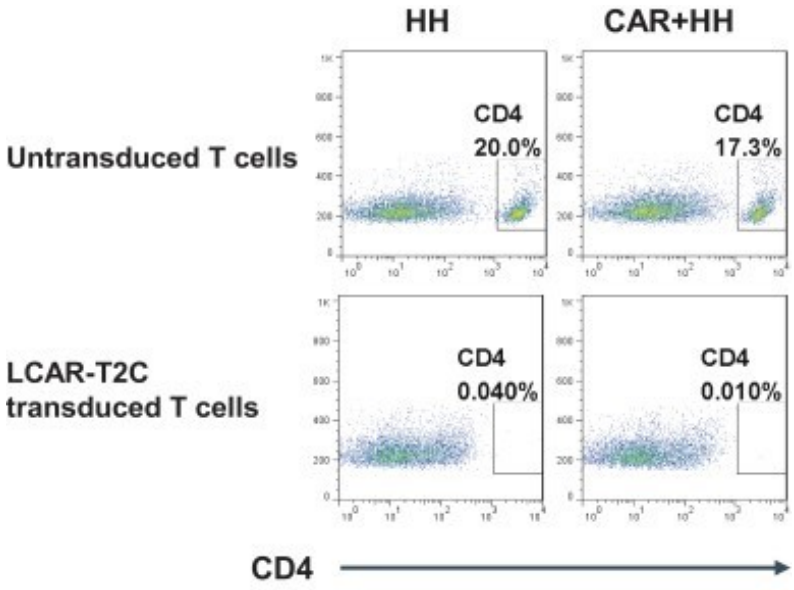
In a preclinical study, we observed that LB1901 as well as a number of other CAR constructs that we tested led to potent killing of T cells expressing CD4. LB1901, however, was the only CAR construct we tested that eliminated CD4 T cells into which the CAR construct was inserted.

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



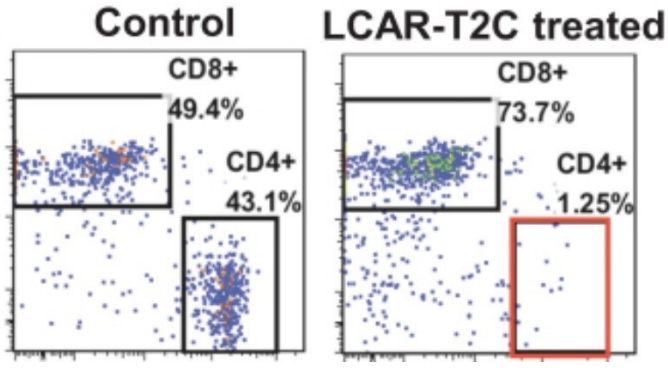
To confirm the ability of LB1901 to effectively target CD4 tumor cells that also express the CAR construct, we deliberately transduced HH, a CD4+ human tumor cell line derived from a patient with CTCL, with the LB1901 CAR construct. The preclinical results showed that LB1901 has the ability to eliminate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



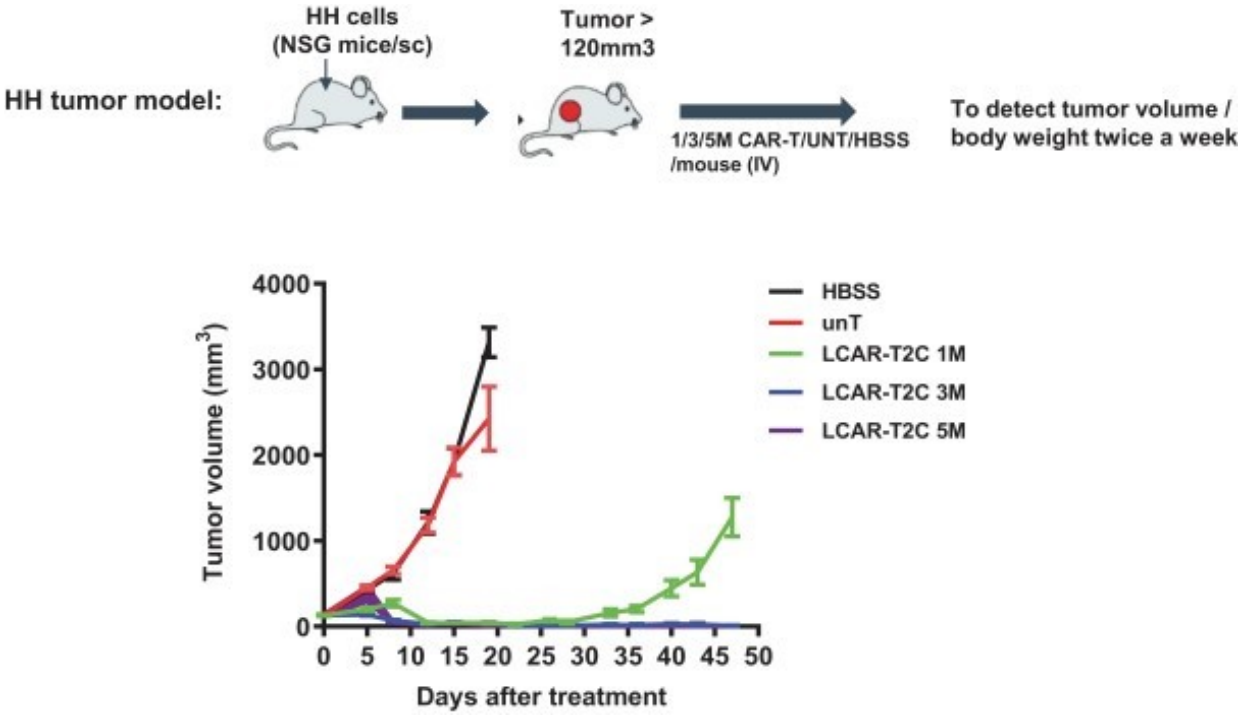
We have observed that LB1901 leads to selective killing of multiple CD4+ T cell lines. We have also observed that CD4+ T cell killing occurs in humanized mice treated with LB1901. In untreated mice, the CD4+ cells represented 43.1 percent of T cells. After treatment with LB1901, the percentage of CD4+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

Other Ongoing Investigator-Initiated and Preclinical Programs in China

In addition to cilta-cel and LB1901, we have a broad portfolio of product candidates in investigator-initiated trials and preclinical development targeting various cancers, solid tumors and infectious diseases. We plan to use data from investigator-initiated clinical trials to prioritize which product candidates to advance into broader clinical testing. In April 2020, we entered the Noile- Immune Agreement (as described below), pursuant to which we obtained a license to develop and commercialize next-generation CAR-T and/or TCR-T cell therapies incorporating Noile-Immune's PRIME (proliferation-inducing and migration-enhancing) technology for up to two targets for all indications and uses. The PRIME technology enables CAR-T and/or TCR-T cells to express and secrete cytokine IL-7 and chemokine CCL19. This technology is designed to improve proliferation and trafficking into solid tumors of both engineered CAR-T and/or TCR-T cells.

Autologous CAR-T Product Candidate Development

We are evaluating an autologous CAR-T therapy targeting CD19 and CD22 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 AML. CLL-1 is a myeloid lineage protein involved in cell signaling and expressed in over 90% of AML cases.

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.

We are also developing an allogenic gamma delta (γδ) T 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 has paid us an upfront fee of $350.0 million, milestone payments of $25.0 million, $30.0 million, and $30.0 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%, and a milestone payment of $75.0 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. Additionally, we are eligible to receive further milestone payments up to $125.0 million for the achievement of specified manufacturing milestones and an additional $1,040.0 million consisting of $105.0 million for the achievement of specified future development milestones, $725.0 million for the achievement of specified regulatory milestones and $210.0 million for the achievement of specified net trade sales milestones.

During the term of the Janssen Agreement neither we nor Janssen may develop or commercialize 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.

Collaborative Research and License Agreement with Noile-Immune Biotech Inc.

In April 2020, we entered into a collaborative research and license agreement with Noile-Immune Biotech Inc. (Noile-Immune), or the Noile-Immune Agreement, pursuant to which we obtained a worldwide, exclusive license to develop and commercialize CAR-T and/or TCR-T cell therapies incorporating Noile-Immune's PRIME (proliferation-inducing and migration-enhancing) technology for up to two targets for all indications and uses. We have the right to nominate such targets during a specific period following the effective date of the Noile-Immune Agreement. Noile-Immune may only refuse our nomination if such targets are the subject of internal development by Noile-Immune, are subject to exclusive third party rights, or are the subject of good faith discussions between Noile-Immune and a third party for exclusive rights, in each case, at the time of our selection. We are solely responsible, at our sole cost, for the development of CAR-T and/or TCR-T cell therapies directed to the selected targets, provided that Noile-Immune may participate in specific aspects of such development subject to our and Noile-Immune's mutual agreement. We are obligated to use commercially reasonable efforts to develop and commercialize such therapies and, in particular, use commercially reasonable efforts to submit an investigational new drug application and achieve a first commercial sale of such a therapy, in each case by a specified period of time in the United States or specified markets in Europe or Asia.

In consideration for the grant of the exclusive license under the Noile-Immune Agreement, we are obligated to pay to Noile-Immune an initial payment upon target selection and milestone payments for the achievement of specified development milestones of up to $70 million in the aggregate on a target-by-target basis. Noile-Immune will also be entitled to receive royalties based on net sales of the products developed under the Noile-Immune Agreement at single-digit percentages, subject to specified reductions. These royalties are payable, on a product-by-product and country-by-country basis until the latest to occur of: the expiration of the last to expire valid claim covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or the tenth anniversary after the first commercial sale of such product in such country.

During the term of the Noile-Immune Agreement, Noile-Immune will not work independently or through or with any affiliate or third party to develop or commercialize any CAR-T and/or TCR-T cell therapy directed to the targets that have been selected by us and approved by Noile-Immune. The Noile-Immune Agreement will remain in force until the expiration on a country-by-country, target-by-target and product-by-product basis of all of our obligations to pay milestones and royalties to Noile-Immune. We may terminate the Noile-Immune Agreement in its entirety or on a country-by-country, target-by-target or product-by-product basis, by providing a specified number of days prior notice to Noile-Immune, if in our reasonable judgement, such termination is justified for any reason, including commercial, scientific or medical reasons. Either party may terminate the Noile-Immune Agreement for cause for the other party's uncured material breach on a specified number of days prior notice or immediately in the event of bankruptcy of the other party.

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 are in the process of establishing a sales, marketing or product distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we will need a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third parties that have sales and marketing experience. According to the Janssen Agreement, we have the right to elect to perform up to 50% of the overall commercialization effort in the United States (excluding any activities that Janssen has the exclusive right to perform). Janssen will commercialize the products in all countries excluding the United States and Greater China in accordance with a specified plan, which will be developed with involvement by a senior commercial representative designated by us. In Greater China, we will be leading the commercialization effort and Janssen will have the right to elect to perform up to 30% of the overall commercialization effort, excluding activities that we have the exclusive right to perform. As we move our product candidates through development toward regulatory approval, we will evaluate several options for each product candidate's commercialization strategy. These options include further building our own internal sales force, entering into a joint marketing collaboration with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally for our clinical and preclinical product candidates. However, we do not own any issued patents covering our clinical and preclinical products and our patent portfolio for such products is currently comprised only of applications. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form that will provide us with meaningful protection for our products. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see 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 U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators,

sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see 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. National phase applications from both these PCTs were filed broadly to acquire patent coverage in a variety of jurisdictions, including in the United States, Greater China (mainland China and Hong Kong), Yemen, Saudi Arabia, Qatar, Oman, Bahrain, Egypt, United Arab Emirates, Europe, South Korea, Brazil, Canada, Chile, Colombia, Costa Rica, Eurasian, Israel, India, Japan, Mexico, Philippines, Ukraine, Vietnam, Malaysia, South Africa, Singapore, Australia and New Zealand. If issued, composition of matter claims issuing from these applications are projected to expire in 2036 and 2037.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021 and one pending PCT application filed in May 2019 that is due for national phase entry in 2021 relating to our LB1901 CD4 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one patent application outside of the United States, and one pending PCT application filed in August 2019 that is due for national phase entry in 2021 relating to a product candidate. If issued, composition of matter claims issuing from this application are projected to expire in 2039.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021, and one pending PCT application filed in May 2019 that is due for national phase entry in 2021 relating to our HIV product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one PCT application relating to our Claudin 18.2 product candidate filed in 2019 that is due for national phase entry in 2022. If issued, composition of matter claims issuing from this application are projected to expire in 2040.

We own one patent application outside of the United States, one published PCT application filed in July 2019 that is due for national phase entry in 2021 and one pending PCT application filed in August 2019 that is due for national phase entry in 2022 relating to our CD20 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039 and 2040.

We own one U.S. patent application, 29 patent applications outside of the United States and one published PCT application filed in 2016 relating to our CD19/CD22 product candidate. National phase applications from this PCT were filed broadly to acquire patent coverage in a variety of jurisdictions. If issued, composition of matter claims issuing from this application are projected to expire in 2036.

We own two patent applications outside of the United States and two pending PCT applications filed in September 2019 that are due for national phase entry in 2021 relating to our LB1901 CD33/CLL-1 product candidate. If issued, composition of matter claims issuing from these applications are projected to expire in 2039.

Manufacturing

The manufacture and delivery of cell therapies to patients involves complex, integrated processes. Commercial success in cell therapies requires a manufacturing process that is reliable, scalable and economical. We are devoting significant resources to process development and manufacturing in order to optimize process robustness, lower failure rates in developing cell therapy product candidates as well as reduce our per-unit manufacturing costs and enable us to quickly achieve regional and global scale if we obtain regulatory approval for any of our product candidates.

We currently have manufacturing sites in China and the United States supplying clinical materials for our trials. We are also in the process of establishing a manufacturing site in Europe. We also intend to expand the manufacturing capacities in the United States, Europe and China for commercialization at both a regional and global scale, if any of our product candidates are approved.

We are employing a systematic approach to manufacturing which is designed to provide a common platform suitable for manufacturing all of our product candidates. This platform allows for parallel processing and the ability to scale for commercial supply in a controlled environment and at an economical cost. We have improved the viral transduction process to help minimize processing inconsistencies and reduce failure rates. In addition, our manufacturing and logistics process is designed to ensure that product integrity is maintained during shipment along with accurate tracking and tracing of shipments.

Our manufacturing and commercialization strategy requires a fully integrated product delivery cycle. We believe having established a manufacturing platform process and manufacturing hubs within the United States, China and Europe suitable for commercialization early in the development of our cell therapies is a competitive advantage. Over time, we expect to expand regional manufacturing capacity and potentially add external supply nodes to meet projected product requirements for commercialization. We believe that anticipated future clinical and commercial demand for 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. Kite has published data on Yescarta in ALL as well. Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, has published data on its anti-CD19 CAR therapy, JCAR017 (liso-cel). bluebird was the first company to publish data on an anti-BCMA CAR therapy, bb2121, in MM.

Due to the promising therapeutic effect of cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies.

Our potential CAR-T cell therapy competitors include:

- Companies developing cell therapies targeting BCMA for the treatment of MM, including Allogene, Autolus, bluebird, Bristol-Myers Squibb, Carsgen, Gracell, Innovent, Poseida Therapeutics, Novartis and Precision Biosciences;
- Additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Regeneron, GSK, Johnson & Johnson and Pfizer.

We also compete with many companies developing cell therapies, including for trial sites, enrollment in our trials and with respect to diseases that we are targeting and may target in the future. In addition, we may compete with cell therapies companies that are focused on development in Asia.

In addition, our commercial success depends on our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary and modular CAR-T cell technology without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of CAR-T cell therapies and including patents owned or controlled by our competitors. In addition, there are frequent allegations of patent infringement in the area of biotechnology. Third parties, including our competitors, may allege that our product candidates, including 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. None of our product candidates has been approved by the FDA for marketing in the United States and the rolling submission of the BLA to the FDA has been initiated in December 2020. Failure to comply with applicable FDA or other requirements at any time during product development, clinical testing, the approval process or after approval may result in administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, suspension or revocation of approved applications, warning letters, product recalls, product seizures, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness of the proposed biologic product candidate for its intended indications;
- preparation of and submission to the FDA of a BLA when adequate data are obtained from pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP regulations; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND application to the FDA. An IND application is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND application is on the general

investigational plan and the protocol(s) for clinical studies. The IND application also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. If the IND sponsor is not able to address FDA's concerns satisfactorily within the 30-day time frame, the IND may be placed on clinical hold. The IND sponsor and the FDA must resolve any outstanding concerns or questions before the IND is cleared by the FDA and the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Generally, a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, or DSMB, which provides recommendation on whether or not a study should move forward at designated check points based on access to certain data from the study. The DSMB may recommend halting of the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. For investigational products developed for oncology indications, the Phase 1 trials are normally conducted in patients with serious or life-threatening diseases without other treatment alternatives.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. For certain indications in patients with serious or life-threatening diseases and with no available therapies, it may be possible to obtain BLA approval based on data from Phase 2 trials if a positive benefit risk profile is demonstrated.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on,

among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the 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 approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

Biosimilarity, which requires that 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 that the reference product was first licensed by the FDA. In addition, the FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the competing product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether 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, 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 will be extended to include information related to payments and other transfers of value provided in the calendar year 2021 to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives effective); 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 eliminate, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In addition, the Tax Act was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. In March 2020, the Supreme Court granted a writ of certiorari and agreed to review the judgement of the federal appeals court. Oral argument was held in the case in November 2020, and a decision is expected by the time the current Supreme Court term ends in June of 2021. Pending action by the Supreme Court and any remand of the action to a court below or further litigation that may follow, which could take an extended period of time, the ACA remains operational. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of

Medicare providers, which will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance over 10 years to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. The FDA also 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. 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. In response, the government agreed to delay the effective date and evaluate the rule adopted by the previous administration. In the interim, the status quo has been restored. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the recent transition to the Biden administration. However, the Biden administration 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, particularly as a result of the recent presidential election. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 State Administration for Market Regulation, or SAMR, which are responsible for consumer protection, advertising, anticorruption, pricing and fair competition matters. The National Intellectual Property Administration is the other half-ministry level agency under the SAMR.

Like the CFDA, the NMPA is still the primary drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and it regulates almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

The NHC (formerly known by the names: the Ministry of Health (MOH) and National Health and Family Planning Commission (NHFPC)), is China's primary healthcare regulatory agency. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites, and regulating the licensure of hospitals and other medical personnel. NHC plays a significant role in drug reimbursement. Furthermore, the NHC and its local counterparts at or below the provincial-level of local government also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, through which public hospitals and their pharmacies acquire drugs.

Also, as part of the 2018 reorganization, the PRC government formed the National Healthcare Security Administration which focuses on regulating reimbursement under the state-sponsored insurance plans.

Non-Clinical Research

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the DRR, nonclinical safety studies must comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. On August 6, 2003, the NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, which was revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory

issued by the NMPA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017, respectively, by the State Council, the Administrative Measures on Good Practice of Experimental Animals jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

Registration Categories

Prior to engaging with the NMPA on research and development and approval, an applicant will need to determine the registration category for its drug candidate (which will ultimately need to be confirmed with the NMPA), which will determine the application requirements for its clinical trial and marketing application.

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, NMPA established a conditional approval program for drugs designated by the CDE that have been approved in the US, EU and Japan within the last 10 years and that meet one of three criteria (1) orphan indications, (2) drugs that treat life threatening illnesses for which there are not effective treatment or preventive methods, and (3) drugs that treat life threatening illnesses and that have a clear clinical advantage over other approved therapies.

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 foreign approval is required prior to the trial, unless the drug has never been approved anywhere in the world. In addition to a standalone China trial to support development, imported drug applicants may establish a site in China that is part of an international multicenter trial, or IMCT, at the outset of the global trial. Domestically manufactured drugs are not subject to foreign approval requirements, and in contrast to prior practice, the NMPA has recently decided to permit those drugs to conduct development via an IMCT as well.

In 2015, the NMPA began to issue an umbrella approval for all phases (typically three) of a new drug clinical trial, instead of issuing approval phase by phase. For certain types of new drug candidates, CTAs may be prioritized over other applications and put in a separate expedited queue for approval.

The NMPA has now adopted a system for clinical trials of new drugs where trials can proceed if after 60 business days, the applicant has not received any objections from the CDE. China is also expanding the number of trial sites by changing from a clinical trial site certification procedure into a notification procedure.

Drug Clinical Trial Registration

Pursuant to the DRR, 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

According to the Interim Measures for the Administration of Human Genetic Resources, promulgated by the Ministry of Science and Technology and the MOH jointly on June 10, 1998, an additional approval is required for any foreign companies or foreign affiliates that conduct trials in China. Prior to beginning a trial, the foreign sponsor and the Chinese clinical trial site are required to obtain approval from the Human Genetic Resources Administration of China, or HGRAC, which is an agency under the Ministry of Science and Technology, to collect any biological samples that contain the genetic material of Chinese human subjects, and to transfer any cross-border transfer of the samples or associated data. Furthermore, one of the key review points for the HGRAC review and approval process is the IP sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights to inventions arising from the samples. Conducting a clinical trial in China without obtaining the relevant HGRAC preapproval will subject the sponsor and trial site to administrative liability, including confiscation of HGRAC samples and associated data, and administrative fines.

On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that foreign-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic

Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. The State Council of PRC issued 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. Foreign entities, individuals and such entities established or actually controlled thereby 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 foreign-owned entities. Pursuant to the new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

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 will become 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 foreign 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 Foreign Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, or the Guidance Principles, as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of foreign clinical trials must meet the authenticity, completeness, accuracy and traceability requirements and such data must be obtained consistent with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without the need for pre-approval clinical trials inside China. Specifically, on October 23, 2018, the NMPA issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, which established a program permitting drugs that have been approved within the last ten years in the United States, EU or Japan and that i) treat orphan diseases, ii) prevent or treat serious life-threatening illnesses for which there is either no effective therapy or prevention in China, or iii) prevent or treat serious life-threatening illnesses and the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to

complete trials in China after the drug is marketed. By May 29, 2019, the CDE has developed two lists of qualifying drugs that meet this criteria.

Clinical Trial Process and Good Clinical Practices

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.

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 which will come into effect 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 version of the NRDL released in 2019 covers 2,643 drugs in total, including 148 new additions, with an emphasis on innovative drugs and drugs that treat cancer and other serious diseases.

Government price controls

On May 4, 2015, the NDRC and six other ministries and commissions in the PRC issued the Opinion on Promoting Drug Pricing Reform, which lifted the government-prescribed maximum retail price for most drugs, including drugs reimbursed by government medical insurance funds, patented drugs, and some other drugs. The government regulates prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

Centralized procurement and tenders

Under current regulations, public medical institutions owned by the government or owned by state-owned or controlled enterprises are required to purchase pharmaceutical products through centralized online procurement processes. There are exceptions for drugs on the National List of Essential Drugs, which must comply with their own procurement rules, and for certain drugs subject to the central government's special control such as toxic, radioactive and narcotic drugs, and traditional Chinese medicines.

The centralized procurement process takes the form of public tenders operated by provincial or municipal-level government agencies. The centralized tender process is typically conducted once every year. The bids are assessed by a committee randomly selected from a database of experts. The committee members assess the bids based on a number of factors, including but not limited to bid price, product quality, clinical effectiveness, product safety, level of technology, qualifications and reputation of the manufacturer, after-sale services and innovation.

According to the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State issued by the General Office of the State Council in January 2019, in the 11 pilot cities drugs will be selected from generic brands for centralized medicine procurement. The selected drugs must pass the consistency evaluation on quality and effectiveness. The policy is aimed at lowering drug costs for patients, reducing transaction costs for enterprises, regulating drug use of institutions, and improving the centralized medicine procurement and pricing system. The centralized procurement is open to all approved enterprises that can produce drugs on the procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs will be considered, and their consistency will be the main criteria for evaluation, while production capacity and stability of the supplier will also be considered.

Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases or released by us to third parties. The privacy of human subjects in clinical trials is also protected under regulations. For example, the case report forms must avoid disclosing names of the human subjects.

These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future, including restrictions on transfer of healthcare data. The Cybersecurity Law that took effect in 2017 designates healthcare as a priority area that is part of critical information infrastructure, and China's cyberspace administration is working to finalize a draft rule on cross- border transfer of personal information.

PRC Regulation of Foreign Investment

Investment activities in China by foreign investors are principally governed by the Guidance Catalogue of Industries for Foreign Investment, or the Catalogue, which was promulgated and is amended from time to time by the MOFCOM and the NDRC. The Special Administrative Measures for the Access of Foreign Investment (Negative List) (2020) issued by the MOFCOM and the NDRC on June 23, 2020 and took into effect from July 23, 2020. 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 an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Foreign Exchange

The PRC Foreign Exchange Administration Regulations promulgated by the State Council on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, respectively, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business; and/or paying the expenses related to the purchase of real estate that is not for self-use, except for the real estate enterprises.

In 2017, new regulations were adopted which, among other things, relax the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation and tighten genuineness and compliance verification of cross-border transactions and cross-border capital flows.

In 2019, SAFE promulgated SAFE Circular 28, which cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the “capital account— account for settled foreign exchange to be paid” to receive the corresponding funds according to relevant provisions.

SAFE Circular 37

In July 2014, SAFE promulgated SAFE Circular 37, which replaces the previous SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is

applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

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

Regulations Relating to Dividend Distributions

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the PRC Company Law, promulgated in 1993 and last amended in 2018 and the Foreign Investment Law and its Implementing Regulations, both came into effect on January 1, 2020. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Labor Laws and Labor Contract Law

Pursuant to the PRC Labor Law promulgated by the Standing Committee of the NPC on July 5, 1994 and last amended on December 29, 2018 and the PRC Labor Contract Law promulgated by the Standing Committee of the NPC on June 29, 2007 and amended on December 28, 2012, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

Regulations Relating to Social Insurance and Housing Provident Funds

In addition, according to the PRC Social Insurance Law promulgated on October 28, 2010 by the Standing Committee of the NPC and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, respectively, employers like our PRC subsidiary in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

Regulations Relating to Enterprise Income Tax

Pursuant to the PRC Enterprise Income Tax Law effective as of January 1, 2008 and as amended on February 24, 2017 and December 29, 2018, respectively, the income tax rate for both domestic and foreign- invested enterprises is 25% with certain exceptions. To clarify certain provisions in the PRC Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law on December 6, 2007, which was amended and became effective on April 23, 2019. Under the PRC Enterprise Income Tax Law and the Implementation Rules of the PRC Enterprise Income Tax Law, enterprises are classified as either "resident enterprises" or "non-resident enterprises." Aside from enterprises established within the PRC, enterprises established outside of China whose "de facto management bodies" are located in China are considered "resident enterprises" and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the PRC Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

The Implementation Rules of the PRC Enterprise Income Tax Law provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

Rest of World Regulation

For other countries outside of the United States and the PRC, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

Facilities

Our principal executive offices are currently located at 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 are currently renovating a significant portion of the warehouse space into GMP manufacturing space for the development and potential commercialization of our pipeline. In addition, we have a research facility located at 10 Knightsbridge Road, Piscataway, New Jersey 08854, where we lease approximately 22,000 square foot facility from Genscript USA Holdings, Inc., or Genscript USA.

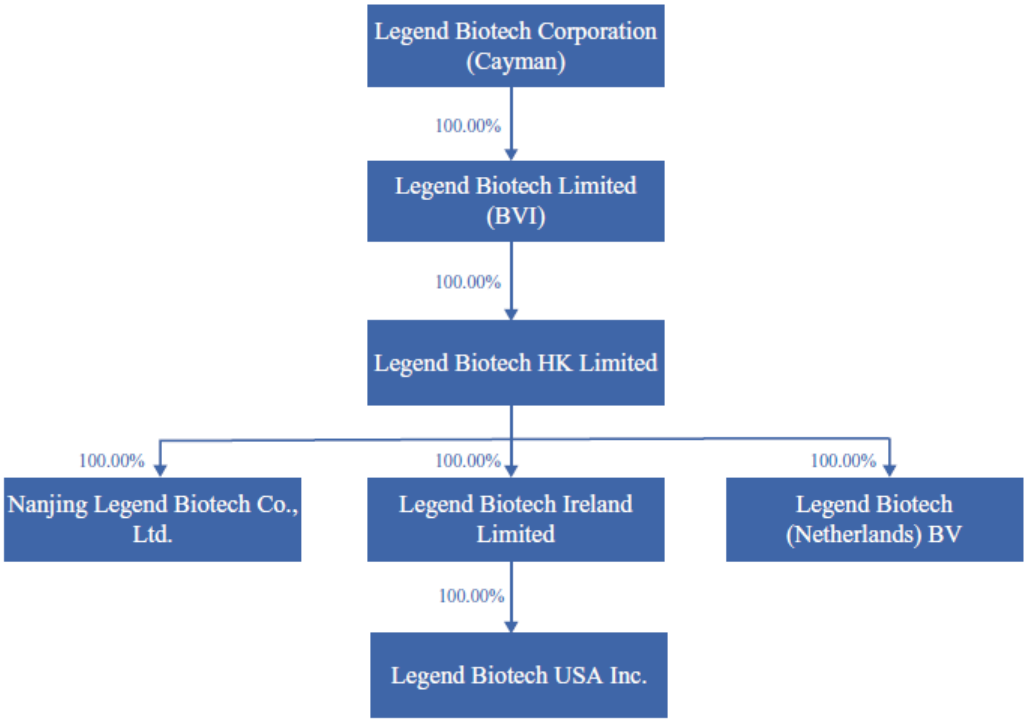
We believe our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

Recent Development

In the quarter ended March 31, 2021, Janssen Biotech Inc., our collaborator, completed the rolling submission of the Biologics License Application (BLA) to the FDA for cilta-cel, an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy for the treatment of patients with relapsed and/or refractory multiple myeloma. The rolling submission was initiated in December 2020.

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

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 are currently renovating a significant portion of the warehouse space into GMP manufacturing space for the development and potential commercialization of our pipeline. In addition, we have a research facility located at 10 Knightsbridge Road, Piscataway, New Jersey 08854, where we lease approximately 22,000 square foot facility from Genscript USA.

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.

For Raritan plant that we collaborate with Janssen, we continue to invest in manufacturing, quality, information technology and distribution capability to support BCMA launch.

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

In China, we are shifting strategies for BCMA commercial production site and looking at 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 "Item 3.A. Selected Financial Data" and our consolidated financial statements appearing elsewhere in this Annual Report on Form F-20. 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. The terms "Company," "Legend Biotech," "we," "our" or "us" as used herein refer to Legend Biotech Corporation and its consolidated subsidiaries unless otherwise stated or indicated by context.

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 800 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.

Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with capital contributions from Genscript, with proceeds from the sale of our Series A Preference Shares and from upfront and milestone payments from Janssen. From inception through December 31, 2020, we received $3.9 million in capital contributions, aggregate gross proceeds of $160.5 million from our sale of Series A Preference Shares, an aggregate of $460.0 million from Janssen under the Janssen Agreement, net proceeds of $450.1 million from our initial public offering, or IPO, and $12.0 million from concurrent private placement by Genscript. As of December 31, 2020, we had $506.0 million in cash and cash equivalents and time deposits.

Since inception, we have incurred significant operating losses. Our net losses were $303.5 million and $133.0 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had accumulated losses of $430.8 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, including those we are developing for the treatment of AML, NHL, TCL, DLBCL, gastric cancer, ovarian cancer, pancreatic cancer and HIV;
- continue our ongoing and planned research and development activities;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

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

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 has paid us an upfront fee of $350.0 million and milestone payments totaling $110.0 million for the achievement of four development milestone events to date. We have achieved an additional milestone of $75.0 million and received payment from Janssen in January 2021. Additionally, we are eligible to receive further milestone payments up to $125.0 million for the achievement of specified manufacturing milestones and an additional $1,040.0 million for the achievement of specified future development, regulatory and net trade sales milestones.

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, 2020, 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, 2020 and 2019, our total research and

development expenses were $164.0 million and $115.7 million, respectively, for our BCMA program and $68.2 million and $46.3 million, respectively, for all other non-BCMA programs.

From inception through December 31, 2020, we have incurred approximately $463.9 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 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

Contract assets

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

Contract liabilities

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

Upfront fees

Upfront payment is allocated to the performance obligations based on the Group's best estimate of their relative stand-alone selling prices. The upfront fees of US$350 million was included in the transaction price upon contract inception in 2017 and fully received by the Group in 2018.

Milestone payments

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

The initial two milestone payments of US$50 million were included in the transaction price upon contract inception in 2017. Subsequently in 2019, an additional two milestones payments of US$60 million were included in the transaction price when the milestones triggered by dosing of a specified numbers of patients in the CARTITUDE-1 clinical trial were achieved. In 2020, an additional milestone with a payment with a payment of US$75 million was achieved relating to the clinical development of cilta-cel. At December 31, 2020, the Group is eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $1,040 million, consisting of $105 million for the achievement of specified future development milestones, $725 million for the achievement of specified regulatory milestones and $210 million for the achievement of specified net trade sales milestones. The Company accessed that achievement of the remaining milestones are highly uncertain and the related milestone payments are not included in the transaction price. The milestone is achieved when the triggering event described in the agreement occurs.

Licenses of intellectual property

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

Steering committee services

In assessing whether the preparation and participation in a Joint Steering Committee which leads to the commercialization of a new drug ("JSC service") is a promised service in the arrangement, the Group concluded that the services are capable of being distinct from the intellectual property licenses and distinct within the context of the contract based on a careful evaluation of the specific facts and circumstances. It was determined that the largest portion of the transaction price should be allocated to the JSC service as the Group is responsible for a significant portion of the development work prior to commercialization. The performance obligation is satisfied over time as services are rendered. Revenue from JSC service is recognized on a straight-line basis over the period when the JSC service is provided.

Research and development costs

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

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

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, 2020, 2019 and 2018, the equity-settled share option expense was US$1,905,000, US$1,272,000 and US $704,000 respectively. Further details are contained in note 25 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 financial position or results of operations. As of December 31, 2020, we have no material interest rate risk exposure.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2020, 2019 and 2018. 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, 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,		Increase (Decrease)
	2020	2019	
		(in thousands)	
Consolidated Statement of Operations Data:			
Revenue	75,676	57,264	18,412
Operating expenses:			
Research and development expenses	(232,160)	(161,943)	(70,217)
Administrative expenses	(23,147)	(6,752)	(16,395)
Selling and distribution expenses	(49,571)	(25,620)	(23,951)
Other income and gains	6,119	7,125	(1,006)
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	(307,622)	(130,370)	(177,252)
Income tax credit/(expense)	4,145	(2,602)	6,747
Loss for the period	(303,477)	(132,972)	(170,505)

Revenue

Revenue for the year ended December 31, 2019 was $57.3 million, compared to $75.7 million for the year ended December 31, 2020. This increase of $18.4 million was primarily driven by revenue recognized from an additional milestone achieved of higher amount. 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, 2019 were $161.9 million, compared to $232.2 million for the year ended December 31, 2020. 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, 2019 were $6.8 million, compared to $23.1 million for the year ended December 31, 2020. 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, 2019 were $25.6 million, compared to $49.6 million for the year ended December 31, 2020. 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, 2019 was $7.1 million, compared to $6.1 million for the year ended December 31, 2020. This decrease of $1.0 million was primarily driven by reduced average interest rate for holding of time deposits that generate interest income.

Other Expenses

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

Income Tax Expense/Credit

Income tax expense for the year ended December 31, 2019 was $2.6 million compared to $4.1 million of income tax credit for the year ended December 31, 2020.

Comparison of Years Ended December 31, 2019 and 2018

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

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

Revenue

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

Operating Expenses

Research and Development Expenses

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

Administrative Expenses

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

Selling and Distribution Expenses

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

Other Income and Gains

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

Income Tax Expense

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

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

Revenue Recognition

Contract liabilities

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

Upfront fees

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

Milestone payments

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining

whether it is probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price. The milestone payments were allocated to the performance obligations based on our best estimate of their relative stand-alone selling prices unless the criteria under IFRS 15.85 are met, where the milestone payments are allocated entirely to the performance obligations which the milestone payments are specifically related to.

The initial two milestone payments from Janssen of $50.0 million were included in the transaction price upon contract inception in 2017. Subsequently in 2019, an additional two milestone payments of $60.0 million were included in the transaction price when the milestones triggered by dosing of a specified number of patients in the CARTITUDE-1 clinical trial were achieved. In 2020, an additional a milestone payment of $75.0 million were included upon the acceptance of filing of a drug approval application for a product by the FDA in the United States. As of December 31, 2020, we were eligible to receive further milestone payments of up to $125.0 million for the achievement of specified manufacturing milestones and an additional $1,040.0 million, consisting of $105.0 million for the achievement of specified future development milestones, $725.0 million for the achievement of specified regulatory milestones and $210.0 million for the achievement of specified net trade sales milestones. We assessed that achievement of the remaining milestones is still highly uncertain and cannot be included in the transaction price. The milestone is achieved when the triggering event described in the agreement occurs.

Licenses of intellectual property

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

Steering committee services

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

Research and development costs

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

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

Share-Based Compensation

We operate a share option scheme 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 note 25 and note 26 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,	
	2020	2019
Expected life of options (years)	10	10
Expected volatility	73.0%-87.2%	66.4%-80.3%
Risk-free interest rate	0.07%-0.91%	1.98%-2.69%
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 2.3 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.

Inflation

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, 2019 or 2018.

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.

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations to date primarily with capital contributions from Genscript, with proceeds from the sale of our Series A Preference Shares and from upfront and milestone payments from Janssen. From inception through December 31, 2020, we have received $3.9 million in capital contributions, aggregate gross proceeds of $160.5 million from our sale of Series A Preference Shares, an aggregate of $460.0 million from Janssen under the Janssen Agreement, net proceeds of $450.1 million from our IPO, and $12.0 million from a concurrent private placement by Genscript. As of December 31, 2020, we had $506.0 million in cash, cash equivalents and time deposits, and accumulated losses of $430.8 million. We had no indebtedness as of December 31, 2020.

Certain of our subsidiaries, including those registered as wholly foreign-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, 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 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,		
	2020	2019	2018
		(in thousands)	
Net cash (used in)/from operating activities	$(223,005)	$ (83,065)	$ 307,682
Net cash used in investing activities	(24,169)	(58,652)	(102,256)
Net cash from financing activities	618,879	14,666	2,501
Net increase/(decrease) in cash and cash equivalents	$ 371,705	$ (127,051)	$ 207,927

Operating Activities

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 $211.8 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 $128.9 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.

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

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was $24.2 million, consisting primarily of $49.8 million in purchases of property, plant, equipment and intangible assets, and purchase of short-term time deposits of $50.0 million, partially offset by recovered the short-term 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 $38.6 million and purchases of short-term time deposits of $75.6 million, partially offset by collection of cash advances from related parties of $63.0 million.

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

Financing Activities

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.

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

Capital Expenditure

Our capital expenditures for the years ended December 31, 2020, 2019 and 2018 amounted to $52.6 million, $46.8 million and $27.1 million, respectively. These expenditures primarily consisted of property, plant, equipment and intangible assets.

As of December 31, 2020, we had commitments for capital expenditures of approximately $33.6 million, 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 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.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. Furthermore, 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.

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.

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. Off-balance Sheet Arrangements

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

F. Tabular Disclosure of Contractual Obligations

The following table sets forth our contractual obligations and commitments as of December 31, 2020:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Lease obligations[1]	$ 1,513	$ 1,383	$ 620	$ 96	$ 3,612
Capital commitment	$33,637	—	—	—	$33,637
Total	$35,150	$ 1,383	$ 620	$ 96	$37,249

(1) Amounts presented in the table represent payments due under operating leases for facilities in New Jersey, Ireland and China that in the aggregate total of $3.6 million.

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

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

G. Safe Harbor

See "Cautionary Statement Regarding Forward-Looking Statements."

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, 2021:

Name	Age	Position
Executive Officers		
Ying Huang, Ph.D.	48	Chief Executive Office and Chief Financial Officer
Lori Macomber	50	Vice President, Finance
Non-Employee Directors		
Ye (Sally) Wang, M.S.	52	Chairwoman of the Board of Directors
Li Zhu Ph.D.	71	Director
Darren Xiaohui Ji, M.D., Ph.D.	59	Independent Director
Corazon D. Sanders Ph.D.	64	Independent Director
Yau Wai Man Philip, CPA	44	Independent Director
Patrick Casey, Ph.D.	64	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. 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.

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.

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 becoming the holding company of the group companies. Prior to joining Genscript, she worked as an Environmental Monitoring Engineer at Shenzhen Futian Environment Protection Surveillance Station. Ms. Wang also serves as a director for 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, and of Beigene, Ltd since August 2020. 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. 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 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, 2020, we paid an aggregate of $1,732,592.88 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, 2020, we paid our non-employee directors $140,255.53. For the year ended December 31, 2020, stock options to purchase 90,000 ordinary shares with an exercise price of $11.50 per ordinary share and an expiration date of June 5th, 2030 were issued to non-employee directors as compensation under the Share Option Scheme and restricted share unit awards for 52,173 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.

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. Dr. Huang is 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. Pursuant to the offer letter, Ms. Macomber is entitled to an annual base salary of $225,000 and is eligible to receive an annual performance bonus. Ms. Macomber participates in our performance-based share option Scheme and is entitled to receive share options awards, which vest in equal installments on each of the first five 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, 2020, options covering 14,241,404 ordinary shares with a weighted-average exercise price of $1.94 per share were outstanding, and 4,076,600 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 members of the Group 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, 2020, restricted share units covering 1,112,457 ordinary shares were outstanding, and 9,887,543 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 six 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 six 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 and Darren Xiaohui Ji, and their term expires at our annual meeting of shareholders in 2021;
- 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.

D. Employees

As of December 31, 2020, we had 882 employees, 128 of whom hold Ph.D. and/or M.D. degrees. Of these 882 employees, 388 are engaged in research and development activities and 76 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,	
	2020	2019
Function:		
General and administrative	76	41
Research and development	388	336
Sales and marketing	24	17
Others	394	251
Total	882	645
Geography:		
United States	295	158
Asia-Pacific	579	479
Ireland	8	8
Total	882	645

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 266,010,256 ordinary shares outstanding as of December 31, 2020. 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, 2020, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Number of ordinary shares beneficially owned	Percentage of Shares Beneficially Owned
5% or Greater Shareholders:		
Genscript Biotech Corporation[1]	169,997,556	63.91%
AquaPoint L.P.[2]	30,320,000	11.40%
Fangliang Zhang, Ph.D.[3]	30,896,554	11.61%
Executive Officers and Directors:		
Ying Huang, Ph.D.[4]	200,000	*
Lori Macomber, M.S. [5]	10,000	*
Ye (Sally) Wang, M.S. [6]	—	—
Darren Xiaohui Ji, M.D., Ph.D.	—	—
Corazon D. Sanders, Ph.D	—	—
Yau Wai Man Philip, CPA	—	—
Li Zhu, Ph.D	—	—
Patrick Casey, Ph.D	—	—
All Current Executive Officers and Directors as a Group (8 persons)[7]	210,000	*

* 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 and (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 on or before July 23, 2020. The address for Genscript is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.

2) Consists of 30,320,000 ordinary shares held by AquaPoint L.P. The address for AquaPoint L.P. is Cayman Corporate Centre, 27 Hospital Road, P.O. Box 1748, George Town KY1-1109, Caymand Islands.

3) Consists of (i) the shares described in footnote (2), and (ii) 576,554 ordinary shares as of December 31, 2020 due to exercise of share options, of which Dr. Zhang has voting power over pursuant to an irrevocable proxy with the holders of such options, including those shares described in footnote (4). 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.

4) Consists of 7,492 ordinary shares as of December 31, 2020 due to exercise of share options and 192,508 ordinary shares underlying options that are exercisable within 60 days of December 31, 2020, both of which Dr. Huang has dispositive power but not voting power over.

5) Consists of 10,000 ordinary shares underlying options that are exercisable within 60 days of December 31, 2020, of which Ms. Macomber has dispositive power but not voting power over.

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.

7) Consists of (i) 7,492 ordinary shares, and (ii) 202,508 ordinary shares that all executive officers and directors as a group have the right to acquire within 60 days following December 31, 2020 pursuant to the exercise of options.

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

As of December 31, 2020, we estimate that 66,564,944 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held in the United States by 8 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, 2020 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 64% of our outstanding ordinary shares as of March 1, 2021. 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.

Concurrent Private Placement

In June 2020, concurrently with our initial public offering, we issued and sold to Genscript 1,043,478 ordinary shares at a price of $11.50 per share for total gross proceeds of $12.0 million.

Animal Facility Lease Agreements

We are party to an animal facility lease agreement with Nanjing Jinsirui Biotechnology Co., Ltd, or Nanjing Jinsirui, a subsidiary of Genscript. Under the agreement, we leased a 1,000 square meters animal facility in Nanjing, China, at a cost of approximately RMB0.1million per month ($7,555 per month, based on the conversion rate of RMB6.7506 to $1.00, which was the average exchange rate for the year ended December 31, 2020) (value-added tax, or VAT, included). The term of the lease was from July 2020 to June 2025.

IT Department and Human Resources Service Level Agreements

In February 2020, we entered into the human resources service level agreement, or the Human Resources Agreement, with Genscript. Pursuant to the agreement, Genscript will provide human resources services to us, such as managing long-term incentives globally and payroll services for Ireland. The term of the agreement is from January 2020 until being terminated by Genscript with one-month's written notice.

Lease Agreement

In February 2018, we entered into a lease agreement with Genscript USA Holdings, Inc., a subsidiary of Genscript. Under the lease agreement, we lease an approximately 22,000 square foot facility in Piscataway, New Jersey at a cost of $60,000 per month. In January 2020, we entered into an additional lease agreement. The lease term is from January 1, 2020 to December 31, 2021. The cost of the lease is expected to be approximately $0.6 million for each of 2020 and 2021.

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 Legend Biotech'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.

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.

As of March 31, 2021, 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, 2020. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Our status as a PFIC is a fact-intensive determination made on an annual basis after the end of each taxable year, 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, 2020, 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 US$100,000 for ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting. 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 individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel located in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in China.

We believe that we should not be considered as a PRC resident enterprise for PRC tax purposes as (i) we are incorporated outside of China and not controlled by a PRC enterprise or PRC enterprise group; and (ii) we do not meet all of the conditions above. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." There can be no assurance that PRC tax authorities will ultimately not take a different view.

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident enterprise holders of our 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. These securities are generally not dependent on interest rate fluctuations that may cause the principal amount of these assets to fluctuate. As a result, a change in market interest rates would not have any significant impact on our financial position or results of operations. As of December 31, 2020, we have no material interest rate risk exposure.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2019 and 2020.

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

Not Applicable.

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. For fiscal year 2020, the depositary shared with us US$0.9 million, after deduction of applicable U.S. taxes.

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, $5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, canceled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing shares or by any party surrendering ADSs and/or to whom ADSs are issued

(including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of U.S.$1.50 per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of U.S.$0.05 or less per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of U.S.$0.05 or less per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the $0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares, ADRs or deposited securities;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within JPMorgan Chase Bank, N.A., or the Bank, and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to an foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosure" page (or successor page) of www.adr.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of an foreign exchange transaction varies according to local market dynamics, which may include

regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

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, 2020, we have not used any of the net proceeds from our IPO. There has been no material change in the planned use of 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.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

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 covered by this Annual Report on Form 20-F, as required by Rule 13a-15(b) under the Exchange Act.

Based upon that evaluation, our management has concluded that, as of December 31, 2020, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file and furnish under the Exchange Act was recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer, Chief Financial Officer and Vice President, Finance, to allow timely decisions regarding required disclosure.

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

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

C. Attestation Report of Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

D. Changes in Internal Control Over Financial Reporting

Other than disclosed below, there were no changes in our internal control over financing reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Previously Identified Material Weakness

In connection with the audits of our consolidated financial statements as of and for the year ended December 31, 2019, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting where we lacked a sufficient number of accounting and financial reporting personnel with requisite knowledge of and experience in application of IFRS and SEC rules, and lacked financial reporting policies and procedures that are commensurate with IFRS and SEC reporting and compliance requirements.

In response to the material weaknesses, we have implemented a number of measures to improve our internal control over financial reporting, including, but not limited to the following:

- We have hired additional qualified financial and accounting staff with IFRS and SEC reporting experience to strengthen our financial reporting capability and completed additional trainings on the application of IFRS and SEC rules;
- We have improved our accounting and financial reporting policies, accounting manual, monthly closing process, and related financial reporting and disclosure procedures;
- We have also established an internal audit department to enhance internal controls and have engaged an independent advisory firm to assist us in assessing the design and effectiveness of our execution of internal controls in accordance with the compliance requirements under the Sarbanes-Oxley Act of 2002 and in improving our overall internal controls and established an audit committee with members who have an appropriate level of financial expertise to oversee our accounting and financial reporting processes as well as our external and internal audits; and
- We have established quarterly meetings with functional heads to identify significant, complex, and/or non-recurring transactions for accounting and financial reporting purposes.

As of December 31, 2020, based on an assessment performed by our management on the performance of the remediation measures described above, we determined that the material weaknesses previously identified in our internal control over financial reporting had been remediated. Although we have determined that the previously identified material weaknesses have been remediated as of December 31, 2020, we cannot assure you that we will not identify other material weaknesses or deficiencies, which could negatively impact our results of operations in future periods. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. It is possible that, had our independent registered public accounting firm conducted an audit of our internal control over financial reporting, such firm might have identified additional material weaknesses and deficiencies.

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 local shelter-in-place orders and other governmental restrictions in the United States and certain international

locations during the year ended December 31, 2020. 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.

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)	
	2019	2020
Audit Fees[1]	—	2,150
Audit-related Fees [2]	—	16
Tax Fees[3]	—	—
All Other Fees[4]	—	—
Total	—	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, 2020, 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

Not applicable.

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.

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
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	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 29, 2020)
4.8*	Underwriting Agreement, dated as of June 5, 2020, by and among the Registrant and underwriters named therein.
8.1*	List of Principal Subsidiaries of the Registrant
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.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed as an exhibit hereto.

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 and Chief Financial Officer

Date: April 2, 2021

LEGEND BIOTECH CORPORATION

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Legend Biotech Corporation (the "Company") as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young Hua Ming LLP
We have served as the Company's auditor since 2020.
Shanghai, the People's Republic of China

April 2, 2021

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

	Notes	2020	2019	2018
		US$'000, except per share data	US$'000, except per share data	US$'000, except per share data
REVENUE	5	75,676	57,264	49,133
Other income and gains	5	6,119	7,125	13,901
Research and development expenses		(232,160)	(161,943)	(60,637)
Administrative expenses		(23,147)	(6,752)	(2,769)
Selling and distribution expenses		(49,571)	(25,620)	(1,160)
Other expenses		(346)	(221)	(2)
Fair value loss of convertible redeemable preferred shares		(79,984)	—	—
Finance costs	7	(4,209)	(223)	(82)
LOSS BEFORE TAX	6	(307,622)	(130,370)	(1,616)
Income tax credit/(expense)	8	4,145	(2,602)	(1,168)
LOSS FOR THE YEAR		(303,477)	(132,972)	(2,784)
Attributable to:				
Equity holders of the parent		(303,477)	(132,972)	(2,784)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	9			
Basic		(1.28)	(0.66)	(0.01)
Diluted		(1.28)	(0.66)	(0.01)
OTHER COMPREHENSIVE (LOSS)/INCOME				
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:				
Exchange differences:				
Exchange differences on translation of foreign operations		(2,142)	182	(1,437)
Net other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods		(2,142)	182	(1,437)
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR, NET OF TAX		(2,142)	182	(1,437)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(305,619)	(132,790)	(4,221)
Attributable to:				
Equity holders of the parent		(305,619)	(132,790)	(4,221)

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
AS AT DECEMBER 31, 2020 AND 2019

	Notes	December 31, 2020	December 31, 2019
		US$'000	US$'000
NON-CURRENT ASSETS			
Property, plant and equipment	10	113,091	70,079
Advance payments for property, plant and equipment		224	665
Right-of-use assets	13	8,009	9,348
Deferred tax assets	22	—	—
Other non-current assets	12	3,973	—
Intangible assets	11	2,852	519
Total non-current assets		128,149	80,611
CURRENT ASSETS			
Inventories	15	1,800	1,157
Trade receivables	16	74,978	29,991
Prepayments, other receivables and other assets	17	10,007	16,777
Pledged short-term deposits	18	384	256
Time deposits	18	50,000	75,559
Cash and cash equivalents	18	455,689	83,364
Total current assets		592,858	207,104
Total assets		721,007	287,715
CURRENT LIABILITIES			
Trade and notes payables	19	5,238	9,586
Other payables and accruals	20	99,168	70,854
Government grants	23	283	—
Lease liabilities	13	1,464	1,027
Contract liabilities	21	55,014	46,294
Total current liabilities		161,167	127,761
NON-CURRENT LIABILITIES			
Contract liabilities	21	275,071	277,765
Lease liabilities	13	1,909	5,058
Other non-current liabilities		554	—
Government grants	23	2,051	—
Total non-current liabilities		279,585	282,823
Total liabilities		440,752	410,584
EQUITY			
Share capital	24	27	20
Reserves/(deficits)	27	280,228	(122,889)
Total ordinary shareholders' equity/(deficit)		280,255	(122,869)
Total equity/(deficit)		280,255	(122,869)
Total liabilities and equity		721,007	287,715

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

	Attributable to equity holders of the parent					
	Share capital	Share premium*	Share-based compensation reserves*	Foreign currency translation reserve*	Retained earnings/ (accumulated losses)*	Total equity/(deficit)
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
As January 1, 2018	20	3,908 *	— *	(236) *	8,474 *	12,166
Loss for the year	—	—	—	—	(2,784)	(2,784)
Other comprehensive loss:						
Exchange differences on translation of foreign operations	—	—	—	(1,437)	—	(1,437)
Total comprehensive loss for the year	—	—	—	**(1,437)**	**(2,784)**	**(4,221)**
Equity-settled share option arrangements	—	—	704	—	—	704
As December 31, 2018	**20**	**3,908** *	**704** *	**(1,673)** *	**5,690** *	**8,649**
Loss for the year	—	—	—	—	(132,972)	(132,972)
Other comprehensive income:						
Exchange differences on translation of foreign operations	—	—	—	182	—	182
Total comprehensive loss for the year	—	—	—	**182**	**(132,972)**	**(132,790)**
Equity-settled share option arrangements	—	—	1,272	—	—	1,272
As December 31, 2019	**20**	**3,908** *	**1,976** *	**(1,491)** *	**(127,282)** *	**(122,869)**
Loss for the year	—	—	—	—	(303,477)	(303,477)
Other comprehensive loss:						
Exchange differences on translation of foreign operations	—	—	—	(2,142)	—	(2,142)
Total comprehensive loss for the year	—	—	—	**(2,142)**	**(303,477)**	**(305,619)**
Conversion of convertible redeemable preferred shares to ordinary shares	2	240,432	—	—	—	**240,434**
Issuance of ordinary shares for initial public offering, net of issurance 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 December 31, 2020	**27**	**708,306** *	**6,314** *	**(3,633)** *	**(430,759)** *	**280,255**

* These reserve accounts comprise the consolidated reserves/(deficits) of US$280,228,000 and US$(122,889,000) in the consolidated statements of financial position as at December 31, 2020 and December 31, 2019, respectively.

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

	Notes	2020	2019	2018
		US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss before tax		(307,622)	(130,370)	(1,616)
Adjustments for:				
Finance income	5	(2,930)	(4,581)	(6,214)
Finance costs	7	4,209	223	82
Provision for/ (reversal of) for the impairment of trade receivables	16	13	1	(60)
Depreciation of property, plant and equipment	10	8,248	4,001	845
Loss on disposal of property, plant and equipment	6	55	—	—
Amortisation of intangible assets	11	192	63	15
Depreciation of right-of-use assets	13	1,493	1,198	823
Fair value loss of convertible redeemable preferred shares		79,984	—	—
Fair value gains on financial assets at fair value change through profit or loss	5	(47)	(474)	(89)
Foreign currency exchange gain, net	5	(66)	(250)	(7,237)
Equity-settled share-based compensation expense		4,760	1,272	704
Deferred government grant	23	(114)	—	—
		(211,825)	(128,917)	(12,747)
Decrease/(Increase) in trade receivables		(45,000)	(3,771)	207,606
Decrease/(Increase) in prepayments, other receivables and other assets		3,366	(3,928)	(2,507)
Increase in other non-current assets		(3,973)	—	—
Increase in inventories		(643)	(22)	(1,124)
Government grant received	23	2,452	—	—
(Decrease)/increase in trade and notes payables		(4,348)	2,011	3,239
Increase in other payables and accruals		20,230	31,727	18,310
Increase in other non-current liabilities		554	—	—
Increase in contract liabilities		6,026	26,466	93,183
Increase of pledged short-term deposits, net		(128)	—	—
Cash (used in) /from operations		(233,289)	(76,434)	305,960
Income tax paid		(278)	(15,432)	—
Finance income received		3,366	9,024	1,804
Interest on loan from related party		—	(24)	—
Income tax received		7,391	—	—
Interest on lease payments		(195)	(199)	(82)
Net cash flow (used in)/from operating activities		(223,005)	(83,065)	307,682

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, 2020, 2019 AND 2018

	Note	2020	2019	2018
		US$'000	US$'000	US$'000
Net cash flows (used in)/from operating activities		(223,005)	(83,065)	307,682
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property, plant and equipment		(45,747)	(38,636)	(20,958)
Purchase of intangible assets		(4,029)	(534)	(63)
Purchase of financial assets at fair value through profit or loss		(22,682)	(314,840)	(6,000)
Cash received from withdrawal of financial assets at fair value through profit or loss		22,682	320,854	—
Cash receipts of investment income		47	—	—
Cash advances to related parties	30	—	(13,006)	(86,943)
Collection of cash advances to related parties	30	—	62,996	11,943
Proceeds from disposal of items of property, plant and equipment		1	74	20
Addition of short-term time deposits		(50,000)	(75,559)	—
Decrease in short-term deposits		75,559	—	—
Addition of pledged short-term deposits		—	(256)	(255)
Decrease in pledged short-term deposits		—	255	—
Net cash flows used in investing activities		(24,169)	(58,652)	(102,256)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from cash advances from related parties	30	—	38,945	35,939
Repayment of cash advances from related parties	30	(4)	(19,223)	(33,219)
Proceeds from loans from related parties	30	—	2,867	—
Repayments of loans from related parties	30	—	(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 exercise of share option		1,464	—	—
Payments of expenses for issuance of convertible redeemable preferred shares		(2,514)	—	—
Principal portion of lease payments		(2,602)	(5,056)	(219)
Net cash flows from financing activities		618,879	14,666	2,501
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		371,705	(127,051)	207,927
Effect of foreign exchange rate changes, net		620	249	124
Cash and cash equivalents at beginning of year	18	83,364	210,166	2,115
CASH AND CASH EQUIVALENTS AT END OF YEAR	18	455,689	83,364	210,166
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances		506,073	159,179	210,421
Less: Pledged short-term deposits		384	256	255
Time deposits		50,000	75,559	—
Cash and cash equivalents as stated in the statement of financial position	18	455,689	83,364	210,166
Cash and cash equivalents as stated in the statement of cash flows		455,689	83,364	210,166

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	—	100	—	Investment holding
Legend Biotech HK Limited ("Legend HK")	Hong Kong June 3, 2015	—	—	100	Investment holding
Nanjing Legend Biotechnology Co., Ltd. ("Legend Nanjing")	PRC November 17, 2014	US$ 62,500,000	—	100	Manufacture and sale of life science research products and services
Legend Biotech USA Incorporated ("Legend USA")	United States of America August 31, 2017	—	—	100	Manufacture and sale of life science research products and services
Legend Biotech Ireland Limited. ("Legend Ireland")	Ireland November 13, 2017	—	—	100	Manufacture and sale of life science research products and services
Legend Biotech (Netherlands) B.V. ("Legend Netherlands")	Netherlands June 12, 2017	—	—	100	Sale of life science research products

2.1 BASIS OF PREPARATION

The consolidated financial statements of the Company and its subsidiaries (collectively referred to as the "Group") have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board (the "IASB"), which comprise all standards and interpretations

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.

2.1 BASIS OF PREPARATION (CONTINUED)

Basis of consolidation

The consolidated financial statements include the financial statements of the Group for the years ended December 31, 2020. 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 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

Amendments to IFRS 3	Definition of a Business
Amendments to IFRS 9, IAS 39 and IFRS 7	Interest Rate Benchmark Reform
Amendment to IFRS 16	Covid-19-Related Rent Concessions (early adopted)
Amendments to IAS 1 and IAS 8	Definition of Material

2.3 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[2]
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform - Phase 2[1]
Amendments to IFRS 10 and IAS 28 (2011)	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[4]
IFRS 17	Insurance Contracts[3]
Amendments to IFRS 17	Insurance Contracts[3, 5]
Amendments to IAS 1	Classification of Liabilities as Current or Non-current[3, 5]
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use[2]
Amendments to IAS 37	Onerous Contracts - Cost of Fulfilling a Contract[2]
Annual Improvements to IFRSs 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41[2]

1 Effective for annual periods beginning on or after 1 January 2021
2 Effective for annual periods beginning on or after 1 January 2022
3 Effective for annual periods beginning on or after 1 January 2023
4 No mandatory effective date yet determined but available for adoption
5 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 1 January 2023

The Group is currently accessing 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures its financial assets at fair value through profit or loss at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Fair value measurement (continued)

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than contract assets and financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

(a) the party is a person or a close member of that person's family and that person

  (i) has control or joint control over the Group;

  (ii) has significant influence over the Group; or

  (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Related parties (continued)

(b) the party is an entity where any of the following conditions applies:

(i) the entity and the Group are members of the same group;

(ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

(iii) the entity and the Group are joint ventures of the same third party;

(iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;

(v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;

(vi) the entity is controlled or jointly controlled by a person identified in (a);

(vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and

(viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost (or valuation) less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets as follows:

Freehold land	Not depreciated
Buildings	2% to 2.6%
Machinery and equipment	10% to 25%
Computer and office equipment	20% to 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 recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Property, plant and equipment and depreciation (continued)

Construction in progress represents equipment under installation, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of installation. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

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

Software	3-10 years

Research and development costs

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

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

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Leases (continued)

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Leasehold land	50 years
Buildings	2 to 10 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(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 recognised as an expense on a straight-line basis over the lease term.

Group as a lessor

When the Group acts as a lessor, it classifies at lease inception (or when there is a lease modification) each of its leases as either an operating lease or a finance lease.

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. Rental income is accounted for on a straight-line basis over the lease terms and is included in revenue in the statement of profit or loss due to its operating nature. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised over the lease term on the same basis as rental income.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for "Revenue recognition" below.

In order for a financial asset to be classified and measured at amortised cost, it needs to give rise to cash flows that are solely payments of principal and interest ("SPPI") on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in the statement of profit or loss.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a "pass-through" arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses ("ECLs") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Impairment of financial assets (continued)

General approach (continued)

Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs.

Simplified approach

For trade receivables and contract assets that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables, and lease liabilities.

Subsequent measurement

Financial liabilities at amortised cost (Loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the first-in, first-out basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have an original maturity of three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group’s cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

Income tax

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

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Income tax (continued)

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- where the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the end of the reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, 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 over the expected useful life of the relevant asset by equal annual instalments.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) License and collaboration revenue

The Group enters into a license and collaboration agreement for research, development, manufacturing and commercialization services with one customer. The terms of the arrangement include: non-refundable upfront fees of US$350 million, milestone payments for the achievement of specified manufacturing milestones, specified development milestones, specified regulatory milestones and specified net trade sales milestones of US$125 million, US$215 million, US$800 million and US$210 million. Milestone payment is a form of variable consideration which is included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The contracts generally do not include a significant financing component.

As part of the accounting for this arrangement, the Group must use significant judgement to determine: (a) the performance obligations; and (b) the method to estimate variable consideration.

At contract inception, the Group assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct.

The Group uses judgement to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. Upon contract inception, the Group has estimated that the total transaction price is constrained to US$400 million which included upfront fees of US$350 million and milestone payments of US$50 million. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Group recognizes revenue as or when the performance obligations under the contract are satisfied. If a milestone or other variable consideration relates specifically to the Group’s efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Group generally allocates that milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Revenue recognition (continued)

Revenue from contracts with customers (continued)

(a) License and collaboration revenue (continued)

The Group recognizes revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria.

- The counterparty simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs.
- The Group's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.
- The Group's performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

The portion of the transaction price that is allocated to performance obligations satisfied at a point in time is recognized as revenue when control of the goods or services is transferred to the counterparty. If the performance obligation is satisfied over time, the portion of the transaction price allocated to that performance obligation is recognized as revenue as the performance obligation is satisfied. The Group adopts an appropriate method of measuring progress for purposes of recognizing revenue. The Group evaluates the measure of progress at the end of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront fees

Upfront payment is allocated to the performance obligations based on the Group's best estimate of their relative stand-alone selling prices. The upfront fees of US$350 million was included in the transaction price upon contract inception in 2017 and fully received by the Group in 2018.

Milestone payments

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

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Revenue recognition (continued)

Revenue from contracts with customers (continued)

(a) License and collaboration revenue (continued)

Milestone payments (continued)

The initial two milestone payments of US$50 million were included in the transaction price at contract inception in 2017. Subsequently in 2019, an additional two 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. At December 31, 2020, the Group is eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones and an additional $1,040 million, consisting of $105 million for the achievement of specified future development milestones, $725 million for the achievement of specified regulatory milestones and $210 million for the achievement of specified net trade sales milestones. The Company accessed that achievement of the remaining milestones 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.

Licenses of intellectual property

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

Steering committee services

In assessing whether the preparation and participation in a Joint Steering Committee which leads to the commercialization of a new drug (“JSC service”) is a promised service in the arrangement, the Group concluded that the services are capable of being distinct from the intellectual property licenses and distinct within the context of the contract based on a careful evaluation of the specific facts and circumstances. It was determined that the largest portion of the transaction price should be allocated to the JSC service as the Group is responsible for a significant portion of the development work prior to commercialization. The performance obligation is satisfied over time as services are rendered. Revenue from JSC service is recognized on a straight-line basis over the period when the JSC service is provided.

Pursuant to the license and collaboration agreement, both the Group and the customer jointly perform research and development activities and share the related costs. The research and development activities conducted by the Company are included within the JSC service performance obligation and are a significant input to the JSC service to achieve commercialisation of the new drug. Therefore, performing such research and development activities under the arrangement is not considered a distinct performance obligation.

(b) Rendering of services

The Group render research and development services to customers by delivering research report. Revenue is recognized at the point in time when the research report is delivered and accepted by the customers.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Revenue recognition (continued)

Revenue from contracts with customers (continued)

(c) Sale of goods

Revenue from the sale of goods is recognised at the point in time when control of the goods is transferred to the customer, generally on delivery of the goods.

Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Dividend income is recognised when the shareholders' right to receive payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

Contract assets

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

Contract liabilities

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

Share-based payments

The Group operates a share option scheme and a restricted stock unit scheme ("RSU 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 note 25 and note 26 to the consolidated financial statements.

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

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Share-based payments (continued)

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect of outstanding options 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 subsidiary which operates in Mainland China are required to participate in a central pension scheme operated by the local municipal government. This subsidiary is required to contribute certain percentage of its payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

Foreign currencies

These consolidated financial statements are presented in United States dollars, which is the Company's functional currency. Each entity in the Group determines its own functional currency and items included in the consolidated financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss.

Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss with the exception of monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognised in other comprehensive income until the net investment is disposed of, at which time the cumulative amount is reclassified to the statement of profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Foreign currencies (continued)

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of certain subsidiaries established in the PRC and Europe are currencies other than the United States dollar. As at the end of the reporting period, the assets and liabilities of these entities are translated into United States dollars at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into United States dollars at the weighted average exchange rates for the year.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the foreign currency translation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

For the purpose of the consolidated statements of cash flows, the cash flows of the subsidiaries established in the PRC and Europe are translated into United States dollars at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of the companies established in the PRC and Europe which arise throughout the year are translated into United States dollars at the weighted average exchange rates for the year.

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

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, 2020, 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

Judgement

In the process of applying the Group's accounting policies, management has made the following judgement, apart from those involving estimations, which has the most significant effect on the amounts recognised in the consolidated financial statements:

Revenue from contracts with customers

The Group has applied the following judgements that significantly affect the determination of the performance obligations and the method to estimate variable consideration of revenue from contracts with customers:

(i) Determining the performance obligations of the contract

A good or service that is promised to a customer is distinct if both of the following criteria are met: (a) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (b) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Group determined that both license and JSC service are each capable of being distinct. In assessing whether each item has standalone value to the customer, the Group considers factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace, which indicates that the customer can benefit from both license and service on their own. The Group also determined that the promises to transfer the license and to provide JSC service are distinct within the context of the contract. The license is separately identifiable in the contract and will be granted at contract inception. The license is not an input that will be integrated with the service which represents a combined output. The preparation and attendance of the various steering committees is to assist in conducting clinical trials and obtaining regulatory approval of the technology, but does not modify the technology itself. In addition, the license and JSC service are not highly interdependent or highly interrelated, because the delivery of license is not dependent on the service to be provided in the future, and accordingly, it is not interdependent or interrelated with the service.

In determining whether the license transfers to a customer either at a point in time or over time, the Group considers whether the nature of the Group's promise in granting the license to a customer is to provide a right to access or a right to use the Group's intellectual property. The Group assessed that the Group provides a right to use the license as the license exists (in terms of form and functionality) at a point in time at which it is granted. The license is already developed and has positive results on cancer patient candidates. The next step is to perform clinical trials again in a controlled and monitored environment.

The Group has allocated the transaction price to license and JSC service based on relative standalone selling prices. The standalone selling prices are not directly observable, and therefore, the Group estimates it using income approach for license and expected cost plus margin approach for JSC service with the assistance of an independent third-party valuer. The Group has considered all information that is reasonably available, including but not limited to, third-party or industry pricing, costs incurred to provide the good or service, related profit margins.

(ii) Determining the method to estimate variable consideration

Certain contract includes milestone payment that give rise to variable consideration. In estimating the variable consideration, the Group is required to use either the expected value method or the most likely amount 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.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (CONTINUED)

Judgement (continued)

Revenue from contracts with customers (continued)

(ii) Determining the method to estimate variable consideration (continued)

Before including any amount of variable consideration in the transaction price, the Group considers whether the amount of variable consideration is constrained. The Group evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each reporting period. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Deferred tax assets

Deferred tax assets are recognised for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses and deductible temporary differences can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies. The outcome of their actual utilisation may be different. The amount of unrecognised deferred tax assets for deductible temporary differences and unused tax losses as at December 31, 2020, and 2019 was US$102,615,000 and US$46,717,000, respectively. Further details are contained in note 8 to the consolidated financial statements.

Share-based compensation

The fair value of share options granted by the Group is estimated using the binomial model. The use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Management estimates expected volatility based on the historical volatility of the stock of comparable companies. Expiration date is the basis for determining the expected life of an option. The risk-free interest rate is based on treasury yield curve rates with a remaining term which approximates to the expected life assumed at the date of grant. Changes in these input variables would affect the amount of expense associated with share-based compensation. The compensation expense recognised for all share-based awards is net of estimated 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, 2020, 2019 and 2018, the equity-settled share option expense was US$1,905,000, US$1,272,000 and US $704,000 respectively. Further details are contained in note 25 to the consolidated financial statements.

4. OPERATING SEGMENT INFORMATION

IFRS 8 *Operating Segments* requires operating segments to be identified on the basis of internal reporting about components of the Group that are regularly reviewed by the chief operating decision-maker in order to allocate resources to segments and to assess their performance. The information reported to the directors of the Company, who are the chief operating decision makers, for the purposes of resource allocation and assessment of performance does not contain discrete operation segment financial information and the directors reviewed the financial results of the Group as a whole. Therefore, no further information on the operating segment is presented.

Geographic information

(a) Revenue from external customers

	2020	2019	2018
	US$'000	US$'000	US$'000
North America	75,676	57,261	48,104
China	—	3	1,029
Total	75,676	57,264	49,133

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

(b) Non-current assets

	December 31, 2020	December 31, 2019
	US$'000	US$'000
China	43,953	27,731
Other countries	84,196	52,880
Total	128,149	80,611

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

Information about major customer

Revenue of US$ 75,676,000, US$57,261,000 and US$48,104,000 for the years ended December 31, 2020, 2019 and 2018, respectively, was derived from sales to a single customer.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2020	2019	2018
	US$'000	US$'000	US$'000
Revenue from contracts with customer			
Rendering of services	—	—	1,029
Sales of goods	—	3	—
License and collaboration revenue			
- Licensing of intellectual property	5,625	4,523	7,570
- JSC service	70,051	52,738	40,534
	75,676	57,264	49,133

5. REVENUE, OTHER INCOME AND GAINS (CONTINUED)

Revenue from the rendering of services, sales of goods and licensing of intellectual property is recognized at a point in time. The non-U.S. territories license amount of US$7.6 million was recognized in 2018 by Legend Ireland. Revenue from licensing of intellectual property in 2018 represents revenue recognized for the right to use the license in non-US territories, which was transferred in 2018 when the customer is able to use and benefit from the license. Revenue from licensing of intellectual property in 2019 represents variable consideration relating to the milestone payments which were constrained in prior years but included in the transaction price in 2019 when the milestones were highly probable achieved. At inception, the amount allocated to licensing of intellectual property was US$30 million for both U.S. and non-U.S. territories, which was updated to US$40.2 million as at December 2020.

Revenue from JSC service is recognized overtime. Transaction price allocated to JSC service is recognized as revenue on straight-line basis over the service period, which is estimated to be 9 years, starting from the point when the license is transferred and JSC activities are initiated. At inception the amount allocated to JSC service was US$370 million for both U.S. and non-U.S. territories, which was updated to US$494.8 million as at December 2020.

The following table shows the amounts of revenue recognized in the current reporting period that were included in the contract liabilities at the beginning of the reporting period and recognized from performance obligations satisfied in previous periods:

	2020 US$'000	2019 US$'000	2018 US$'000
Revenue recognized that was included in contract liabilities at the beginning of the reporting period:			
License and collaboration revenue			
- JSC service	46,777	40,324	30,212

	2020 US$'000	2019 US$'000	2018 US$'000
Revenue recognized from performance obligation satisfied in previous periods:			
License and collaboration revenue			
- Licensing of intellectual property	5,625	4,523	—
- JSC service	15,591	6,334	—
	21,216	10,857	—

Performance obligations

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at December 31, 2020, 2019 and 2018 are as follows:

	December 31, 2020 US$'000	December 31, 2019 US$'000	December 31, 2018 US$'000
Amounts expected to be recognized as revenue:			
Within 1 year	55,014	46,294	40,324
1 - 2 years	55,014	46,294	40,324
2 - 3 years	55,014	46,294	40,324
3 - 4 years	55,014	46,294	40,324
After 4 years	110,029	138,883	160,935
	330,085	324,059	322,231

5. REVENUE, OTHER INCOME AND GAINS (CONTINUED)

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue relate to JSC service, of which the performance obligations are to be satisfied over the collaboration period, which is estimated to be 9 years. The amounts disclosed above do not include variable consideration which is constrained.

	2020	2019	2018
	US$'000	US$'000	US$'000
Other income and gains			
Foreign currency exchange gain, net	66	250	7,237
Government grants (note 23)	3,072	1,682	361
Finance income	2,930	4,581	6,214
Fair value gains on financial assets at fair value change through profit or loss	47	474	89
Rental income	4	138	—
	6,119	7,125	13,901

6. LOSS BEFORE TAX

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

	Notes	2020	2019	2018
		US$'000	US$'000	US$'000
Loss on disposal of property, plant and equipment		55	—	—
Provision for/(reversal of) the impairment of trade receivables, net	16	13	1	(60)
IPO expenses		1,439	—	—
Employee benefit expense (excluding directors' remuneration):				
Wages and salaries		70,682	37,038	12,039
Pension scheme contributions (defined contribution schemes)		640	1,166	416
Equity-settled share-based compensation expense		4,357	1,272	704

7. FINANCE COSTS

	2020	2019	2018
	US$'000	US$'000	US$'000
Interest on lease liabilities	195	199	82
Interest on an entrusted loan from a related party	—	24	—
Expenses for issuance of convertible redeemable preferred shares	4,014	—	—
Total	4,209	223	82

8. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains.

British Virgin Islands

Under the current laws of the British Virgin Islands ("BVI"), Legend Biotech Limited ("Legend BVI") is not subject to tax on income or capital gains. Additionally, upon payments of dividends by the Group's subsidiaries incorporated in the British Virgin Islands to their shareholders, no withholding tax will be imposed.

Hong Kong

Under the current laws of Hong Kong, the subsidiary which operates in Hong Kong is subject to a corporate income tax ("CIT") at a rate of 16.5% on the taxable income. Under the Hong Kong tax law, the subsidiaries in Hong Kong are exempted from income tax on their foreign derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

United States of America

Under the current laws of the United States of America ("USA"), the subsidiary which operates in the United States of America is subject to federal tax at a rate of 21% and state tax at a rate of 11.5% in New Jersey. Dividends payable by the Group's US entity, to non US resident enterprises shall be subject to 30% withholding tax, unless the respective non US resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with US that provides for a reduced withholding tax rate or an exemption from withholding tax.

Ireland

Under the current laws of the Ireland, the subsidiary which operates in Ireland is subject to CIT at a rate of 12.5% on the taxable income. Dividend withholding tax is imposed on distributions made by Irish companies at a rate of 20% with many exemptions provided.

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income. During the years ended December 31, 2020, 2019 and 2018, 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.

8. INCOME TAX (CONTINUED)

Netherlands

Under the current laws of Netherlands, the subsidiary which operates in Netherlands is subject to CIT at a rate of 25% on the taxable income. A tax rate of 16.5% (2019: 19% and 2018: 20%) applies to the first EUR200,000 of taxable income. The statutory withholding tax rate for dividends is 15% while several exemptions and reductions can apply.

	2020 US$'000	2019 US$'000	2018 US$'000
Current – United States of America	(3,613)	(65,948)	64,312
Current – Elsewhere	(532)	(371)	913
Deferred (note 22)	—	68,921	(64,057)
Total tax charge for the year	(4,145)	2,602	1,168

A reconciliation of the tax expense applicable to loss before tax at the statutory rates for the countries (or jurisdictions) in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates is as follows:

	2020 US$'000	%	2019 US$'000	%	2018 US$'000	%
Loss before tax	(307,622)		(130,370)		(1,616)	
At the statutory blended income tax rate of 30.1% (2019 and 2018: 30.1%)	(92,548)	30.1	(39,222)	30.1	(486)	30.1
Effect of tax rate differences in other countries	38,012	(12.4)	6,395	(4.9)	(605)	37.4
Research and development credit	(6,451)	2.1	(3,746)	2.9	(2,341)	144.9
Statutory income/expense	—	—	—	—	46.0	(2.9)
Effect of non-deductible expenses	1,817	(0.6)	188	(0.1)	112	(6.9)
Tax losses and deductible temporary differences not recognized	55,898	(18.2)	44,844	(34.5)	1,462	(90.5)
Option income tax benefit	(1,331)	0.4	—	—	—	—
Prior year true up	658	(0.2)	(6,598)	5.1	(76)	4.7
Uncertain tax positions	(272)	0.1	272	(0.2)	3,056	(189.1)
Withholding tax on interest	278	(0.1)	393	(0.3)	—	—
Others	(206)	0.1	76	(0.1)	—	—
Tax (benefit)/charge at the Group's effective rate	(4,145)	1.3	2,602	(2.0)	1,168	(72.3)

9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 236,305,234, 200,000,000 and 200,000,000 in issue during the years 2020, 2019 and 2018, 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, 2020, 2019 and 2018 in respect of a dilution as the impact of the outstanding share options and restricted stock units 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:

	2020	2019	2018
	US$'000	US$'000	US$'000
Earnings			
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(303,477)	(132,972)	(2,784)
	Number of shares		
	2020	2019	2018
Shares			
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	236,305,234	200,000,000	200,000,000

10. PROPERTY, PLANT AND EQUIPMENT

	Freehold land	Buildings	Machinery and equipment	Computer and office equipment	Transportation equipment	Construction in progress	Total
	US'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2020							
At January 1, 2020							
Cost	2,889	32,527	27,992	1,314	42	10,136	74,900
Accumulated depreciation	—	(1,534)	(2,940)	(341)	(6)	—	(4,821)
Net carrying amount	2,889	30,993	25,052	973	36	10,136	70,079
At January 1, 2020, net of accumulated depreciation	2,889	30,993	25,052	973	36	10,136	70,079
Additions	—	—	—	560	—	49,497	50,057
Disposals	—	—	(165)	—	—	—	(165)
Depreciation provided during the year	—	(2,560)	(4,593)	(1,091)	(4)	—	(8,248)
Exchange realignment	—	375	775	12	2	204	1,368
Transfers from construction in progress	—	12,929	8,459	1,422	—	(22,810)	—
At December 31, 2020, net of accumulated depreciation	2,889	41,737	29,528	1,876	34	37,027	113,091
At December 31, 2020:							
Cost	2,889	45,831	37,400	3,308	44	37,027	126,499
Accumulated depreciation	—	(4,094)	(7,872)	(1,432)	(10)	—	(13,408)
Net carrying amount	2,889	41,737	29,528	1,876	34	37,027	113,091

10. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

	Freehold land	Buildings	Machinery and equipment	Computer and office equipment	Transportation equipment	Construction in progress	Total
	US'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2019							
At January 1, 2019							
Cost	—	127	4,217	367	43	24,335	29,089
Accumulated depreciation	—	(30)	(830)	(73)	(1)	—	(934)
Net carrying amount	—	97	3,387	294	42	24,335	28,155
At January 1, 2019, net of accumulated depreciation	—	97	3,387	294	42	24,335	28,155
Additions	2,889	9,476	1,586	53	—	32,310	46,314
Disposals	—	—	(74)	—	—	—	(74)
Depreciation provided during the year	—	(1,505)	(2,219)	(273)	(4)	—	(4,001)
Exchange realignment	—	(77)	(70)	(4)	(2)	(162)	(315)
Transfers from construction in progress	—	23,002	22,442	903	0	(46,347)	—
At December 31, 2019, net of accumulated depreciation	2,889	30,993	25,052	973	36	10,136	70,079
At December 31, 2019:							
Cost	2,889	32,527	27,992	1,314	42	10,136	74,900
Accumulated depreciation	—	(1,534)	(2,940)	(341)	(6)	—	(4,821)
Net carrying amount	2,889	30,993	25,052	973	36	10,136	70,079

During the years ended December 31, 2020 and 2019, the additions of property, plant and equipment included the charge from a customer under a license and collaboration agreement amounting to US$13,663,000 and US$19,765,000 , respectively.

11. INTANGIBLE ASSETS

	Software US$'000
December 31, 2020	
At January 1, 2020	
Cost	598
Accumulated amortisation	(79)
Net carrying amount	519
At January 1, 2020, net of accumulated amortisation	519
Additions	2,583
Amortisation provided during the year	(192)
Exchange realignment	(58)
At December 31, 2020, net of accumulated amortisation	2,852
At December 31, 2020	
Cost	3,186
Accumulated amortisation	(334)
Net carrying amount	2,852
December 31, 2019	
At January 1, 2019	
Cost	67
Accumulated amortization	(18)
Net carrying amount	49
At January 1, 2019, net of accumulated amortisation	49
Additions	534
Amortisation provided during the year	(63)
Exchange realignment	(1)
At December 31, 2019, net of accumulated amortisation	519
At December 31, 2019	
Cost	598
Accumulated amortisation	(79)
Net carrying amount	519

12. OTHER NON-CURRENT ASSETS

	December 31, 2020 US$'000	December 31, 2019 US$'000
VAT recoverable	3,542	—
Prepayments	431	—
	3,973	—

13. LEASES

The Group as a lessee

The Group has lease contracts for land and buildings. Leases of buildings (including car park spaces) generally have lease terms between 2 and 10 years. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these land leases. Other buildings and rooms generally have lease terms of 12 months 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.

(a) Right-of-use assets

The carrying amounts of the Group's right-of-use assets and the movements during the year are as follows:

	Prepaid land lease payments	Buildings	Total
	US$'000	US$'000	US$'000
December 31, 2020			
Right-of-use assets at January 1, 2020, net of accumulated depreciation	4,630	4,718	9,348
Increase	—	491	491
Lease modification	—	(928)	(928)
Exchange realignment	318	273	591
Depreciation of right-of-use assets	(97)	(1,396)	(1,493)
At December 31, 2020	4,851	3,158	8,009
December 31, 2019			
Right-of-use assets at January 1, 2019, net of accumulated depreciation	—	3,733	3,733
Additions	4,677	2,163	6,840
Exchange realignment	—	(27)	(27)
Depreciation of right-of-use assets	(47)	(1,151)	(1,198)
At December 31, 2019	4,630	4,718	9,348

13. LEASES (CONTINUED)

The Group as a lessee (continued)

(b) Lease liabilities

Lease liabilities are as indicated below:

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term.

	2020 US$'000	2019 US$'000
Carrying amount at January 1	6,085	4,317
Increase	491	6,840
Lease modification	(928)	—
Accretion of interest recognised during the year	195	199
Payments	(2,797)	(5,255)
Exchange realignment	327	(16)
Carrying amount at December 31	3,373	6,085
Analyzed into:		
Current portion	1,464	1,027
Non-current portion	1,909	5,058
	3,373	6,085

	2020 US$'000	2019 US$'000
Interest on lease liabilities	195	199
Depreciation charge of right-of-use assets	1,493	1,198
Expense relating to short-term leases	69	272
Total amount recognized in profit or loss	1,757	1,669

(c) The amounts recognised in profit or loss in relation to leases are as follows:

The maturity analysis of lease liabilities is disclosed in note 31 to the financial statements. The total cash outflow for leases is disclosed in note 28(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. Rental income recognised by the Group for the year ended December 31, 2020 was US$4,000 (2019: 138,000), details of which are included in note 5 to the financial statements.

At December 31, 2020 and 2019, the undiscounted minimum lease payments receivables by the Group in future periods under non-cancellable operating leases with its tenants are as follows:

	2020 US$'000	2019 US$'000
Within one year	4	16

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$160,450,000.

The key terms of the Series A Preference Shares are summarised 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.

14. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

(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.

The movement of the convertible redeemable preferred shares is set out as below:

	December 31, 2020
	US$'000
At January 1, 2020	—
Issuance of the Series A Preference Shares on March 30, 2020 and on April 16, 2020	160,450
Fair value loss of the Series A Preferred Shares	79,984
Conversion to ordinary shares	(240,434)
At December 31, 2020	—

15. INVENTORIES

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Raw materials and consumables	1,800	1,157

16. TRADE RECEIVABLES

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Trade receivables	75,000	30,000
Less: Impairment of trade receivables	(22)	(9)
	74,978	29,991

16. TRADE RECEIVABLES (CONTINUED)

The Group's trading terms with its customers are mainly on credit. The credit period is 30 to 90 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by management. Trade receivables are non-interest-bearing. The Group has concentration of credit risk as 100% and 100% of trade receivables were due from one single customer under a license and collaboration agreement as at December 31, 2020 and 2019, respectively.

Movements in the loss allowance for impairment of trade receivables were as follows:

	Total
	US$'000
At January 1, 2020	9
Impairment losses reversed	(9)
Impairment losses recognised	22
At December 31, 2020	22
At January 1, 2019	8
Impairment losses reversed	(8)
Impairment losses recognised	9
At December 31, 2019	9

The Group applies the simplified approach to providing for expected credit losses prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. The Group performed an impairment analysis at the end of each year by considering the probability of default of the debtors or comparable companies with published credit ratings.

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

	As at December 31, 2020		
	Gross carrying amount	Expected loss rate	Expected credit loss
	USD'000		USD'000
Within 3 months	75,000	0.03%	22

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

17. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Interest receivable	80	516
Other receivables	264	1,044
Income tax refund	4,267	—
Prepaid income tax	—	7,210
VAT recoverable	1,941	4,206
Prepayments	3,455	3,801
	10,007	16,777

As at December 31, 2020 and 2019, included in the Group's other receivables were amounts due from the Group's related parties that are repayable on demand of US$20,000 and US$291,000, respectively (note 30).

None of the above assets is either past due or impaired. The financial assets included in the above balances relate to receivables for which there was no recent history of default. The majority of the above balances were settled within 12 months and had no history of default. The Group estimated that the expected credit loss for the above receivables is insignificant.

18. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Cash and bank balances	506,073	159,179
Less: Pledged short-term deposits	(384)	(256)
Time deposits	(50,000)	(75,559)
Cash and cash equivalents	455,689	83,364
Denominated in USD	451,165	69,846
Denominated in RMB	4,335	13,180
Denominated in EUR	189	338
Cash and cash equivalents	455,689	83,364

The cash and bank balances of the Group denominated in Renminbi ("RMB") amounted to US$4,335,000 and US$13,180,000 in the consolidated statements of financial position as at December 31, 2020 and December 31, 2019, respectively. The RMB is not freely convertible into other currencies, however, under Mainland China's Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

The pledged deposit as at December 31, 2020 was pledged for issuing bank notes payables to suppliers of the Group and for credit card facilities. The pledged deposit as at December 31, 2019 was pledged for credit card facilities.

18. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS (CONTINUED)

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.

19. TRADE AND NOTES PAYABLES

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Trade payables	4,911	9,586
Notes payable	327	—
	5,238	9,586

The trade payables are non-interest-bearing and are normally settled on 60-day terms.

As at December 31, 2020 and 2019, included in the Group's trade payables were amounts due to the Group's related parties of US$2,103,000 and US$5,225,000, respectively (note 30).

20. OTHER PAYABLES AND ACCRUALS

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Accrued payroll	13,609	6,633
Other payables	85,559	64,221
	99,168	70,854

Other payables are non-interest-bearing and repayable on demand.

As at December 31, 2020 and 2019, included in the Group's other payables were amounts due to the Group's related parties of US$3,736,000 and US$1,544,000, respectively (note 30).

21. CONTRACT LIABILITIES

Details of contract liabilities are as follows:

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Advances received from customers		
License and collaboration revenue		
- JSC service	330,085	324,059
Current	55,014	46,294
Non-current	275,071	277,765

21. CONTRACT LIABILITIES (CONTINUED)

The movements in contract liabilities during the year are as follows:

	US$'000
At January 1, 2020	324,059
Advance received/due for payment	75,000
Transferred to revenue	(75,676)
Exchange realignment	6,702
At December 31, 2020	330,085
At January 1, 2019	297,593
Advance received/due for payment	85,217
Transferred to revenue	(57,261)
Exchange realignment	(1,490)
At December 31, 2019	324,059

Contract liabilities include advances received/due for payment under the license and collaboration agreement at the end of each year. The increase in contract liabilities in 2020 and 2019 was mainly due to the increase in milestone payments from a customer in relation to the agreement.

22. DEFERRED TAX

The movements in deferred tax assets during the year are as follows:

Deferred tax assets

	Amortized and accrued	Expense of share Options	Unrealised profit from intercompany	Contract liabilities	Losses available for offsetting against future taxable profits	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
At January 1, 2019	953	90	7,487	60,387	—	68,917
Deferred tax charged to the statement of profit or loss during the year	(953)	(90)	(7,487)	(60,391)	—	(68,921)
Exchange realignment	—	—	—	4	—	4
Gross deferred tax assets at December 31, 2019 and 2020	—	—	—	—	—	—

The Group has tax losses arising in Hong Kong of US$25,000 in 2020 (2019: US$919,000) 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$63,600,000 in 2020 (2019: US$30,766,000) that will expire in 5 years for offsetting against future taxable profits of the companies in which the losses arose.

The Group has tax losses arising in the Netherlands of US$12,000 in 2020 (2019: US$2,000) that can be carried back for 1 year and carried forward for 9 years for offsetting against taxable profits of the company.

22. DEFERRED TAX (CONTINUED)

The Group has tax losses arising in Ireland of US$47,412,000 in 2020 (2019: US$31,594,000) that can be carried back for 1 year and carried forward indefinitely for offsetting against taxable profits of the company.

The Group has tax losses arising in the United States of US$33,050,000 in 2020 (2019: US$57,792,000) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognized in respect of these tax losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

Deferred tax assets have not been recognised in respect of the following items:

	2020 US$'000	2019 US$'000
Deductible temporary differences	74,409	59,399
Tax losses	144,099	121,073
	218,508	180,472

Deferred income tax assets are recognised for tax losses carried-forward to the extent that realization of the related tax benefit through future taxable profits is probable. Deferred tax assets have not been recognized in respect of the above items as it is not considered probable that taxable profits will be available against which the above items can be utilized.

Pursuant to the PRC Corporate Income Tax Law, a 10% withholding tax is levied on dividends declared to foreign investors from the foreign investment enterprises established in Mainland China. The requirement is effective from January 1, 2008 and applies to earnings after December 31, 2007. A lower withholding tax rate may be applied if there is a tax treaty between Mainland China and the jurisdiction of the foreign investors. For the Group, the applicable rate is 10%. The Group is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in Mainland China in respect of earnings generated from January 1, 2008.

At December 31, 2020 and 2019, the subsidiary in Mainland China had no distributable retained earnings.

According to the US tax laws, dividends payable by the Group's US entity, to non-US resident enterprises shall be subject to 30% withholding tax. A lower withholding tax rate may be applied if there is a tax treaty between US and the jurisdiction of the foreign investors. For the Group, the applicable rate is 5%. The Group is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in US.

At December 31, 2020 and 2019, the subsidiary in US had no distributable retained earnings.

23. GOVERNMENT GRANTS

	2020	2019
	US$'000	US$'000
Deferred government grants	2,334	—
Current	283	—
Non-current	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.

24. SHARE CAPITAL AND SHARE PREMIUM

Shares

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Authorised:		
500,000,000 ordinary shares of US$0.0001 each	50	50
Issued and fully paid:		
266,010,256 (2019: 200,000,000) ordinary shares of US$0.0001 each	27	20

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 option	1,681,996	1	1,885	1,886
At December 31, 2020	266,010,256	27	708,306	708,333

25. 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:

	2020		2019		2018	
	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,	0.9273	18,013	0.7782	14,311	0.5000	8,100
Granted during the year	15.6128	679	1.4973	3,757	1.0000	7,990
Forfeited during the year	0.9963	(2,769)	1.0909	(55)	0.5073	(1,779)
Exercised during the year	1.0131	(1,682)	—	—	—	—
At December 31,	1.9353	14,241	0.9273	18,013	0.7782	14,311
Exercisable at December 31	1.0703	4,619	0.7852	2,484	—	—

25. SHARE OPTION SCHEME (CONTINUED)

The weighted average share price at the date of exercise for share options exercised during the year was $14.9131 per share (2019 and 2018: 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, 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		

December 31, 2018

Number of options '000	Exercise price* US$ per share	Exercise period
6,347	0.5	2019/12/25 - 2027/12/25
7,288	1.0	2019/07/01 - 2028/08/29
676	1.0	2019/12/31 - 2028/12/30
14,311		

* 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 was US$6,666,000 (US$9.817 each) (2019: US$1,099,000, US$0.294 each; 2018: US$4,329,000, US$0.269 each). The Group recognised share option expense of US$1,905,000 (2019: US$1,272,000, 2018: US$704,000) during the year ended December 31, 2020.

25. SHARE OPTION SCHEME (CONTINUED)

The fair value of equity-settled share options granted during the period was estimated, using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used:

	2020	2019	2018
Dividend yield (%)	—	—	—
Expected volatility (%)	73.0-87.2	66.4-80.3	64.2-66.4
Risk-free interest rate (%)	0.07-0.91	1.98-2.69	2.48-2.87
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$15.6128 used in the share option fair value valuation model during the year ended December 31, 2020.

As at December 31, 2020, the Company had 14,241,000 share options outstanding under the Scheme. The exercise in full of the outstanding share options would, under the present capital structure of the Company, result in the issue of 14,241,000 additional ordinary shares of the Company, an additional share capital of US$1,424 and a share premium of US$23,122,000 (before issue expenses).

26. 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 2020, 2019 and 2018 was as follow:

	2020	
	Number of RSU	Weighted average grant date fair value
	’000	US$ per unit
Outstanding at January 1	—	—
Granted during the year	1,139	15.3639
Forfeited during the year	(26)	16.3350
Outstanding at December 31	1,113	15.3409

The weighted-average remaining contractual life for outstanding RSUs granted under the RSU Scheme was 8.84 years as of December 31, 2020.

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$17,497,000 (US$15.364 each), of which the Group recognised a RSU expense of US$2,855,000 during the year ended 31 December 2020.

27. RESERVES

The amounts of the Group's reserves and the movements therein for the current and prior years are presented in the consolidated statement of changes in equity on page F-5 of the consolidated financial statements.

The foreign currency translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of operations with a functional currency other than US$.

Under PRC laws and regulations, there are restrictions on the Company's PRC subsidiaries with respect to transferring certain of their net assets to the Company either in the form of dividends, loans, or advances. Amounts of net assets restricted include paid in capital and statutory reserve funds of the Company's PRC subsidiary and the net assets, totaling US$26.0 million and US$24.0 million as at December 31, 2020 and 2019, respectively.

28. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

(a) Major non-cash transactions

For the years ended December 31, 2020, 2019 and 2018, the Group had non-cash additions to right-of-use assets of US$491,000, US$2,163,000 and US$4,280,000, and lease liabilities of US$491,000, US$ 2,163,000 and US$4,280,000, in respect of lease arrangements for buildings, respectively.

For the years ended December 31, 2019 and 2018, the Group had non-cash additions to property, plant and equipment of US$8,945,000 and US$7,280,000, respectively.

For the year ended December 31, 2019, Genscript Biotech Corporation utilized the balance due from the Group to settle the balance due to Genscript USA Incorporated in the amount of US$4,364,000.

For the year ended December 31, 2019, Genscript Biotech Corporation and Genscript USA Incorporated utilized the outstanding balance due from the Group to settle part of the outstanding balance due to the Group of US$19,510,000 and US$5,539,000, respectively.

For the year ended December 31, 2020, the Group had non-cash additions to finance costs of US$1,500,000 and other payable of US$1,500,000, 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 $79,984,000 of convertible redeemable preferred shares.

28. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS (CONTINUED)

(b) Changes in liabilities arising from financing activities

	Convertible redeemable preferred shares	Other payables to related parties	Lease liabilities
		US$'000	US$'000
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 28(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
At January 1, 2018	—	1,968	269
Additions of lease liabilities	—	—	4,280
Changes from financing cash flows	—	2,720	(219)
Interest expense	—	—	82
Interest paid classified as operating cash flows	—	—	(82)
Foreign exchange movement	—	—	(13)
At December 31, 2018	—	4,688	4,317

28. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS (CONTINUED)

(c) Total cash outflow for leases

The total cash outflow for leases included in the statement of cash flows is as follows:

	2020 US$'000	2019 US$'000	2018 US$'000
Right-of-use assets			
Within operating activities	195	199	82
Within financing activities	2,602	5,056	219
Short-term leases	69	272	—
	2,866	5,527	301

29. CAPITAL COMMITMENTS

The Group had the following capital commitments at the end of the year:

	2020 US$'000	2019 US$'000	2018 US$'000
Construction in progress	33,637	2,844	2,628

30. RELATED PARTY TRANSACTIONS

Company	Relationship
Nanjing Jinsirui Biotechnology Co., Ltd.	Company controlled by the ultimate holding company
Jinsikang Technology (Nanjing) Co., Ltd.	Company controlled by the ultimate holding company
Nanjing Bestzyme Bioengineering Co., Ltd.	Company controlled by the ultimate holding company
Shanghai Jingrui Biotechnology Co., Ltd.	Company controlled by the ultimate holding company
Jiangsu Genscript Biotech Co., Ltd	Company controlled by the ultimate holding company
Genscript (HongKong) Ltd.	Company controlled by the ultimate holding company
Genscript USA Incorporated	Company controlled by the ultimate holding company
Genscript USA Holdings Inc	Company controlled by the ultimate holding company
Genscript Biotech (Netherlands) B.V.	Company controlled by the ultimate holding company
Yangtze Investment USA Inc.	Company controlled by the ultimate holding company
Genscript Biotech Corporation	Company controlled by the ultimate holding company

(a) In addition to the transactions detailed elsewhere in these consolidated financial statements, the Group had the following transactions with related parties during the year:

(i) Services provided to related parties:

	2020 US$'000	2019 US$'000	2018 US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	—	—	1,029

30. RELATED PARTY TRANSACTIONS (CONTINUED)

(a) In addition to the transactions detailed elsewhere in these consolidated financial statements, the Group had the following transactions with related parties during the year (continued):

(ii) Sales of materials to related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	—	3	—

The terms of these services and materials were charged based on the prices agreed by both parties.

(iii) Purchases from related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	4,162	4,480	2,500
Genscript USA Incorporated	424	296	191
Shanghai Jingrui Biotechnology Co., Ltd.	—	—	18
Jiangsu Genscript Biotech Co., Ltd	41	198	2
Genscript USA Holdings Inc	—	4	—
Genscript Biotech (Netherlands) B.V.	7	—	—
	4,634	4,978	2,711

The transactions were made according to the published prices and conditions offered by related parties to their major customers.

(iv) Management fee:

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	—	—	511
Genscript (HongKong) Ltd	59	—	—
Genscript USA Incorporated	95	198	222
	154	198	733

The management fee was charged by related parties based on the cost of services provided.

(v) Shared services:

During the years ended December 31, 2020, 2019 and 2018, Nanjing Jinsirui Biotechnology Co., Ltd. provided certain accounting, legal, IT and administrative shared services to the Group for a consideration of 3,298,000, US$2,121,000 and nil, respectively.

(vi) Short term lease of properties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	—	265	—

The lease was made according to the contractual price and the lease term is 12 months.

30. RELATED PARTY TRANSACTIONS (CONTINUED)

(a) In addition to the transactions detailed elsewhere in these consolidated financial statements, the Group had the following transactions with related parties during the year (continued):

(vii) Cash advances from related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	28,199	—
Nanjing Jinsirui Biotechnology Co., Ltd.	—	2,168	21,735
Genscript USA Incorporated	—	8,000	14,200
Jinsikang Technology (Nanjing) Co., Ltd.	—	578	—
Genscript (HongKong) Ltd.	—	—	4
	—	38,945	35,939

(viii) Repayment of cash advances from related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	4,335	—
Nanjing Jinsirui Biotechnology Co., Ltd.	—	6,310	19,019
Genscript USA Incorporated	—	8,000	14,200
Jinsikang Technology (Nanjing) Co., Ltd.	—	578	—
Genscript (HongKong) Ltd.	4	—	—
	4	19,223	33,219

(ix) Cash advances to related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	13,006	55,000
Genscript USA Incorporated	—	—	20,000
Jinsikang Technology (Nanjing) Co., Ltd.	—	—	1,493
Nanjing Bestzyme Bioengineering Co., Ltd.	—	—	10,450
	—	13,006	86,943

(x) Collection of cash advances to related parties:

	2020	2019	2018
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	48,496	—
Genscript USA Incorporated	—	14,500	—
Jinsikang Technology (Nanjing) Co., Ltd.	—	—	1,493
Nanjing Bestzyme Bioengineering Co., Ltd.	—	—	10,450
	—	62,996	11,943

The above cash advances from/to related parties were unsecured, interest free and repayable on demand.

30. RELATED PARTY TRANSACTIONS (CONTINUED)

(a) In addition to the transactions detailed elsewhere in these consolidated financial statements, the Group had the following transactions with related parties during the year (continued):

(xi) Entrusted loan from a related party:

	2020	2019	2018
	US$'000	US$'000	US$'000
Jinsikang Technology (Nanjing) Co., Ltd.	—	2,867	—

(xii) Repayments of entrusted loan from a related party:

	2020	2019	2018
	US$'000	US$'000	US$'000
Jinsikang Technology (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.

(xiii) Purchase of equipment

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	54	7	14

(xiv) Sale of equipment

	2020	2019	2018
	US$'000	US$'000	US$'000
Nanjing Jinsirui Biotechnology Co., Ltd.	—	13	12

The sale or purchase of equipment was made at their respective carrying values.

(b) Outstanding balances with related parties:

The Group had the following significant balances with its related parties at the end of the year:

(i) Due from related parties

	December 31, 2020	December 31, 2019
	US$'000	US$'000
Other receivables		
Yangtze Investment USA Inc.	—	20
Genscript USA Incorporated	6	93
Nanjing Jinsirui Biotechnology Co., Ltd.	14	178
	20	291

30. RELATED PARTY TRANSACTIONS (CONTINUED)

(b) Outstanding balances with related parties (continued):

(ii) Due to related parties

	December 31, 2020 US$'000	December 31, 2019 US$'000
Trade payables		
Nanjing Jinsirui Biotechnology Co., Ltd.	1,547	4,109
Genscript USA Incorporated	555	1,097
Jiangsu Genscript Biotech Co., Ltd	1	15
Genscript USA Holdings Inc	—	4
	2,103	5,225

	December 31, 2020 US$'000	December 31, 2019 US$'000
Other payables		
Nanjing Jinsirui Biotechnology Co., Ltd.	3,736	—
Genscript USA Incorporated	—	1,006
Genscript (HongKong) Ltd.	—	538
	3,736	1,544

	December 31, 2020 US$'000	December 31, 2019 US$'000
Lease liabilities		
Genscript USA Holdings Inc	582	2,114
Nanjing Jinsirui Biotechnology Co., Ltd.	351	1,303
	933	3,417

Except for lease liabilities with incremental borrowing rates between 2.00% and 7.28% repayable over 5 years, all other related party balances are unsecured and repayable on demand.

(c) Compensation of key management personnel of the Group:

	2020 US$'000	2019 US$'000	2018 US$'000
Short-term employee benefits	1,733	1,036	692
Equity-settled share-based compensation expense	529	590	210
Termination payment	774	—	—
Total compensation paid to key management personnel	3,036	1,626	902

31. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the reporting periods are as follows:

As at December 31, 2020

Financial assets

	Financial assets at amortised cost
	US$'000
Trade receivables	74,978
Financial assets included in prepayments, other receivables and other assets (note 17)	344
Time deposits	50,000
Pledged deposits	384
Cash and cash equivalents	455,689
	581,395

Financial liabilities

	Financial liabilities at amortised cost
	US$'000
Trade and notes payables	5,238
Financial liabilities included in other payables and accruals (note 20)	85,559
Lease liabilities	3,373
	94,170

As at December 31, 2019

Financial assets

	Financial assets at amortised cost
	US$'000
Trade receivables	29,991
Financial assets included in prepayments, other receivables and other assets (note 17)	1,560
Time deposits	75,559
Pledged deposits	256
Cash and cash equivalents	83,364
	190,730

31. FINANCIAL INSTRUMENTS BY CATEGORY (CONTINUED)

Financial liabilities

	Financial liabilities at amortised cost
	US$'000
Trade and notes payables	9,586
Financial liabilities included in other payables and accruals (note 20)	64,221
Lease liabilities	6,085
	79,892

32. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

As at December 31, 2020, 2019 and 2018, the fair values of the Group's financial assets or liabilities approximated to their respective carrying amounts.

Management has assessed that the fair values of cash and cash equivalents, pledged deposits, time deposits, financial assets included in prepayments, other receivables and other assets, trade receivables, trade and notes payables and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group's finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the finance manager. At each reporting date, the finance department analyzed the movements in the values of financial instruments and determined the major inputs applied in the valuation. The valuation was reviewed and approved by the finance manager. The valuation process and results are discussed with the directors once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

During the years ended December 31, 2020, 2019 and 2018, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and liabilities.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise cash and cash equivalents, pledged deposits, time deposits, financial assets at fair value through profit or loss, prepayments, other receivables and other assets, and financial liabilities included in other payables and accruals. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade receivables and trade and notes payables, which arise directly from its operations.

The main risks arising from the Group's financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

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 15% in 2020 (2019 and 2018: 22% and 39%) of the Group's sales were denominated in currencies other than the functional currencies of the operating units making the sale.

As at December 31, 2020, 2019 and 2018, 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$'000
Year ended December 31, 2020		
If US$ 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)
Year ended December 31, 2018		
If US$ strengthens against RMB	5	343
If US$ weakens against RMB	(5)	(343)
If US$ strengthens against EUR	5	3,829
If US$ weakens against EUR	(5)	(3,829)

Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group's policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group's exposure to bad debts is not significant. For transactions that are not denominated in the functional currency of the relevant operating unit, the Group does not offer credit terms without the specific approval of the Head of Credit Control.

The credit risk of the Group's other financial assets, which comprise cash and cash equivalents, pledged deposits, financial assets at fair value through profit or loss and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments. Further quantitative data in respect of the Group's exposure to credit risk arising from trade receivables and other receivables are disclosed in notes 16 and 17 to the consolidated financial statements, respectively.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

Credit risk (continued)

Since the Group trades only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by debtor. The Group had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 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, 2020

	Less than 1 years US$'000	Over 1 years US$'000	Total US$'000
Trade and notes payables	5,238	—	5,238
Other payables and accruals	85,559	—	85,559
Lease liabilities	1,464	2,099	3,563
	92,261	2,099	94,360

As at December 31, 2019

	Less than 1 years US$'000	Over 1 years US$'000	Total US$'000
Trade and notes payables	9,586	—	9,586
Other payables and accruals	64,221	—	64,221
Lease liabilities	1,027	5,860	6,887
	74,834	5,860	80,694

Capital management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain a strong credit rating and healthy capital ratios in order to support its business and maximise shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the reporting periods.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

Capital management (continued)

The Group monitors capital using a gearing ratio, which is total liabilities divided by total assets. The gearing ratios as at the end of each year were as follows:

	December 31, 2020 US$'000	December 31, 2019 US$'000
Total liabilities	440,752	410,584
Total assets	721,007	287,715
Gearing ratio	61%	143%

34. APPROVAL OF THE CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements were approved and authorised for issue by the board of directors on April 2, 2021.

Exhibit 2.5

Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act

As of December 31, 2020, Legend Biotech Corporation (the "Company," "we," "us" and "our") had the following series of securities registered pursuant to Section 12 of the Exchange 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.

Description of Ordinary Shares

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 by the Cayman Islands.

According to our amended and restated memorandum and articles of association (adopted by a Special Resolution passed on May 26, 2020), our authorized share capital is $200,000 divided into 2,000,000,000 shares, of which (i) 1,999,000,000 are designated as ordinary shares of a par value of $0.0001 each and (ii) 1,000,000 of such class or classes (however designated) of shares, par value $0.0001 each, as our board of directors may determine in accordance with our amended and restated memorandum and articles of association. All of our issued and outstanding ordinary shares are fully paid.

As of December 31, 2020, we had 266,010,256 ordinary shares issued and outstanding.

Each American Depositary Share, ADS, represents two ordinary shares, par value $0.0001 per share.

Preemptive Rights

Our shareholders do not have preemptive purchase rights.

Limitations, Qualifications, and Differences Between Classes of Shares

Our board of directors may, without further action by our shareholders, fix the rights, preferences, privileges, and restrictions of up to an aggregate of 1,000,000 other shares, including preference shares, in one or more classes or series and authorize their issuance. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our ordinary shares. The issuance of our other shares, including potentially preference shares, could adversely affect the voting power of holders of ADSs and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of other shares, including preference shares, could have the effect of delaying, deferring, or preventing a change of control or other corporate action. We have no present plan to issue any preference shares.

Rights of Other Types of Securities

Not applicable.

Rights of Ordinary Shares

The following are 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.

Objects of Our Company. Under our amended and restated memorandum and articles of association, the objects of our company are unrestricted and we have the full power and authority to carry out any object not prohibited by the law of the Cayman Islands.

Ordinary Shares. Our ordinary shares are issued in registered form and are issued when registered in our register of shareholders. We may not issue shares to bearer. Our shareholders who are nonresidents of the Cayman Islands may freely hold and vote their shares.

Dividends. The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our amended memorandum and restated articles of association provide that the directors may, before recommending or declaring any dividend, set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall, in the absolute discretion of the directors, be applicable for meeting contingencies or for equalizing dividends or for any other purpose to which those funds may be properly applied. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or the credit standing in our company's share premium account, provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid.

Voting Rights. Holders of our ordinary shares shall be entitled to one vote per ordinary share. Voting at any shareholders' meeting is by show of hands unless a poll is demanded (before or on the declaration of the result of the show of hands). A poll may be demanded by the chairman of such meeting or any one or more shareholders who together hold not less than 10% of the votes attaching to the total ordinary shares which are present in person or by proxy at the meeting.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the outstanding ordinary shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our amended and restated memorandum and articles of association. Holders of the ordinary shares may, among other things, divide or combine their shares by ordinary resolution.

General Meetings of Shareholders. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our amended and restated memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by a majority of our board of directors. Advance notice of at least ten calendar days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. A quorum required for any general meeting of shareholders consists of at least one shareholder present or by proxy, representing not less than one-third of all votes attaching to all of our shares in issue and entitled to vote.

The Companies Act provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated memorandum and articles of association provide that upon the requisition of shareholders representing in aggregate not less than one-third of the votes attaching to the issued and outstanding shares of our company entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting.

Shareholders seeking to bring business before the annual general meeting or to nominate candidates for election to our board of directors at the annual general meeting are required to deliver notice not later than the 90th day nor earlier than the 120th day prior to the scheduled date of the annual general meeting.

Liquidation. On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay the whole of the share capital, the assets will be distributed so that the losses are borne by our shareholders in proportion to the par value of the shares held by them.

Calls on Shares and Forfeiture of Shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders at least 14 days prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Shares. The shares of our ordinary shares are not subject to redemption by operation of a sinking fund or otherwise. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined by our board of directors. We may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Act, the redemption or repurchase of any share may be paid out of our profits or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

Inspection of Books and Records. Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our corporate records (except for the memorandum and articles of association of our company, any special resolutions passed by our company and the register of mortgages and charges of our company). However, we will provide our shareholders with annual audited financial statements.

Exempted Company. We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Transfer of Ordinary Shares

Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as The Nasdaq Global Select Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within three months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of The Nasdaq Select Global Market, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

Variations of Rights of Shares

If at any time our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound-up, may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking pari passu with such existing class of shares.

Issuance of Additional Shares

Our amended and restated memorandum of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our amended and restated memorandum of association also authorizes our board of directors to establish from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including:

- the designation of the series;

- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights;
- the rights and terms of redemption and liquidation preferences; and
- any other powers, preferences and relative, participating, optional and other special rights.

Our board of directors may issue preference shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Anti-Takeover Provisions

Some provisions of our amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares without any further vote or action by our shareholders; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our amended and restated memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Differences in Corporate Law

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and accordingly there are significant differences between the Companies Act and the current Companies Act of England. In addition, the Companies Act differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements. The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (i) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (ii) a "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (a) a special resolution of the shareholders of each constituent company, and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose a company is a "parent" of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provide the dissenting shareholder complies strictly with the procedures set out in the Companies Act. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Act also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of schemes of arrangement, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act.

The Companies Act also contains a statutory power of compulsory acquisition which may facilitate the "squeeze out" of dissentient minority shareholder upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares affected within four months, the offeror may, within a two-month period commencing on the expiration of such four month period, require the holders of the remaining shares to transfer such shares to the offeror on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' Suits. In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company, and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands court can be expected to follow and apply the common law principles (namely the rule in Foss v. Harbottle and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Indemnification of Directors and Executive Officers and Limitation of Liability. Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our amended and restated memorandum and articles of association.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Directors' Fiduciary Duties. Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party, and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder Action by Written Resolution. Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Our amended and restated articles of association provide that no action shall be taken by the shareholders except at an annual or extraordinary general meeting called in accordance with our amended and restated articles of association and no action shall be taken by the shareholders by written consent or electronic transmission.

Shareholder Proposals. Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing

documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Companies Act provides shareholders with only limited rights to requisition a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated articles of association allow our shareholders holding in aggregate not less than one-third of all votes attaching to the issued and outstanding shares of our company entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. As an exempted Cayman Islands company, we may but are not obliged by law to call shareholders' annual general meetings. See "-Our Amended and Restated Memorandum and Articles of Association-General Meetings of Shareholders" for more information on the rights of our shareholders' rights to put proposals before the annual general meeting.

Cumulative Voting. Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled for a single director, which increases the shareholder's voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands but our amended and restated articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

Removal of Directors. Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our amended and restated articles of association, directors may be removed only for cause by an ordinary resolution of our shareholders. In addition, a director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his office by notice in writing to the company; (iv) without special leave of absence from our board of directors, is absent from three consecutive meetings of the board and the board resolves that his office be vacated; or (v) is removed from office pursuant to any other provisions of our amended and restated memorandum and articles of association.

Transactions with Interested Shareholders. The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

Dissolution; Winding up. Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Act and our amended and restated articles of association, our company may be dissolved, liquidated or wound up by a special resolution of our shareholders.

Variation of Rights of Shares. Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our amended and restated articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the written consent of the holders of two-thirds of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

Amendment of Governing Documents. Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under the Companies Act and our amended and restated memorandum and articles of association, our memorandum and articles of association may only be amended by a special resolution of our shareholders.

Rights of Non-resident or Foreign Shareholders

There are no limitations imposed by our amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

History of Securities Issuances

The following is a summary of the events that have changed the number of our share capital since January 1, 2017.

- On October 19, 2017, we issued an aggregate of 169,680,000 ordinary shares to GenScript Biotech Corporation.
- On October 19, 2017, we issued an aggregate of 30,320,000 ordinary shares to AquaPoint L.P.
- From January 1, 2017 to December 31, 2017, we issued options to purchase an aggregate of 8,100,000 ordinary shares to employees with an exercise price of $0.50.
- From January 1, 2018 to December 31, 2018, we issued options to purchase an aggregate of 7,990,000 ordinary shares to employees with an exercise price of $1.00.
- From January 1, 2019 to December 31, 2019, we issued options to purchase an aggregate of 20,000 ordinary shares to employees with an exercise price of $1.00 , options to purchase an aggregate of 3,235,000 ordinary shares to employees with an exercise price of $1.50, options to purchase an aggregate of 502,000 ordinary shares to employees with an exercise price of $11.50.
- On March 30, 2020, we issued 19,308,262 Series A Preference Shares to new investors for aggregate gross proceeds of $150.5 million.
- On April 16, 2020, we issued 1,283,367 Series A Preference Shares to a new investor for aggregate gross proceeds of $10.0 million.
- On June 9, 2020, we issued 1,043,478 ordinary shares to GenScript for aggregate gross proceeds of $12.0 million.
- On June 9, 2020, we issued 21,188,750 ADSs, representing 42,377,500 ordinary shares, in our initial public offering for aggregate gross proceeds of $487.3 million.

- From January 1, 2020 to December 31, 2020, we issued options to purchase an aggregate of 90,000ordinary shares to employees with an exercise price of $11.5, options to purchase an aggregate of 569,000 ordinary shares to employees with an exercise price of $ 16.335, options to purchase an aggregate of 20,000 ordinary shares to employees with an exercise price of $ 13.575, and restricted stock units representing 1,138,863 ordinary shares.

Options

As of December 31, 2020, there were options to purchase 14,241,404 ordinary shares outstanding with a weighted average exercise price of $1.9353 per ordinary share. The options generally lapse after 10 years from date of grant.

Restricted Stock Units

As of December 31, 2020, there were restricted stock units outstanding representing 1,112,457ordinary shares upon vesting.

Registration Rights

Holders of the 20,591,629 ordinary shares, which we refer to as registrable securities, or their transferees are entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act pursuant to an investors' rights agreement by and among us and certain of our shareholders, until such shares can otherwise be sold without restriction under Rule 144, or until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of our ordinary shares as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

If the holders of a majority of the registrable securities request in writing that we effect a registration with respect to at least 40% of such registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed $30.0 million), we may be required to register their ordinary shares. We are obligated to effect at most two registrations in response to these demand registration rights.

If at any time after we become entitled under the Securities Act to register securities on a registration statement on Form F-3, 20% of the holders of the registrable securities then outstanding request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least $10.0 million, we will be required to file such registration statement within 45 days after the date of such request; provided, however, that we will not be required to effect such a registration if, within any twelve-month period, we have already effected two registrations on Form F-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Ordinarily, other than selling expenses, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of our counsel; and reasonable fees and disbursements of a counsel for the selling holders up to $80,000.

The registration rights terminate upon the earliest of (i) the closing of a liquidation event, as defined in our second amended and restated articles of association, or, with respect to the registration rights of an individual holder, (ii) when the holder can sell all of such holder's registrable securities in a three-month period without restriction under Rule 144 under the Securities Act or (iii) upon the fifth anniversary of the closing of our initial public offering.

Listing

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

Debt Securities

Not applicable.

Warrants and Rights

Not applicable.

Other Securities

Not applicable.

Description of American Depositary Shares

American Depositary Receipts

JPMorgan Chase Bank, N.A., or JPMorgan, as depositary, 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, under the deposit agreement among ourselves, the depositary, yourself as an ADR holder and all other ADR holders, and all beneficial owners of an interest in the ADSs evidenced by ADRs from time to time.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

The ADS to share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you.

A beneficial owner is any person or entity having a beneficial ownership interest ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner of ADSs is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the deposit agreement solely through the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner of ADSs and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive which reflect your ownership of ADSs.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an

ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder or beneficial owner, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Cayman Island law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder or of a beneficial owner. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the shares, you must rely on it to exercise the rights of a shareholder on your behalf.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to this annual report on Form 20-F. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the annual report and the attached deposit agreement on the SEC's website at http://www.sec.gov.

Share Dividends and Other Distributions

How will I receive dividends and other distributions on the shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Shares.* In the case of a distribution in shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such shares. Only whole ADSs will be issued. Any shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.

- *Rights to receive additional shares.* In the case of a distribution of rights to subscribe for additional shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:

  (i) sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or

  (ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

- *Other Distributions.* In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth in the "Depositary Receipt Sale and Purchase of Security" section of https://www.adr.com/Investors/FindOutAboutDRs, the location and contents of which the depositary shall be solely responsible for.

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit shares or evidence of rights to receive shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance.

Shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of JPMorgan Chase Bank, N.A., as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited shares for the account and to the order of the depositary, in each case for the benefit of ADR holders. ADR holders and beneficial owners thus have no direct ownership interest in the shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares. The deposited shares and any such additional items are referred to as "deposited securities."

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

Upon each deposit of shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Record Dates

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights at a meeting of holders of shares, or
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR,
- to receive any notice or to act in respect of other matters,

all subject to the provisions of the deposit agreement.

Voting Rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the shares which underlie your ADSs. As soon as practicable after receipt from us of notice of any meeting at which the holders of shares are entitled to vote, or of our solicitation of consents or proxies from holders of shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least 30 days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a "voting notice" stating (i) final information particular to such vote and meeting and any solicitation materials, (ii) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of Cayman Islands law, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder's ADRs and (iii) the manner in which such instructions may be given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder's name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders' instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders' ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

To the extent that (A) we have provided the depositary with at least 35 days' notice of the proposed meeting, (B) the voting notice will be received by all ADR holders and beneficial owners no less than 10 days prior to the date of the meeting and/or the cut-off date for the solicitation of consents, and (C) the depositary does not receive instructions on a particular agenda item from an ADR holder (including, without limitation, any entity or entities acting on behalf of the nominee for DTC) in a timely manner, such ADR holder shall be deemed, and in the deposit agreement the depositary is instructed to deem such ADR holder, to have instructed the depositary to give a discretionary proxy for such agenda item(s) to a person designated by us to vote the deposited securities represented by the ADSs for which actual instructions were not so given by all such ADR holders on such agenda item(s), provided that no such instruction shall be deemed given and no discretionary proxy shall be given unless (1) we inform the depositary in writing (and we agree to provide the depositary with such instruction promptly in writing) that (a) we wish such proxy to be given with respect to such agenda item(s), (b) there is no substantial opposition existing with respect to such agenda item(s) and (c) such agenda item(s), if approved, would not materially or adversely affect the rights of holders of shares, and (2) the depositary has obtained an opinion of counsel, in form and substance satisfactory to the depositary, confirming that (i) the granting of such discretionary proxy does not subject the depositary to any reporting obligations in the Cayman Islands, (ii) the granting of such proxy will not result in a violation of the laws, rules, regulations or permits of the Cayman Islands, (iii) the voting arrangement and deemed instruction as contemplated herein will be given effect under the laws, rules and regulations of the Cayman Islands, and (iv) the granting of such discretionary proxy will not under any circumstances result in the shares represented by the ADSs being treated as assets of the depositary under the laws, rules or regulations of the Cayman Islands.

The depositary may from time to time access information available to it to consider whether any of the circumstances described above exist, or request additional information from us in respect thereto. By taking any such action, the depositary shall not in any way be deemed or inferred to have been required, or have had any duty or responsibility (contractual or otherwise), to monitor or inquire whether any of the circumstances described above existed. In addition to the limitations provided for in the deposit agreement, ADR holders and beneficial owners are advised and agree that (a) the depositary will rely fully and exclusively on us to inform it of any of the circumstances set forth above, and (b) neither the depositary, the custodian nor any of their respective agents shall be obliged to inquire or investigate whether any of the circumstances described above exist and/or whether we

complied with our obligation to timely inform the depositary of such circumstances. Neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners (i) as a result of our failure to determine that any of the circumstances described above exist or our failure to timely notify the depositary of any such circumstances or (ii) if any agenda item which is approved at a meeting has, or is claimed to have, a material or adverse effect on the rights of holders of shares. Because there is no guarantee that ADR holders and beneficial owners will receive the notices described above with sufficient time to enable such ADR holders or beneficial owners to return any voting instructions to the depositary in a timely manner, ADR holders and beneficial owners may be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us in such circumstances, and neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners in such circumstances.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, regulation, or requirement of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of or solicitation of consents or proxies from holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such ADR holders with or otherwise publicizes to such ADR holders instructions on how to retrieve such materials or receive such materials upon request (*i.e.*, by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

We have advised the depositary that under Cayman Islands law and our constituent documents, each as in effect as of the date of the deposit agreement, voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands) demanded. In the event that voting on any resolution or matter is conducted on a show of hands basis in accordance with our constituent documents, the depositary will refrain from voting and the voting instructions received by the depositary from ADR holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by ADR holders or beneficial owners.

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and Other Communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and Expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, $5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, canceled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of U.S.$1.50 per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of U.S.$0.05 or less per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of U.S.$0.05 or less per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the $0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares, ADRs or deposited securities;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within JPMorgan Chase Bank, N.A., or the Bank, and/or its affiliates in order to enter into spot foreign exchange

transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to an foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosure" page (or successor page) of www.adr.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of an foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of Taxes

ADR holders or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, including, without limitation, any Chinese Enterprise Income Tax owing if the SAT Circular 82 issued by the SAT or any other circular, edict, order or ruling, as issued and as from time to time amended, is applied or otherwise, such tax or other governmental charge shall be paid by the ADR holder thereof to the depositary and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect of such tax or other governmental charge. Notwithstanding the depositary's right to seek payment from current and former beneficial owners, by holding or owning, or having held or owned, an ADR, the ADR holder thereof (and prior ADR holder thereof) acknowledges and agrees that the depositary has no obligation to seek payment of amounts owing from any current or former beneficial owner. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees or

charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, SWIFT, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders and beneficial owners a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

Any amendments or supplements which (i) are reasonably necessary (as agreed by us and the depositary) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act of 1933 or (b) the ADSs or shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADRs shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depositary's or our website or upon request from the depositary).

How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered ADR holders unless a successor depositary shall not be operating under the deposit agreement within 60 days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 60th day after our notice of removal was first provided to the depositary.

After the date so fixed for termination, (a) all direct registration ADRs shall cease to be eligible for the direct registration system and shall be considered ADRs issued on the ADR register maintained by the depositary and (b) the depositary shall use its reasonable efforts to ensure that the ADSs cease to be DTC eligible so that neither DTC nor any of its nominees shall thereafter be a registered holder of ADRs. At such time as the ADSs cease to be DTC eligible and/or neither DTC nor any of its nominees is a registered holder of ADRs, the depositary shall (a) instruct its custodian to deliver all shares to us along with a general stock power that refers to the names set forth on the ADR register maintained by the depositary and (b) provide us with a copy of the ADR register maintained by the depositary. Upon receipt of such shares and the ADR register maintained by the depositary, we have agreed to use our best efforts to issue to each registered ADR holder a Share certificate representing the Shares represented by the ADSs reflected on the ADR register maintained by the depositary in such registered ADR holder's name and to deliver such Share certificate to the registered ADR holder at the address set forth on the ADR register maintained by the depositary. After providing such instruction to the custodian and delivering a copy of the ADR register to us, the depositary and its agents will perform no further acts under the deposit agreement or the ADRs and shall cease to have any obligations under the deposit agreement and/or the ADRs.

Notwithstanding anything to the contrary, in connection with any such termination, the depositary may, in its sole discretion and without notice to us, establish an unsponsored American depositary share program (on such terms as the depositary may determine) for our shares and make available to ADR holders a means to withdraw the shares represented by the ADSs issued under the deposit agreement and to direct the deposit of such shares into such

unsponsored American depositary share program, subject, in each case, to receipt by the depositary, at its discretion, of the fees, charges and expenses provided for under the deposit agreement and the fees, charges and expenses applicable to the unsponsored American depositary share program.

Limitations on Obligations and Liability to ADR holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial or other ownership of, or interest in, any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, ourselves and our respective agents, provided, however, that no disclaimer of liability under the Securities Act of 1933 is intended by any of the limitations of liabilities provisions of the deposit agreement. The deposit agreement provides that each of us, the depositary and our respective agents will:

- incur or assume no liability (including, without limitation, to holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of the Cayman Islands, Hong Kong, the People's Republic of China, the United States or any other country or jurisdiction, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism, nationalization, expropriation, currency restrictions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, computer failure or circumstance beyond our, the depositary's or our respective agents' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- incur or assume no liability (including, without limitation, to holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;

- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve it in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be against all expense (including fees and disbursements of counsel) and liability be furnished as often as may be requested;
- not be liable (including, without limitation, to holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, any person presenting shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information and/or, in the case of the depositary, us; or
- may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADSs or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADSs or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the custodian having (i) committed fraud or willful misconduct in the provision of custodial services to the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide services such as, but not limited to, attendance at any meetings of security holders of issuers. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services. The depositary shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depositary has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of the Cayman Islands, Hong Kong, the People's Republic of China, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

Additionally, none of us, the depositary or the custodian shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depositary is under no obligation to provide the ADR

holders and beneficial owners, or any of them, with any information about our tax status. Neither we nor the depositary shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary. Neither the depositary nor any of its agents shall be liable for any indirect, special, punitive or consequential damages (including, without limitation, legal fees and expenses) or lost profits, in each case of any form incurred by any person or entity (including, without limitation holders or beneficial owners of ADRs and ADSs), whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each ADR holder and beneficial owner) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory). No provision of the deposit agreement or the ADRs is intended to constitute a waiver or limitation of any rights which an ADR holder or any beneficial owner may have under the Securities Act of 1933 or the Securities Exchange Act of 1934, to the extent applicable.

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADRs.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of, or interest in, deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof.

Books of Depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other ADR holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed at any time or from time to time, when deemed expedient by the depositary or, in the case of the issuance book portion of the ADR Register, when reasonably requested by the Company solely in order to enable the Company to comply with applicable law.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Appointment

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs,
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR or ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and
- acknowledge and agree that (i) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (ii) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (iii) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (iv) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us, ADR holders, beneficial owners and/or their respective affiliates may have interests, (v) nothing contained in the deposit agreement or any ADR(s) shall (A) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (B) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships or to account for any profit made or payment received in any such transactions or relationships, (vi) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (vii) notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

Governing Law

The deposit agreement, the ADSs and the ADRs are governed by and construed in accordance with the internal laws of the State of New York. In the deposit agreement, we have submitted to the non-exclusive jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may also be instituted by the depositary against us in any competent court in the Cayman Islands, Hong Kong, the People's Republic of China, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each irrevocably agree that any legal suit, action or proceeding against or involving ADR holders or beneficial owners brought by us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may be instituted in a state or federal court in New York, New York, irrevocably waive any objection which you may have to the laying of venue of any such proceeding, and irrevocably submit to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding. By holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each also irrevocably agree that any legal suit, action or proceeding against or involving the depositary brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York.

Notwithstanding the foregoing, (i) the depositary may, in its sole discretion, elect to institute any dispute, suit, action, controversy, claim or proceeding directly or indirectly based on, arising out of or relating to the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including without limitation

any question regarding its or their existence, validity, interpretation, performance or termination, against any other party or parties to the deposit agreement (including, without limitation, against ADR holders and beneficial owners of interests in ADSs), by having the matter referred to and finally resolved by an arbitration conducted under the terms described below, and (ii) the depositary may in its sole discretion require, by written notice to the relevant party or parties, that any dispute, suit, action, controversy, claim or proceeding against the depositary by any party or parties to the deposit agreement (including, without limitation, by ADR holders and beneficial owners of interests in ADSs) shall be referred to and finally settled by an arbitration conducted under the terms described below. Any such arbitration shall be conducted in the English language either in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association or in Hong Kong following the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL).

Jury Trial Waiver

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory), including any claim under the U.S. federal securities laws.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. The waiver to right to a jury trial in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depositary's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Exhibit 4.8

LEGEND BIOTECH CORPORATION

18,425,000 AMERICAN DEPOSITARY SHARES

REPRESENTING

36,850,000 ORDINARY SHARES, $0.0001 PAR VALUE PER SHARE

UNDERWRITING AGREEMENT

June 5, 2020

June 5, 2020

Morgan Stanley & Co. LLC
J.P. Morgan Securities LLC
Jefferies LLC
c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, New York 10036

c/o J.P. Morgan Securities LLC
383 Madison Avenue
New York, New York 10179

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

Legend Biotech Corporation, an exempted company incorporated in the Cayman Islands (the "**Company**"), proposes to issue and sell to the several Underwriters named in Schedule I hereto (the "**Underwriters**"), for whom Morgan Stanley & Co. LLC ("**Morgan Stanley**"), J.P. Morgan Securities LLC ("**J.P. Morgan**") and Jefferies LLC ("**Jefferies**") are acting as representatives (the "**Representatives**"), 18,425,000 American Depositary Shares representing 36,850,000 ordinary shares, $0.0001 par value per share (the "**Firm ADSs**").

The Company also proposes to issue and sell to the several Underwriters not more than an additional 2,763,750 American Depositary Shares representing 5,527,500 ordinary shares, $0.0001 par value per share (the "**Additional ADSs**"), if and to the extent that the Representatives shall have determined to exercise, on behalf of the Underwriters, the right to purchase such American Depositary Shares granted to the Underwriters in Section **Error! Reference source not found.** hereof. The Firm ADSs and the Additional ADSs are hereinafter collectively referred to as the "**ADSs**." The ordinary shares, $0.0001 par value per share, of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the "**Ordinary Shares**."

The ADSs are to be issued pursuant to a deposit agreement dated June 5, 2020 (the "**Deposit Agreement**") among the Company, JPMORGAN Chase Bank, N.A., as Depositary (the "**Depositary**"), and the owners and holders from time to time of the American Depositary Receipts (the "**ADRs**") issued by the Depositary and evidencing the ADSs. Each American Depositary Share will initially represent the right to receive two Ordinary Shares deposited pursuant to the Deposit Agreement.

The Company has filed with the Securities and Exchange Commission (the "**Commission**") a registration statement on Form F-1 (File No. 333-238232), including a preliminary prospectus, relating to the Ordinary Shares represented by the ADSs. The

registration statement, as amended at the time it becomes effective, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the "**Securities Act**"), is hereinafter referred to as the "**Registration Statement**"; the prospectus in the form first used to confirm sales of ADSs (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the "**Prospectus**." If the Company has filed an abbreviated registration statement to register additional ADSs pursuant to Rule 462(b) under the Securities Act (a "**Rule 462 Registration Statement**"), then any reference herein to the term "**Registration Statement**" shall be deemed to include such Rule 462 Registration Statement. The Company has filed a registration statement on Form F-6 (No. 333-238581) relating to the ADSs with the Commission (such registration statement on Form F-6, including all exhibits thereto, as amended at the time such registration statement becomes effective, being hereafter referred to as the "**ADS Registration Statement**"). The Company has also filed, in accordance with Section 12 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), a registration statement on Form 8-A (the "**Form 8-A Registration Statement**") to register the Ordinary Shares of the Company under Section 12(b) of the Exchange Act.

For purposes of this Underwriting Agreement (the "**Agreement**"), "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, "**preliminary prospectus**" shall mean each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted information pursuant to Rule 430A under the Securities Act that was used after such effectiveness and prior to the execution and delivery of this Agreement, "**Time of Sale Prospectus**" means the preliminary prospectus contained in the Registration Statement at the time of its effectiveness together with the documents and pricing information set forth in Schedule II hereto, and "**broadly available road show**" means a "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act that has been made available without restriction to any person. As used herein, the terms "Registration Statement," "preliminary prospectus," "Time of Sale Prospectus" and "Prospectus" shall include the documents, if any, incorporated by reference therein as of the date hereof.

1. *Representations and Warranties*. The Company represents and warrants to and agrees with each of the Underwriters that:

(a) Each of the Registration Statement and the ADS Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement or the ADS Registration Statement is in effect, and no proceedings for such purpose or pursuant to Section 8A under the Securities Act are pending before or, to the Company's knowledge, threatened by the Commission.

(b) (i) Each of the Registration Statement and the ADS Registration Statement , when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or

supplement, any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) each of the Registration Statement, the ADS Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will comply, as of the date of such amendment or supplement, in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the ADSs in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section **Error! Reference source not found.**), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, (iv) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus, as of its date, does not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, or as of the Closing Date and each Option Closing Date (as defined in Section 2), any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the representations and warranties set forth in this paragraph do not apply to statements or omissions in the Registration Statement, the Time of Sale Prospectus or the Prospectus based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives or on their behalf expressly for use therein, it being understood and agreed that the only such information is that described in Section 8(b).

(c) The Company is not an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies, or if filed after the effective date of this Agreement will comply when filed, in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule II hereto, and electronic road shows, if any, each furnished to the Underwriters before first use, the Company has not prepared, used or referred to, and will not, without the Representatives' prior consent, prepare, use or refer to, any free writing prospectus.

(d) The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own or lease its property and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction (to the extent the concept of good standing or an equivalent concept is applicable in such jurisdiction) in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing (to the extent the concept of good standing or an equivalent concept is applicable in such jurisdiction) would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(e) Each significant subsidiary (as such term is defined in Rule 1-02 of Regulation S-X under the Exchange Act) of the Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation (to the extent the concept of good standing or an equivalent concept is applicable in such jurisdiction), has the corporate power and authority to own or lease its property and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction (to the extent the concept of good standing or an equivalent concept is applicable in such jurisdiction) in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued shares of capital stock of each significant subsidiary (as such term is defined in Rule 1-02 of Regulation S-X under the Exchange Act) of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims, except to the extent that such liens, encumbrances, equity or claims would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(f) This Agreement has been duly authorized, executed and delivered by the Company.

(g) The Deposit Agreement has been duly authorized and, when executed and delivered by the Company and, assuming due authorization, execution and delivery by the Depositary, will constitute a valid and legally binding agreement of the Company, enforceable in accordance with its terms, subject, as to enforceability, to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles, and upon issuance by the Depositary of ADRs evidencing ADSs and the deposit of Ordinary Shares in

respect thereof in accordance with the provisions of the Deposit Agreement, such ADRs will be duly and validly issued and the persons in whose names the ADRs are registered will be entitled to the rights specified therein and in the Deposit Agreement; and the Deposit Agreement and the ADRs conform in all material respects to the descriptions thereof contained in each of the Time of Sale Prospectus and the Prospectus.

(h) The authorized share capital of the Company conforms as to legal matters in all material respects to the description thereof contained in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(i) The Ordinary Shares outstanding prior to the issuance of the Ordinary Shares represented by the ADSs to be sold pursuant to this Agreement have been duly authorized and are validly issued, fully paid and non-assessable.

(j) The Ordinary Shares represented by the ADSs to be sold pursuant to this Agreement have been duly authorized and, when issued, delivered and paid for in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Ordinary Shares will not be subject to any preemptive or similar rights that have not been validly waived.

(k) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement and the Deposit Agreement, and the issuance and sale of the ADSs and the deposit of the Ordinary Shares after the execution, delivery and performance of this Agreement and the Deposit Agreement, will not contravene any provision of (i) applicable law, (ii) the certificate of incorporation or memorandum and articles of association of the Company, (iii) any agreement or other instrument binding upon the Company or any of its subsidiaries that is material to the Company and its subsidiaries, taken as a whole, or (iv) any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company or any subsidiary, except that in the case of clauses (i), (iii) and (iv) above, where such contravention would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or on the power or ability of the Company to perform its obligations under this Agreement; and no consent, approval, authorization or order of, or qualification with, any governmental body, agency or court is required for the performance by the Company of its obligations under this Agreement, except such as has previously been obtained and such as may be required by the securities or Blue Sky laws of the various states or foreign jurisdictions or the rules and regulations of the Financial Industry Regulatory Authority ("**FINRA**") in connection with the offer and sale of the ADSs.

(l) There has not occurred any material adverse change, or any development involving a prospective material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company

and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus.

(m) There are no legal or governmental proceedings pending or, to the Company's knowledge, threatened to which the Company or any of its subsidiaries is a party or to which any of the properties of the Company or any of its subsidiaries is subject (i) other than proceedings accurately described in all material respects in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and proceedings that would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or a material adverse effect on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated by each of the Registration Statement, the Time of Sale Prospectus and the Prospectus or (ii) that are required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus and are not so described in all material respects; and there are no statutes, regulations, contracts or other documents to which the Company or any of its subsidiaries is subject or by which the Company or any of its subsidiaries is bound that are required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus or to be filed as exhibits to the Registration Statement that are not described in all material respects or filed as required.

(n) Each preliminary prospectus filed as part of the Registration Statement as originally filed or as part of any amendment thereto, or filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.

(o) The Company is not, and after giving effect to the offering and sale of the ADSs and the application of the proceeds thereof as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.

(p) The Company and each of its subsidiaries, taken as a whole, (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(q) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(r) Except as have been validly waived or complied with in connection with the issuance and sale of the ADSs contemplated hereby and as have been described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Ordinary Shares registered pursuant to the Registration Statement.

(s) (i) None of the Company or any of its subsidiaries or affiliates, or any director, officer or employee thereof, or, to the Company's knowledge, any agent or representative of the Company or of any of its subsidiaries or affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment, giving or receipt of money, property, gifts or anything else of value, directly or indirectly, to any government official (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) ("**Government Official**") in order to influence official action, or to any person in violation of any applicable anti-corruption laws; (ii) the Company and each of its subsidiaries and affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintained and will continue to maintain policies and procedures reasonably designed to promote and achieve compliance with such laws and with the representations and warranties contained herein; and (iii) neither the Company nor any of its subsidiaries will use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.

(t) The operations of the Company and each of its subsidiaries are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and each of its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations

or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(u) (i) None of the Company, any of its subsidiaries, or any director, officer, or employee thereof, or, to the Company's knowledge, any agent, affiliate or representative of the Company or any of its subsidiaries, is an individual or entity ("**Person**") that is, or is owned or controlled by one or more Persons that are:

(A) the subject of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "**Sanctions**"), or

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea and Syria).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions, except to the extent permitted for a Person required to comply with Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Company and each of its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory that at the time of the dealing or transaction is or was the subject of Sanctions, except to the extent permitted for a Person required to comply with Sanctions.

(v) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company and its subsidiaries, taken as a whole, have not incurred any material liability or obligation, direct or contingent, nor entered into

any material transaction; (ii) the Company has not purchased any of its outstanding share capital (except for acquisitions of share capital by the Company pursuant to agreements that permit the Company to repurchase such shares or in connection with the exercise of the Company's right of first refusal with respect to transfers of such shares upon the applicable party's termination of service to the Company), nor declared, paid or otherwise made any dividend or distribution of any kind on its share capital other than ordinary and customary dividends; and (iii) there has not been any material change in the share capital and/or capital stock (other than the exercise or forfeiture of equity awards outstanding on such respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, in each case granted pursuant to equity compensation plans described in the Registration Statement, the Time of Sale Prospectus and the Prospectus), short-term debt or long-term debt of the Company and its subsidiaries, taken as a whole.

(w) The Company and its subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property (other than intellectual property, which is covered by Section 1(x) below) owned by them which is material to the business of the Company and its subsidiaries, taken as a whole, in each case free and clear of all liens, encumbrances and defects except such as are described in the Registration Statement, the Time of Sale Prospectus and the Prospectus or such as do not materially diminish the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries; and any real property and buildings held under lease by the Company and its subsidiaries are held by them under valid, subsisting and, to the Company's knowledge, enforceable leases with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such property and buildings by the Company and its subsidiaries, taken as a whole, in each case except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(x) (i) The Company and its subsidiaries solely and exclusively own or have a license to all patents, inventions, copyrights, know how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names and all other intellectual property and similar proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing, as applicable) (collectively, "**Intellectual Property Rights**") used in, held for use in or reasonably necessary to the conduct of their businesses; (ii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity, scope or enforceability of any such Intellectual Property Rights and, to the Company's knowledge, the Intellectual Property Rights owned or controlled by, or licensed to, the Company or any of its subsidiaries are valid, subsisting and enforceable; (iii) neither the Company nor any of its subsidiaries has received any written notice alleging any infringement, misappropriation or other violation of

Intellectual Property Rights of any third party by the Company or any of its subsidiaries; (iv) to the Company's knowledge, no third party is infringing, misappropriating or otherwise violating, or has infringed, misappropriated or otherwise violated, any valid Intellectual Property Rights owned or in-licensed by the Company or any of its subsidiaries; (v) to the Company's knowledge, neither the Company nor any of its subsidiaries infringes, misappropriates or otherwise violates, or has infringed, misappropriated or otherwise violated, any valid Intellectual Property Rights of any third party; (vi) all employees or contractors engaged in the development of Intellectual Property Rights on behalf of the Company or any subsidiary of the Company have executed an invention assignment agreement whereby such employees or contractors presently assign all of their right, title and interest in and to such Intellectual Property Rights to the Company or the applicable subsidiary, and to the Company's knowledge no such agreement has been breached or violated; and (vii) the Company and its subsidiaries use, and have used, commercially reasonable efforts to appropriately maintain all information intended to be maintained as a trade secret.

(y) (i) The Company and its subsidiaries use and have used any and all software and other materials distributed under a "free," "open source," or similar licensing model (including but not limited to the MIT License, Apache License, GNU General Public License, GNU Lesser General Public License and GNU Affero General Public License) ("**Open Source Software**") in compliance with all license terms applicable to such Open Source Software; and (ii) neither the Company nor any of its subsidiaries uses or distributes or has used or distributed any Open Source Software in any manner that requires or has required (A) the Company or any of its subsidiaries to permit reverse engineering of any software code or other technology owned by the Company or any of its subsidiaries or (B) any software code or other technology owned by the Company or any of its subsidiaries to be (1) disclosed or distributed in source code form, (2) licensed for the purpose of making derivative works or (3) redistributed at no charge.

(z) (i) Except as would not, individually or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, the Company and each of its subsidiaries have complied and are presently in compliance with all internal and external Company privacy policies, contractual obligations, applicable laws, statutes, judgments, orders, rules and regulations of any court or arbitrator or other governmental or regulatory authority and any other legal obligations, in each case, relating to the collection, use, transfer, import, export, storage, protection, disposal and disclosure by the Company or any of its subsidiaries of personal, personally identifiable, sensitive, confidential or regulated data ("**Data Security Obligations**", and such data, "**Data**"); (ii) neither the Company nor any of its subsidiaries has received any notification of or complaint regarding and is unaware of any other facts that, individually or in the aggregate, would reasonably indicate non-compliance with any Data Security Obligation; and (iii) there is no action, suit, investigation or proceeding by or before any court or governmental agency, authority or body pending or threatened

against the Company or any of its subsidiaries alleging non-compliance with any Data Security Obligation.

(aa) Except as would not, individually or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, the Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications and databases ("**IT Systems**") are adequate for, and operate and perform appropriately as required in connection with, the operation of the business of the Company and its subsidiaries, free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and each of its subsidiaries have taken all technical and organizational measures necessary to protect the IT Systems and Data used in connection with the operation of the Company's and its subsidiaries' businesses. Without limiting the foregoing, the Company and its subsidiaries have used reasonable efforts to establish, maintain, implement, and comply with, reasonable information technology, information security, cyber security and data protection controls, policies and procedures, that are designed to protect against and prevent breach, destruction, loss, unauthorized distribution, use, access, disablement, misappropriation or modification, or other compromise or misuse of any IT Systems or Data used in connection with the operation of the Company's and its subsidiaries' businesses ("**Breach**"). Except as would not, individually or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, the Company has experienced no such Breach, and the Company and its subsidiaries have not been notified of and have no knowledge of any event or condition that would reasonably be expected to result in, any such Breach.

(bb) No material labor dispute with the employees of the Company or any of its subsidiaries exists, or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that could, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(cc) The Company and each of its subsidiaries, taken as a whole, are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the businesses in which they are engaged, except where the failure to be insured would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole; neither the Company nor any of its subsidiaries has been refused any insurance coverage sought or applied for; and neither the Company nor any of its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(dd) The Company and each of its subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct their respective businesses, including, without limitation, from the Regulatory Authorities (as defined in Section 1(nn)), except where the failure to obtain such certificates, authorizations or permits would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, and neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(ee) The financial statements (including the related notes thereto) included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, together with the related schedules and notes thereto, comply as to form in all material respects with the applicable accounting requirements of the Securities Act and present fairly the consolidated financial position of the Company and its subsidiaries as of the dates shown and its results of operations and cash flows for the periods shown, and such financial statements have been prepared in conformity with International Financial Reporting Standard ("**IFRS**") as issued by the International Accounting Standards Board applied on a consistent basis throughout the periods covered thereby except for any normal year-end adjustments in the Company's quarterly financial statements. The other financial information included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly in all material respects the information shown thereby.

(ff) The statistical, industry and market related data included in the Registration Statement, the Time of Sale Prospectus and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate and such data is consistent with the sources from which they are derived, in each case in all material respects.

(gg) Ernst & Young Hua Ming LLP, who have certified certain financial statements of the Company and its subsidiaries and delivered its report with respect to the audited consolidated financial statements filed with the Commission as part of the Registration Statement and included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is an independent registered public accounting firm with respect to the Company within the meaning of the Securities Act and the applicable rules and regulations thereunder adopted by the Commission and the Public Company Accounting Oversight Board (United States).

(hh) The Company and its subsidiaries, taken as a whole, maintain systems of "internal control over financial reporting," as defined in Rule 13(a)-

15(f) under the Exchange Act, that comply with the requirements of the Exchange Act and are designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Since the end of the Company's most recent audited fiscal year, there has been (i) no material weakness in the Company's "internal control over financial reporting," as defined in Rule 13(a)-15(f) under the Exchange Act (whether or not remediated), except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and (ii) no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.

(ii) The Company has not sold, issued or distributed any Ordinary Shares during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(jj) The Company and each of its subsidiaries have filed all federal, state, local and foreign income and other tax returns required to be filed through the date of this Agreement or have requested extensions thereof (except where the failure to file would not, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole) and have paid all taxes required to be paid thereon (except for cases in which the failure to file or pay would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or, except as currently being contested in good faith and for which reserves required by IFRS have been created in the financial statements of the Company, or, except to the extent that such taxes have been accrued on the Company's financial statements in accordance with IFRS), and no unpaid tax deficiency has been determined adversely to the Company or any of its subsidiaries which, singly or in the aggregate, has had (nor does the Company nor any of its subsidiaries have any notice or knowledge of any unpaid tax deficiency which could reasonably be expected to be determined adversely to the Company or its subsidiaries and which could reasonably be expected to have) a material adverse effect on the Company and its subsidiaries, taken as a whole.

(kk) From the time of initial confidential submission of the Registration Statement to the Commission through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**").

(ll) The Company (i) has not alone engaged in any Testing-the-Waters Communication with any person other than Testing-the-Waters Communications with the consent of the Representatives with entities that are reasonably believed to be qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are reasonably believed to be accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act. "**Testing-the-Waters Communication**" means any communication with potential investors undertaken in reliance on Section 5(d) or Rule 163B of the Securities Act.

(mm) As of the time of each sale of the ADSs in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (A) the Time of Sale Prospectus, (B) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (C) any individual Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that this representation and warranty does not apply to any statements or omissions based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives or on their behalf expressly for use therein, it being understood and agreed that the only such information is that described in Section 8(b).

(nn) The Company has operated at all times and is currently in compliance in all material respects with all applicable statutes, rules, regulations and policies of the U.S. Food and Drug Administration (the "**FDA**") and applicable foreign regulatory authorities, including the National Medical Product Administration of the People's Republic of China ("**PRC**"), the European Medicines Agency of the European Union and the Pharmaceutical and Medical Device Agency of Japan (collectively, the "**Regulatory Authorities**") and all applicable federal, state, local and foreign health care laws, including, without limitation:

(i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder;

(ii) the Public Health Service Act and the regulations promulgated thereunder;

(iii) the Orphan Drug Act and the regulations promulgated thereunder;

(iv) the PRC Drug Administration Law and the regulations promulgated thereunder;

(v) the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. Section 1320a-7a), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), all applicable federal, state, local and all foreign criminal laws relating to health care fraud and abuse, including but not limited to the U.S. False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") (42 U.S.C. Section 1320d et seq.), the exclusions law (42 U.S.C. Section 1320a-7), the statutes and regulations of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes;

(vi) the Standards for Privacy of Individually Identifiable Health Information, the Security Standards, and the Standards for Electronic Transactions and Code Sets promulgated under HIPAA, the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder and any state or non-U.S. counterpart thereof;

(vii) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, and the regulations promulgated thereunder;

(viii) all other local, state, federal, national, supranational and foreign laws, relating to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company; (clauses (i) through (vii), collectively, "**Health Care Laws**").

(oo) (i) The studies, tests and preclinical and clinical trials conducted by or on behalf of or sponsored by the Company or in which the Company has participated, were, and if still pending are, being conducted in all material respects in accordance with standard medical and experimental protocols, procedures and controls pursuant to accepted professional scientific research standards and procedures, and all applicable Health Care Laws, the rules and regulations of the Regulatory Authorities and current Good Clinical Practices and Good Laboratory Practices; (ii) the descriptions of the results of such studies and trials contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus are accurate and complete in all material respects and fairly present the

data derived from such trials and studies; (iii) the Company has no knowledge of any other studies or trials not described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the results of which call into question the results described or referred to in the Registration Statement, the Time of Sale Prospectus and the Prospectus; (iv) the Company has provided the Underwriters with all substantive written notices, correspondence and summaries of all other communications provided to the Company or its subsidiaries from the Regulatory Authorities; and (v) the Company has not received any written notices, correspondence or other communications from any Regulatory Authority or any other governmental entity alleging or asserting material noncompliance with any applicable Health Care Law or requiring or threatening the termination, modification or suspension of any studies or trials that are described in the Registration Statement, the Time of Sale Prospectus and the Prospectus or the results of which are referred to in the Registration Statement, the Time of Sale Prospectus and the Prospectus, and, to the Company's knowledge, there are no reasonable grounds for the same.

(pp) (i) Except as would not, individually or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and, all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were timely, complete, accurate and not misleading on the date filed (or were corrected or supplemented by a subsequent submission); (ii) the Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or Regulatory Authority, other governmental entity or third party alleging that any Company or product operation or activity is in violation of any Health Care Laws, including, without limitation, any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Regulatory Authority or governmental entity, nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (iii) the Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Regulatory Authority or other governmental entity; and (iv) neither the Company nor any of its employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to an inquiry, investigation, proceeding or other similar action by a Regulatory Authority or other governmental entity that could reasonably be expected to result in debarment, suspension, or exclusion.

(qq) Neither the Company nor any of its subsidiaries has any securities rated by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act.

(rr) No stamp, documentary, issuance, registration, transfer, withholding, capital gains, income or other taxes or duties are payable by or on behalf of the Underwriters, the Company or any of its subsidiaries in the Cayman Islands or the PRC or to any taxing authority thereof or therein in connection with (i) the execution, delivery or consummation of this Agreement, (ii) the creation, allotment and issuance of the Ordinary Shares represented by the ADSs, (iii) the deposit with the Depositary of the Ordinary Shares represented by the ADSs by the Company against issuance of ADRs evidencing the ADSs, (iv) the sale and delivery of the ADSs to the Underwriters or purchasers procured by the Underwriters, or (v) the resale and delivery of the ADSs by the Underwriters in the manner contemplated herein.

(ss) The Company does not expect to be a "passive foreign investment company" ("**PFIC**") for U.S. federal income tax purposes for its current taxable year.

(tt) The Company has entered into a side letter agreement with the Depositary (the "**Depositary Side Letter**"), instructing the Depositary not to accept any shareholder's deposit of Ordinary Shares in the Company's American Depositary Receipt facility or issue any new ADRs evidencing the ADSs to any shareholder or any third party subject to exceptions stated in the Depositary Side Letter and further instruction by the Company.

(uu) The Company is a "foreign private issuer" as defined in Rule 405 of the Securities Act.

2. *Agreements to Sell and Purchase.* The Company hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the terms and conditions hereinafter stated, agrees, severally and not jointly, to purchase from the Company the respective numbers of Firm ADSs set forth in Schedule I hereto opposite its name at $21.39 per ADSs (the "**Purchase Price**").

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Company agrees to sell to the Underwriters the Additional ADSs, and the Underwriters shall have the right to purchase, severally and not jointly, up to 2,763,750 Additional ADSs at the Purchase Price, provided, however, that the amount paid by the Underwriters for any Additional ADSs shall be reduced by an amount per ADS equal to any dividends declared by the Company and payable on the Firm ADSs but not payable on such Additional ADSs. The Representatives may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice not later than 30 days after the date of this Agreement. Any exercise notice shall specify the number of Additional ADSs to be purchased by the Underwriters and the date on which such Additional ADSs are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the closing date for the Firm ADSs or later than ten business days after the date of such notice. Additional ADSs may be purchased as provided in Section **Error!**

Reference source not found. hereof solely for the purpose of covering over-allotments made in connection with the offering of the Firm ADSs. On each day, if any, that Additional ADSs are to be purchased (an "**Option Closing Date**"), each Underwriter agrees, severally and not jointly, to purchase the number of Additional ADSs (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of Additional ADSs to be purchased on such Option Closing Date as the number of Firm ADSs set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of Firm ADSs.

3. *Terms of Public Offering*. The Company is advised by the Representatives that the Underwriters propose to make a public offering of their respective portions of the ADSs as soon after the Registration Statement and this Agreement have become effective as in the Representatives' judgment is advisable. The Company is further advised by the Representatives that the ADSs are to be offered to the public initially at $23.00 per ADS (the "**Public Offering Price**") and to certain dealers selected by the Representatives at a price that represents a concession not in excess of $0.9660 a share under the Public Offering Price.

4. *Payment and Delivery.* Payment for the Firm ADSs shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Firm ADSs for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on June 9, 2020, or at such other time on the same or such other date, not later than June 16, 2020, as shall be designated in writing by the Representatives. The time and date of such payment are hereinafter referred to as the "**Closing Date**."

Payment for any Additional ADSs shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Additional ADSs for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on the date specified in the corresponding notice described in Section **Error! Reference source not found.** or at such other time on the same or on such other date, in any event not later than July 17, 2020, as shall be designated in writing by the Representatives.

The Firm ADSs and Additional ADSs shall be registered in such names and in such denominations as the Representatives shall request not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be. The Firm ADSs and Additional ADSs shall be delivered to Morgan Stanley on the Closing Date or an Option Closing Date, as the case may be, for the respective accounts of the several Underwriters, with any transfer taxes payable in connection with the transfer of the ADSs to the Underwriters duly paid, against payment of the Purchase Price therefor.

5. *Conditions to the Underwriters' Obligations*. The obligations of the Company to sell the ADSs to the Underwriters and the several obligations of the Underwriters to purchase and pay for the ADSs on the Closing Date are subject to the

condition that the Registration Statement shall have become effective not later than 4:00 P.M. (New York City time) on the date hereof.

The several obligations of the Underwriters are subject to the following further conditions:

(a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:

(i) no order suspending the effectiveness of the Registration Statement shall be in effect, and no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or threatened by the Commission; and

(ii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus that, in the Representatives judgment, is material and adverse and that makes it, in the Representatives' judgment, impracticable to market the ADSs on the terms and in the manner contemplated in the Time of Sale Prospectus.

(b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed on behalf of the Company by an executive officer of the Company, to the effect set forth in Sections **Error! Reference source not found.** and 5(a)(ii) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

(c) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Cooley LLP, outside counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(d) The Underwriters shall have received on the Closing Date an opinion of Morrison & Foerster LLP, outside intellectual property counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(e) The Underwriters shall have received on the Closing Date an opinion of Panitch Schwarze Belisario & Nadel, LLP, outside intellectual

property counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(f) The Underwriters shall have received on the Closing Date an opinion of Klarquist Sparkman, LLP, outside intellectual property counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(g) The Underwriters shall have received on the Closing Date an opinion of Harney Westwood & Riegels, Cayman Islands counsel for the Company, dated the Closing Date, substantially in the form of Exhibit C hereto.

(h) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Davis Polk & Wardwell LLP, counsel for the Underwriters, dated the Closing Date, in form and substance satisfactory to the Underwriters.

(i) The Underwriters shall have received on the Closing Date an opinion of JunHe LLP, People's Republic of China counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(j) The Underwriters shall have received on the Closing Date an opinion of Jingtian & Gongcheng, People's Republic of China counsel for the Underwriters, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

(k) The Underwriters shall have received on the Closing Date an opinion of Pepper Hamilton LLP, counsel for the Depositary, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

With respect to the negative assurance letters to be delivered pursuant to Sections 5(c) and 5(h) above, Cooley LLP and Davis Polk & Wardwell LLP may state that their opinions and beliefs are based upon their participation in the preparation of the Registration Statement, the Time of Sale Prospectus and the Prospectus and any amendments or supplements thereto and review and discussion of the contents thereof, but are without independent check or verification, except as specified.

The opinions of Cooley LLP, Morrison & Foerster LLP, Panitch Schwarze Belisario & Nadel, LLP, Klarquist Sparkman, LLP, Harney Westwood & Riegels, Davis Polk & Wardwell LLP, JunHe LLP, Jingtian & Gongcheng and Pepper Hamilton LLP described in Section **Error! Reference source not found.**, Section 5(d), Section 5(e), Section 5(f), Section 5(g), Section 5(h), Section 5(i), Section 5(j) and Section 5(k) above, respectively, shall be rendered to the Underwriters at the request of the Company and shall so state therein.

(l) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the

case may be, in form and substance satisfactory to the Underwriters, from Ernst & Young Hua Ming LLP, an independent registered public accounting firm, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided* that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.

(m) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between the Representatives and certain shareholders, officers and directors of the Company relating to restrictions on sales and certain other dispositions of Ordinary Shares or certain other securities, delivered to the Representatives on or before the date hereof (the "**Lock-up Agreements**"), shall be in full force and effect on the Closing Date.

(n) The several obligations of the Underwriters to purchase Additional ADSs hereunder are subject to the delivery to the Underwriters on the applicable Option Closing Date of the following:

(i) a certificate, dated the Option Closing Date and signed by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 5(b) hereof remains true and correct as of such Option Closing Date;

(ii) an opinion and negative assurance letter of Cooley LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(c) hereof;

(iii) an opinion of Morrison & Foerster LLP, outside intellectual property counsel for the Company, dated the Option Closing Date , substantially in the same form and substance as the opinion required by Section 5(d) hereof.

(iv) an opinion of Panitch Schwarze Belisario & Nadel, LLP, outside intellectual property counsel for the Company, dated the Option Closing Date , substantially in the same form and substance as the opinion required by Section 5(e) hereof.

(v) an opinion of Klarquist Sparkman, LLP, outside intellectual property counsel for the Company, dated the Option Closing Date , substantially in the same form and substance as the opinion required by Section 5(f) hereof.

(vi) an opinion of Harney Westwood & Riegels, Cayman Islands counsel for the Company, dated the Option Closing Date, relating

to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(g) hereof;

(vii) an opinion and negative assurance letter of Davis Polk & Wardwell LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(h) hereof;

(viii) an opinion of JunHe LLP, People's Republic of China counsel for the Company, dated the Option Closing Date, relating to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(i) hereof;

(ix) an opinion of Jingtian & Gongcheng, People's Republic of China counsel for the Underwriters, dated the Option Closing Date, relating to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(j) hereof;

(x) an opinion of Pepper Hamilton LLP, counsel for the Depositary, dated the Option Closing Date, relating to the Additional ADSs to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(k) hereof;

(xi) a letter dated the Option Closing Date, in form and substance satisfactory to the Underwriters, from Ernst & Young Hua Ming LLP, an independent registered public accounting firm, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 5(l) hereof; *provided* that the letter delivered on the Option Closing Date shall use a "cut-off date" not earlier than three business days prior to such Option Closing Date;

(xii) such other documents as the Representatives may reasonably request, including with respect to the good standing of the Company and its subsidiaries, the due authorization and issuance of the Additional ADSs to be sold on such Option Closing Date and other matters related to the issuance of such Additional ADSs.

(o) The Company and the Depositary shall have executed and delivered the Deposit Agreement and, in the case of the Company, the Depositary Side Letter, instructing the Depositary not to accept any shareholder's deposit of Ordinary Shares in the Company's American Depositary Receipt facility or issue any new ADRs evidencing the ADSs to any shareholder or third party, unless consented to by the Company, and the Deposit Agreement shall be in full force and effect on the Closing Date and each Option Closing Date. The Company and

the Depositary shall have taken all actions necessary to permit the deposit of the Ordinary Shares and the issuance of the ADSs representing such Ordinary Shares in accordance with the Deposit Agreement.

(p) The Depositary shall have furnished or caused to be furnished to the Representatives a certificate of one of its authorized officers satisfactory to the Representatives with respect to the deposit with it of the Ordinary Shares against issuance of the ADSs, the execution, issuance, countersignature and delivery of the ADSs pursuant to the Deposit Agreement and such other matters related thereto as the Representatives may reasonably request.

(q) The Firm Shares and Additional Shares, if any, shall have been approved for listing on the Nasdaq Global Market, subject to official notice of issuance.

6. *Covenants of the Company*. The Company covenants with each Underwriter as follows:

(a) To furnish the Representatives, without charge, four signed copies of the Registration Statement (including exhibits thereto) and for delivery to each other Underwriter a conformed copy of the Registration Statement (without exhibits thereto) and to furnish to the Representatives in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period mentioned in Section **Error! Reference source not found.** or **Error! Reference source not found.** below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as the Representatives may reasonably request.

(b) Before amending or supplementing the Registration Statement, the Time of Sale Prospectus or the Prospectus, to furnish to the Representatives a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which the Representatives reasonably object, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) To furnish to the Representatives a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which the Representatives reasonably object.

(d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

(e) If the Time of Sale Prospectus is being used to solicit offers to buy the ADSs at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the reasonable opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) If, during such period after the first date of the public offering of the ADSs as in the reasonable opinion of counsel for the Underwriters the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the reasonable opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses the Representatives will furnish to the Company) to which ADSs may have been sold by the Representatives on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law.

(g) To endeavor to qualify the ADSs for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives shall reasonably request; *provided* that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the ADSs, or taxation in any jurisdiction where it is not now so subject.

(h) To make generally available to the Company's security holders and to the Underwriters as soon as practicable an earnings statement covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(i) Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, to pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel and the Company's accountants in connection with the registration and delivery of the ADSs and Ordinary Shares represented thereby under the Securities Act and all other fees or expenses in connection with the preparation and filing of the Registration Statement, the ADS Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including all printing costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the ADSs and Ordinary Shares represented thereby to the Underwriters, including any transfer or other taxes payable thereon, (iii) the reasonable and documented cost of printing or producing any Blue Sky or Legal Investment memorandum in connection with the offer and sale of the ADSs and Ordinary Shares represented thereby under state securities laws and all expenses in connection with the qualification of the ADSs and Ordinary Shares represented thereby for offer and sale under state securities laws as provided in Section **Error! Reference source not found.** hereof, including filing fees and the reasonable and documented fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky or Legal Investment memorandum, (iv) all filing fees in respect of the reasonable fees and disbursements of counsel to the Underwriters incurred in connection with the review and qualification of the offering of the ADSs and Ordinary Shares represented thereby by FINRA (provided that the amount payable by the Company with respect to the fees and disbursements of counsel for the Underwriters incurred pursuant to subsections (iii) and (iv) of this Section **Error! Reference source not found.** shall not exceed $40,000 in the aggregate), (v) all fees and expenses in connection with the preparation and filing of the registration statement on Form 8-A relating to the ADSs and all costs and expenses incident to listing the ADSs on the Nasdaq Global Market, (vi) the cost of printing certificates representing the Ordinary Shares, (vii) the costs and charges of any transfer agent, registrar or depositary, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the ADSs, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with

the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and fifty percent (50%) of the cost of any aircraft chartered in connection with the road show (the remaining fifty percent (50%) of the cost of such aircraft to be paid by the Underwriters), (ix) the document production charges and expenses associated with printing this Agreement and (x) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section. It is understood, however, that except as provided in this Section, Section **Error! Reference source not found.** entitled "Indemnity and Contribution" and the last paragraph of Section **Error! Reference source not found.** below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the ADSs by them and any advertising expenses connected with any offers they may make and all travel and other expenses of the Underwriters or any of their employees incurred by them in connection with participation in investor presentations on any "road show" undertaken in connection with the marketing of the offering of the ADSs, other than the cost of aircraft chartered in connection with the road show, for which the Underwriters agree to pay for the other fifty percent (50%) not paid for by the Company, as described above.

(j) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the ADSs within the meaning of the Securities Act and (ii) completion of the Restricted Period (as defined in this Section **Error! Reference source not found.**).

(k) If at any time following the distribution of any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act there occurred or occurs an event or development as a result of which such Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(l) The Company will deliver to each Underwriter (or its agent), on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as each Underwriter may reasonably request in connection with the verification of the foregoing Certification.

(m) The Company shall pay, and shall indemnify and hold the Underwriters harmless against, any stamp, issue, registration, documentary, sales,

transfer income, capital gains or other similar taxes or duties imposed under the laws of the Cayman Islands or any political sub-division or taxing authority thereof or therein that is payable in connection with (i) the execution, delivery, consummation or enforcement of this Agreement, (ii) the creation, allotment and issuance of the ADSs (iii) the sale and delivery of the ADSs to the Underwriters or purchasers procured by the Underwriters, or (iv) the resale and delivery of the ADSs by the Underwriters in the manner contemplated herein.

(n) All sums payable by the Company under this Agreement shall be paid free and clear of and without deductions or withholdings of any present or future taxes or duties, unless the deduction or withholding is required by law, in which case the Company shall pay such additional amount as will result in the receipt by each Underwriter of the full amount that would have been received had no deduction or withholding been made.

(o) All sums payable to an Underwriter shall be considered exclusive of any value added or similar taxes. Where the Company is obliged to pay value added or similar tax on any amount payable hereunder to an Underwriter, the Company shall in addition to the sum payable hereunder pay an amount equal to any applicable value added or similar tax.

(p) To comply with the terms of the Deposit Agreement so that the ADSs will be issued by the Depositary and delivered to each Underwriter's participant account in DTC, pursuant to this Agreement on the Closing Date and each applicable Option Closing Date.

The Company also covenants with each Underwriter that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of the Prospectus (the "**Restricted Period**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares or ADSs or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Ordinary Shares or ADSs, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Ordinary Shares, ADSs or such other securities, in cash or otherwise or (3) file any registration statement with the Commission relating to the offering of any Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares or ADSs.

The restrictions contained in the preceding paragraph shall not apply to (A) the Ordinary Shares represented by ADSs to be sold hereunder, (B) the issuance by the Company of Ordinary Shares or ADSs upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof as described in the Registration Statement, the Time of Sale Prospectus and Prospectus, (C) the grant of options,

restricted stock units or any other type of equity award described in the Registration Statement, the Time of Sale Prospectus and Prospectus, or the issuance of Ordinary Shares or ADSs by the Company (whether upon the exercise of stock options or otherwise) to employees, officers, directors, advisors or consultants of the Company pursuant to employee benefit plans in effect on the date hereof and described in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided* that each recipient of Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares pursuant to this clause (C) shall execute a lock-up agreement substantially in the form of Exhibit A hereto with respect to the remaining portion of the Restricted Period, (D) the filing by the Company of a registration statement on Form S-8 relating to the issuance, vesting, exercise or settlement of equity awards granted or to be granted pursuant to any employee benefit plan in effect on the date hereof and described in the Registration Statement, the Time of Sale Prospectus and Prospectus, (E) facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Ordinary Shares or ADSs, *provided* that (i) such plan does not provide for the transfer of Ordinary Shares or ADSs during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Ordinary Shares or ADSs may be made under such plan during the Restricted Period, (F) the sale or issuance of or entry into an agreement to sell or issue Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares or ADSs in connection with one or more mergers; acquisitions of securities, businesses, property or other assets, products or technologies; joint ventures; commercial relationships or other strategic corporate transactions or alliances; *provided* that the aggregate amounts of Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares or ADSs (on an as-converted, as-exercised or as-exchanged basis) that the Company may sell or issue or agree to sell or issue pursuant to this paragraph shall not exceed 10% of the total number of Ordinary Shares or ADSs of the Company issued and outstanding immediately following the completion of the transactions contemplated by this Agreement determined on a fully-diluted basis, and *provided further* that each recipient of Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares or ADSs pursuant to this clause (F) shall execute a lock-up agreement substantially in the form of Exhibit A hereto with respect to the remaining portion of the Restricted Period or (G) the Ordinary Shares to be sold pursuant to a concurrent private placement as described in the Registration Statement, the Time of Sale Prospectus and Prospectus; *provided* that each recipient of Ordinary Shares, ADSs or any securities convertible into or exercisable or exchangeable for Ordinary Shares pursuant to this clause (G) shall execute a lock-up agreement substantially in the form of Exhibit A hereto with respect to the remaining portion of the Restricted Period.

If the Representatives, in their sole discretion, agree to release or waive the restrictions on the transfer of Ordinary Shares or ADSs set forth in a Lock-up Agreement for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a

press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

7. *Covenants of the Underwriters*. Each Underwriter, severally and not jointly, covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) of the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

8. *Indemnity and Contribution.* (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) that arise out of, or are based upon, any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act (a "road show"), the Prospectus or any amendment or supplement thereto, or any Testing-the-Waters Communication, or arise out of, or are based upon, any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any such untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein, it being understood and agreed that the only such information furnished by the Underwriters through the Representatives consists of the information described as such in paragraph (b) below. The Company agrees and confirms that references to "affiliates" of Morgan Stanley that appear in this Agreement shall be understood to include Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.

(b) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information relating to such Underwriter furnished to the Company in writing by such Underwriter through or on behalf of the Representatives expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show or the Prospectus or any amendment or supplement thereto,

it being understood and agreed that the only such information furnished by any Underwriter through the Representatives consists of the following information in the Prospectus: the concession figure in the third paragraph and the information set forth in the seventh and fourteenth paragraphs, in each case under the caption "Underwriters."

(c) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section **Error! Reference source not found.** or **Error! Reference source not found.**, such person (the "**indemnified party**") shall promptly notify the person against whom such indemnity may be sought (the "**indemnifying party**") in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed in writing to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all such indemnified parties and that all such fees and expenses shall be reimbursed as they are incurred. Such firm shall be designated in writing by the Representatives, in the case of parties indemnified pursuant to Section **Error! Reference source not found.**, and by the Company, in the case of parties indemnified pursuant to Section **Error! Reference source not found.**. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and

indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) To the extent the indemnification provided for in Section **Error! Reference source not found.** or **Error! Reference source not found.** is unavailable to an indemnified party or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand from the offering of the ADSs or (ii) if the allocation provided by clause **Error! Reference source not found.** above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause **Error! Reference source not found.** above but also the relative fault of the Company on the one hand and of the Underwriters on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand in connection with the offering of the ADSs shall be deemed to be in the same respective proportions as the net proceeds from the offering of the ADSs (after deducting underwriting discounts and commissions but before deducting expenses) received by the Company and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate Public Offering Price of the ADSs. The relative fault of the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Underwriters' respective obligations to contribute pursuant to this Section **Error! Reference source not found.** are several in proportion to the respective number of ADSs they have purchased hereunder, and not joint.

(e) The Company and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section **Error! Reference source not found.** were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section **Error! Reference source not found.**. The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in Section **Error! Reference source not found.** shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred

by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section **Error! Reference source not found.**, no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the ADSs underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section **Error! Reference source not found.** are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

(f) The indemnity and contribution provisions contained in this Section **Error! Reference source not found.** and the representations, warranties and other statements of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter or by or on behalf of the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the ADSs.

9. *Termination*. The Underwriters may terminate this Agreement by notice given by the Representatives to the Company, if after the execution and delivery of this Agreement and prior to or on the Closing Date or any Option Closing Date, as the case may be, (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, the Nasdaq Global Market or other relevant exchanges, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal, New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in the Representatives' judgment, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in the Representatives' judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the ADSs on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

10. *Effectiveness; Defaulting Underwriters*. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase ADSs that it has or they have agreed to purchase hereunder on such date, and the aggregate number of ADSs which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is

not more than one-tenth of the aggregate number of the ADSs to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm ADSs set forth opposite their respective names in Schedule I bears to the aggregate number of Firm ADSs set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as the Representatives may specify, to purchase the ADSs which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; *provided* that in no event shall the number of ADSs that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 10 by an amount in excess of one-ninth of such number of ADSs without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm ADSs and the aggregate number of Firm ADSs with respect to which such default occurs is more than one-tenth of the aggregate number of Firm ADSs to be purchased on such date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Firm ADSs are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter or the Company. In any such case either the Representatives or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional ADSs and the aggregate number of Additional ADSs with respect to which such default occurs is more than one-tenth of the aggregate number of Additional ADSs to be purchased on such Option Closing Date, the non-defaulting Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional ADSs to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional ADSs that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, or if for any reason the Company shall be unable to perform its obligations under this Agreement (other than by reason of a default by the Underwriters or the occurrence of any of the events described in clauses (i), (iii), (iv) or (v) of Section 9), the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all out-of-pocket expenses (including the fees and disbursements of their counsel) reasonably incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

11. *Entire Agreement.* (a) This Agreement, together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the ADSs, represents the entire agreement between the Company and the Underwriters with respect to the

preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the ADSs.

(b) The Company acknowledges that in connection with the offering of the ADSs: (i) the Underwriters have acted at arm's length, are not agents of, and owe no fiduciary duties to, the Company or any other person, (ii) the Underwriters owe the Company only those duties and obligations set forth in this Agreement, any contemporaneous written agreements and prior written agreements (to the extent not superseded by this Agreement), if any, and (iii) the Underwriters may have interests that differ from those of the Company. The Company waives to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the ADSs.

12. *Recognition of the U.S. Special Resolution Regimes*. (a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United State.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section a "**BHC Act Affiliate**" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "**Covered Entity**" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). "**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. "**U.S. Special Resolution Regime**" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

13. *Counterparts*. This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and

Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

14. *Applicable Law*. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.

15. *Submission to Jurisdiction; Appointment of Agents for Service*. (a) The Company irrevocably submits to the non-exclusive jurisdiction of any New York State or United States Federal court sitting in The City of New York (the "**Specified Courts**") over any suit, action or proceeding arising out of or relating to this Agreement, the Time of Sale Prospectus, the Prospectus, the Registration Statement or the offering of the ADSs (each, a "**Related Proceeding**"). The Company irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of venue of any Related Proceeding brought in such a court and any claim that any such Related Proceeding brought in such a court has been brought in an inconvenient forum. To the extent that the Company has or hereafter may acquire any immunity (on the grounds of sovereignty or otherwise) from the jurisdiction of any court or from any legal process with respect to itself or its property, the Company irrevocably waives, to the fullest extent permitted by law, such immunity in respect of any such suit, action or proceeding.

(b) The Company hereby irrevocably appoints Yuan Xu, the Chief Executive Officer of the Company, at 2101 Cottontail Lane, Somerset, New Jersey 08873, as its agent for service of process in any Related Proceeding and agrees that service of process in any such Related Proceeding may be made upon it at the office of such agent. The Company waives, to the fullest extent permitted by law, any other requirements of or objections to personal jurisdiction with respect thereto. The Company represents and warrants that such agent has agreed to act as the Company's agent for service of process, and the Company agrees to take any and all action, including the filing of any and all documents and instruments, that may be necessary to continue such appointment in full force and effect.

16. *Judgment Currency*. If for the purposes of obtaining judgment in any court it is necessary to convert a sum due hereunder into any currency other than United States dollars, the parties hereto agree, to the fullest extent permitted by law, that the rate of exchange used shall be the rate at which in accordance with normal banking procedures the Underwriters could purchase United States dollars with such other currency in The City of New York on the business day preceding that on which final judgment is given. The obligation of the Company with respect to any sum due from it to any Underwriter or any person controlling any Underwriter shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first business day following receipt by such Underwriter or controlling person of any sum in such other currency, and only to the extent that such Underwriter or controlling person may in accordance with normal banking procedures purchase United States dollars with such other currency. If the United States dollars so purchased are less than the sum

originally due to such Underwriter or controlling person hereunder, the Company agrees as a separate obligation and notwithstanding any such judgment, to indemnify such Underwriter or controlling person against such loss. If the United States dollars so purchased are greater than the sum originally due to such Underwriter or controlling person hereunder, such Underwriter or controlling person agrees to pay to the Company an amount equal to the excess of the dollars so purchased over the sum originally due to such Underwriter or controlling person hereunder.

17. *Taxes.* If any sum payable by the Company under this Agreement is subject to tax in the hands of an Underwriter or taken into account as a receipt in computing the taxable income of that Underwriter (excluding net income taxes on underwriting commissions payable hereunder), the sum payable to the Underwriter under this Agreement shall be increased to such sum as will ensure that the Underwriter shall be left with the sum it would have had in the absence of such tax.

18. *Headings*. The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.

19. *Notices*. All communications hereunder shall be in writing and effective only upon receipt and if to the Underwriters shall be delivered, mailed or sent to Morgan Stanley in care of Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department; J.P. Morgan Securities LLC, 383 Madison Avenue, New York, New York, Attention: Equity Syndicate Desk, with a copy to the Legal Department; and to Jefferies LLC, 520 Madison Avenue New York, NY 10022 (fax: (646) 619-4437), Attention: General Counsel; and if to the Company shall be delivered, mailed or sent to Legend Biotech Corporation, Attention: Ying Huang, 2101 Cottontail Lane, Somerset, New Jersey 08873.

Very truly yours,

LEGEND BIOTECH CORPORATION

By: /s/ Yuan Xu
Name: Yuan Xu
Title: Chief Executive Officer

[Signature page follows]

Accepted as of the date hereof

Morgan Stanley & Co. LLC
J.P. Morgan Securities LLC
Jefferies LLC

Acting severally on behalf of themselves
and the several Underwriters named in
Schedule I hereto.

By: Morgan Stanley & Co. LLC

By: /s/ Kalli Dircks
Name: Kalli Dircks
Title: Executive Director

By: J.P. Morgan Securities LLC

By: /s/ David Ke
Name: David Ke
Title: Executive Director

By: Jefferies LLC

By: /s/ Michael Brinkman
Name: Michael Brinkman
Title: Managing Director

SCHEDULE I

Underwriter	Number of Firm ADSs To Be Purchased
Morgan Stanley & Co. LLC	6,725,125
J.P. Morgan Securities LLC	6,725,125
Jefferies LLC	4,974,750
Total:	18,425,000

SCHEDULE II

Time of Sale Prospectus

1. Preliminary Prospectus issued May 29, 2020

2. **Pricing Information Provided Orally by Underwriters**

   Firm ADSs: 18,425,000 representing 36,850,000 Ordinary Shares

   Option ADSs: 2,763,750 representing 5,527,500 Ordinary Shares

   Public Offering Price Per ADS: $23.00

EXHIBIT A

FORM OF LOCK-UP AGREEMENT

[•], 2020

Morgan Stanley & Co. LLC
J.P. Morgan Securities LLC
Jefferies LLC
c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, New York 10036

c/o J.P. Morgan Securities LLC
383 Madison Avenue
New York, New York 10179

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

The undersigned understands that Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC (together, the "**Representatives**") propose to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Legend Biotech Corporation, an exempted company incorporated in the Cayman Islands (the "**Company**"), providing for the public offering (the "**Public Offering**") by the several Underwriters, including the Representatives (the "**Underwriters**"), of ordinary shares, par value $0.0001 per share, of the Company (the "**Ordinary Shares**") in the form of American Depositary Shares (collectively with the Ordinary Shares, the "**Securities**").

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, and will not publicly disclose an intention to, during the period commencing on the date hereof and ending 180 days after the date of the final prospectus (the "**Prospectus**") relating to the Public Offering (the "**Restricted Period**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Securities beneficially owned (as such term is used in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for Securities or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Securities, whether any such transaction described in

clause (1) or (2) above is to be settled by delivery of Securities or such other securities, in cash or otherwise. The foregoing sentence shall not apply to:

(a) transactions relating to Securities acquired in the Public Offering or in open market transactions after the completion of the Public Offering;

(b) transfers of Securities or any security convertible into or exercisable or exchangeable for Securities (i) as a bona fide gift, or for bona fide estate planning purposes, upon death or by will, testamentary document or intestate succession, (ii) to an immediate family member of the undersigned or to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this agreement, "immediate family" shall mean any relationship by blood, current or former marriage or adoption, not more remote than first cousin), (iii) not involving a change in beneficial ownership, or (iv) if the undersigned is a trust, to any beneficiary of the undersigned or the estate of any such beneficiary;

(c) distributions of Securities or any security convertible into or exercisable or exchangeable for Securities to stockholders, direct or indirect affiliates (within the meaning set forth in Rule 405 under the Securities Act of 1933, as amended), current partners (general or limited), members or managers of the undersigned, as applicable, or to the estates of any such stockholders, affiliates, partners, members or managers;

(d) (i) the receipt by the undersigned from the Company of Securities upon the exercise of options or warrants, insofar as such options or warrants are outstanding as of the date of the Prospectus, *provided* that such options or warrants are described in the Prospectus and the Securities received upon exercise of such option or warrant shall remain subject to this agreement or (ii) the transfer of Securities or any securities convertible into Securities to the Company upon a vesting event of the Company's securities or upon the exercise of options or warrants to purchase the Company's securities on a "cashless" or "net exercise" basis to the extent permitted by the instruments representing such options or warrants so long as such "cashless" exercise or "net exercise" is effected solely by the surrender of outstanding options or warrants to the Company and the Company's cancellation of all or a portion thereof to pay the exercise price and/or withholding tax obligations, but for the avoidance of doubt, excluding all methods of exercise that would involve a sale of any Securities relating to options or warrants, whether to cover the applicable exercise price, withholding tax obligations or otherwise, *provided* that in the case of either (i) or (ii), no filing under Section 16(a) of the Exchange Act, or any other public filing or disclosure of such receipt or transfer by or on behalf of the undersigned shall be required or shall be voluntarily made within 60 days after the date of the Prospectus, and after such 60th day, any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in (i) or (ii), as the case may be, (B) no shares were sold by the reporting person and (C) in the case of (i), the shares received upon exercise of the option are subject to a lock-up agreement with the Underwriters of the Public Offering;

(e) sales of securities pursuant to the terms of the Underwriting Agreement;

(f) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Securities, *provided* that (i) such plan does not provide for the transfer of Securities during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Securities may be made under such plan during the Restricted Period;

(g) the transfer of Securities or any security convertible into or exercisable or exchangeable for Securities that occurs by operation of law pursuant to a qualified domestic order in connection with a divorce settlement or other court order;

(h) any transfer of Securities or any security convertible into or exercisable or exchangeable for Securities to the Company pursuant to any contractual arrangement under which the Company has the option to repurchase such shares or a right of first refusal with respect to transfers of such shares in the event the undersigned ceases to provide services to the Company, *provided* that such contractual arrangement is disclosed in the Prospectus or filed as an exhibit to the Registration Statement on Form F-1 relating to the Public Offering to be filed with the Securities and Exchange Commission, and *provided further* that no filing under the Exchange Act or other public filing, report or announcement reporting a change in beneficial ownership of Securities shall be required or shall be voluntarily made during the Restricted Period within 60 days after the date the undersigned ceases to provide services to the Company, and after such 60th day, if the undersigned is required to file a report under the Exchange Act reporting a change in beneficial ownership of Securities during the Restricted Period, the undersigned shall clearly indicate in the footnotes thereto that the filing relates to the termination of the undersigned's employment or other services and no other filing or public announcement shall be made voluntarily during the Restricted Period in connection with such transfer;

(i) the conversion of outstanding preferred shares of the Company into Securities prior to or in connection with the consummation of the Public Offering, *provided* that any such Securities received upon such conversion shall be subject to the terms of this agreement and *provided further* that any filing required under Section 16(a) of the Exchange Act during the Restricted Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (i); and

(j) the transfer of Securities or any security convertible into or exercisable or exchangeable for Securities pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by the Board of Directors of the Company, made to all holders of Securities involving a Change of Control (as defined below), *provided* that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Securities owned by the undersigned shall remain subject to the restrictions contained in this agreement;

provided that in the case of any sale, transfer or distribution pursuant to clause (a) (b), or (c), no filing under Section 16(a) of the Exchange Act or any other public filing or

disclosure reporting a reduction in beneficial ownership of Securities shall be required or shall be voluntarily made during the Restricted Period;

provided further that in the case of any distribution pursuant to clause (c), such distribution shall not involve a disposition for value;

provided further that in the case of any transfer or distribution pursuant to clause (b), (c) or (g), each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this agreement; and

provided further that in the case of any transfer pursuant to clause (g), no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure shall be voluntarily made during the Restricted Period, and any required filing shall clearly indicate in the footnotes thereto that such transfer is by operation of law, court order or in connection with a divorce settlement, as the case may be.

For the purposes of clause (j), "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an Underwriters pursuant to the Public Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 75% of the outstanding voting securities of the Company (or the surviving entity).

In addition, the undersigned agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any Securities or any security convertible into or exercisable or exchangeable for Securities. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Securities except in compliance with the foregoing restrictions.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing restrictions shall be equally applicable to any issuer-directed Securities the undersigned may purchase in the Public Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Securities, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same

terms described in this agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

The undersigned hereby consents to receipt of this agreement in electronic form and understand and agree that this letter agreement may be signed electronically. If any signature is delivered by facsimile transmission, electronic mail, or otherwise by electronic transmission evidencing an intent to sign this agreement (including any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com), such facsimile transmission, electronic mail or other electronic transmission shall create a valid and binding obligation of the undersigned with the same force and effect as if such signature were an original. Execution and delivery of this agreement by facsimile transmission, electronic mail or other electronic transmission is legal, valid and binding for all purposes.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

Notwithstanding anything to the contrary contained herein, this agreement will automatically terminate and the undersigned will be released from all obligations hereunder upon the earliest to occur, if any, of (i) the Company, on the one hand, or all of the Representatives, on the other hand, advises in writing that it has determined not to proceed with the Public Offering prior to the execution of the Underwriting Agreement, (ii) the Company files an application with the Securities and Exchange Commission to withdraw the registration statement related to the Public Offering, (iii) the date the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities to be sold thereunder, or (iv) December 31, 2020, if the Underwriting Agreement has not been executed by such date.

This agreement shall be governed by and construed in accordance with the laws of the State of New York.

[Signature page follows]

Very truly yours,

IF AN INDIVIDUAL:

_____
(duly authorized signature)

Name:_____
(please print full name)

Address:

_____

_____

E-mail: _____

IF AN ENTITY:

_____
(please print complete name of entity)

By:_____
(duly authorized signature)

Name:_____
(please print full name)

Title:_____
(please print full title)

Address:

_____

_____

E-mail: _____

EXHIBIT B

FORM OF WAIVER OF LOCK-UP

_____, 20__

[Name and Address of
Officer or Director
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by Legend Biotech Corporation (the "**Company**") of [•] American Depositary Shares representing [•] ordinary shares, $0.0001 par value per share (the "**ADSs**"), of the Company and the lock-up agreement dated ____, 2020 (the "**Lock-up Agreement**"), executed by you in connection with such offering, and your request for a [waiver] [release] dated ____, 20__, with respect to ____ ADSs.

Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Agreement, but only with respect to the ADSs, effective _____, 20__; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Agreement shall remain in full force and effect.

Very truly yours,

Morgan Stanley & Co. LLC
J.P. Morgan Securities LLC
Jefferies LLC

Acting severally on behalf of themselves and the several Underwriters named in Schedule I to the Underwriting Agreement.

By: Morgan Stanley & Co. LLC

By: _____
Name:
Title:

By: J.P. Morgan Securities LLC

By: _____
Name:
Title:

By: Jefferies LLC

By: _____
Name:
Title:

cc: Company

FORM OF PRESS RELEASE

Legend Biotech Corporation
[Date]

Legend Biotech Corporation (the "**Company**") announced today that Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC, the lead book-running managers in the Company's recent public sale of _____ American Depositary Shares (the "**ADSs**") representing ordinary shares are [waiving][releasing] a lock-up restriction with respect to ____ [ADSs][ordinary shares] of the Company held by [certain officers or directors] [an officer or director] of the Company. The [waiver][release] will take effect on ____, 20__ , and the [ADSs][ordinary shares] may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

EXHIBIT C

FORM OF OPINION OF HARNEY WESTWOOD & RIEGELS

[●] 2020
DRAFT

raymond.ng@harneys.com
+852 5806 7883
053431-0001-RLN

The parties set out in Appendix I

Dear Sir or Madam

Legend Biotech Corporation (the *Company*)

We are attorneys-at-law qualified to practise in the Cayman Islands and have been asked to provide this legal opinion to you with regard to the laws of the Cayman Islands in relation to the Underwriting Agreement (as defined in Schedule 1) entered into by the Company in connection with a registration statement on Form F-1, including all amendments or supplements thereto (the ***Registration Statement***, which term does not include any other document or agreement whether or not specifically referred to therein or attached as an exhibit or schedule thereto), originally filed with the U.S. Securities and Exchange Commission on [●] under the U.S. Securities Act of 1933, as amended (the Securities Act) involving an initial public offering (the ***IPO***) of [●] American depositary shares (the ***American Depositary Shares***) representing [●] ordinary shares, US$0.0001 par value per share, of the Company, or [●] ordinary shares of the Company if the underwriters exercise their over-allotment option in full (the ***Shares***). In this opinion ***Companies Law*** means the Companies Law (2020 Revision) of the Cayman Islands.

This letter of opinion is delivered to you pursuant to Section 5(e) of the Underwriting Agreement. Capitalised terms used but not defined herein shall have the meaning given to them in the Underwriting Agreement.

For the purposes of giving this opinion, we have examined the Documents (as defined in **Error! Reference source not found.**). We have not examined any other documents, official or corporate records or external or internal registers and have not undertaken or been instructed to undertake any further enquiry or due diligence in relation to the transaction which is the subject of this opinion.

In giving this opinion we have relied upon the assumptions set out in **Error! Reference source not found.** which we have not verified.

Based solely upon the foregoing examinations and assumptions and having regard to legal considerations which we deem relevant, and subject to the qualifications set out in **Error! Reference source not found.**, we are of the opinion that under the laws of the Cayman Islands:

1 **Existence and Good Standing**. The Company is an exempted company duly incorporated with limited liability, and is validly existing and in good standing under the laws of the Cayman Islands, with power and authority (corporate and other) to own its properties and conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. It is a separate legal entity and is subject to suit in its own name.

2 **Capacity and Power**. The execution and delivery of each of the Agreements by the Company and the performance of its obligations thereunder, including the issue and sale of the Shares (or any portion thereof) being delivered on the Closing Date, the consummation of the transactions contemplated by the Transaction Documents (as defined in **Error! Reference source not found.**), and the filing of each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, are within the corporate capacity and power of the Company and have been duly authorised and approved by all necessary corporate action of the Company.

3 **No Conflict.** The execution, performance and delivery of each of the Agreements do not violate, constitute a default under, conflict with or result in a breach of:

(a) any of the provisions of the Memorandum and Articles of Association (as defined in Schedule 1);

(b) any law or regulation applicable to the Company in the Cayman Islands currently in force; or

(c) any existing and applicable order or decree of any governmental or regulatory authority or agency in the Cayman Islands.

4 **Allotment and Issue.** The offer of the American Depository Shares representing the Shares and the allotment and issue by the Company of the Shares on the basis contemplated in the Transaction Documents have been duly authorised by the Company by the Resolutions (as defined in **Error! Reference source not found.**) and, upon payment and delivery as contemplated by the Agreements, will be validly issued and credited as fully paid and non-assessable. The offer of the American Depository Shares representing the Shares and the allotment and issue of the Shares do not conflict with or result in a breach of any terms or provisions of the Memorandum and Articles of Association or any law, public rule, or regulation applicable to the Company in the Cayman Islands currently in force.

5 **Share Capital.** Based on the Memorandum and Articles of Association, the Company has an authorised share capital of US$200,000 divided into 1,999,000,000 ordinary shares, par value US$0.0001 each and 1,000,000 shares of

a par value of US$0.0001 each of such class or classes (however designated) as the Board of Directors may determine in accordance with Article 9 of the Memorandum and Articles of Association. When allotted, issued, paid for and registered in the Register of Members (as defined in Schedule 1), the Shares are considered to be legally and validly allotted and issued, fully paid and non-assessable and will conform to the description of the Shares contained in the Registration Statement and will rank *pari passu* in all respects with all other issued Shares subject to the rights, privileges and restrictions set forth in the Memorandum and Articles of Association. Based solely on our review of the Corporate Documents, the issued share capital of the Company prior to the issue of the Shares is [●] shares of a par value of US$[0.0001] each and all of the issued shares in the capital of the Company:

(a) have been duly and validly authorised and issued;

(b) are fully paid and non-assessable;

(c) were not issued in violation of any pre-emptive or similar rights under Caymans Islands law or the Memorandum and Articles of Association; and

(d) conform to the description thereof in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

6 **Due Execution.** Each of the Underwriting Agreement and the Deposit Agreement has been duly executed for and on behalf of the Company.

7 **Enforceability.** Each of the Agreements will be treated by the courts of the Cayman Islands as the legally binding and valid obligations of the Company enforceable in accordance with its terms.

8 **Authorisation and Approvals.** No authorisations, consents, orders, licenses, qualifications, permissions, approvals or formal exemptions from any governmental, regulatory, municipal or judicial authority or agency or other public body in the Cayman Islands are required and no notice to, declaration, registration or other filing with or action by any Cayman Islands governmental, regulatory, municipal or judicial authority or other public body is required in connection with:

(a) the execution, delivery, performance and enforcement or admissibility in evidence of each of the Agreements;

(b) the exercise of any of the Company's rights under each of the Agreements;

(c) the performance of any of the Company's obligations under each of the Agreements;

(d) issue, circulation and distribution of the Registration Statement;

(e) the offering offer of the American Depository Shares representing the Shares and the allotment, issue and sale of the Shares;

(f) the listing of the American Depository Shares representing the Shares; or

(g) the payment of any dividends and other distributions declared and payable by the Company to the holder of Shares and any other amount under the Transaction Documents.

9 **Filings.** It is not necessary to ensure the legality, validity, enforceability or admissibility in evidence of the Agreements that any document be filed, recorded or enrolled with any governmental, regulatory or judicial authority in the Cayman Islands.

10 **Judgment Currency**. Any monetary judgment in a court of the Cayman Islands in respect of a claim brought in connection with each of the Agreements is likely to be expressed in the currency in which such claim is made as such courts have discretion to grant a monetary judgment expressed otherwise than in the currency of the Cayman Islands.

11 **Taxes**. There are no stamp duties (other than the stamp duties mentioned in paragraph **Error! Reference source not found.** of **Error! Reference source not found.**), income taxes, withholdings, levies, registration taxes, recording, filing or other fees or charges now imposed, or which under the present laws of the Cayman Islands could in the future become imposed, in connection with the execution, delivery, performance, enforcement or admissibility in evidence of the Agreements or on any payment to be made by the Company or any other person pursuant to the Agreements.

12 **Interest**. There is no applicable usury or interest limitation law in the Cayman Islands which would restrict the recovery of payments or performance by the Company of its obligations under each of the Agreements.

13 **Enforcement of Judgments**. Any final and conclusive monetary judgment for a definite sum obtained against the Company in the courts of New York State (the ***Court***) in respect of any of the Agreements would be treated by the courts of the Cayman Islands as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary provided that:

(a) the Court had jurisdiction in the matter and the Company either submitted to such jurisdiction or was resident or carrying on business within such jurisdiction and was duly served with process;

(b) the judgment given by the Court was not in respect of penalties, fines, taxes or similar fiscal or revenue obligations;

(c) in obtaining judgment there was no fraud on the part of the person in whose favour judgment was given or on the part of the Court;

(d) recognition or enforcement in the Cayman Islands would not be contrary to public policy; and

(e) the proceedings pursuant to which judgment was obtained were not contrary to the principles of natural justice.

14 **Adverse Consequences.** Under the laws of the Cayman Islands, none of the parties to the Agreements (other than the Company) will be deemed to be resident, domiciled or carrying on any commercial activity in the Cayman Islands or subject to any tax in the Cayman Islands by reason only of the execution and performance of the Agreements, nor is it necessary for the execution, performance and enforcement of the Agreements that any such party be licensed, authorised or qualified to carry on business in the Cayman Islands. It is not necessary under the laws of the Cayman Islands to enable the parties to the Agreements (other than the Company) to enforce their rights under the Agreement provided that they are not otherwise engaged in business in the Cayman Islands.

15 **Choice of Law and Submission to Jurisdiction.** The choice of the laws of New York State as the governing law of each of the Agreements would be upheld as a valid choice of law by the courts of the Cayman Islands and applied by such courts in proceedings in relation to such Agreement as the proper law thereof and the submission by the Company to the jurisdiction of the courts of New York State, and the appointment of an agent to receive service of proceedings in New York State are valid and binding as a matter of Cayman Islands law.

16 **Immunity.** Neither the Company nor any of its properties or assets has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution or otherwise) under the laws of the Cayman Islands. The irrevocable and unconditional waiver and agreement of the Company contained in section [15](a) of the Underwriting Agreement and Section 22 of the Deposit Agreement not to plead or claim any such immunity in any legal action, suit or proceeding based on such Agreement is valid and binding under the laws of the Cayman Islands.

17 **Indemnification.** The indemnification and contribution provisions set out in section 8 of the Underwriting Agreement do not contravene the public policy or laws of the Cayman Islands.

18 ***Pari Passu* Obligations**. The obligations of the Company under each of the Agreements constitute direct obligations that (save as expressly subordinated thereby) rank at least *pari passu* with all its other unsecured obligations (other than those preferred by law).

19 **Exchange Controls.** There are no foreign exchange controls or foreign exchange regulations under the currently applicable laws of the Cayman Islands.

20 **Sovereign Immunity.** The Company is not entitled to claim immunity from suit or enforcement of a judgment on the ground of sovereignty or otherwise in the courts of the Cayman Islands in respect of proceedings against it in relation to the Agreements and the execution of each of the Agreements and performance of its obligations under the Agreements by the Company constitute private and commercial acts.

21 **Court Search.** Based solely on our inspection of the Register of Writs and Other Originating Process in the Grand Court of the Cayman Islands (the ***Court Register***) on [*court search date*] from the date of incorporation of the Company (the ***Court Search***), the Court Register disclosed no writ, originating summons, originating motion, petition (including any winding-up petition), counterclaim nor third party notice (***Originating Process***) nor any amended Originating Process pending before the Grand Court of the Cayman Islands, in which the Company is identified as a defendant or respondent.

22 **Register of Members**. The Register of Members of the Company is *prima facie* evidence of the matters set out therein and a member registered in the Register of Members of the Company will be deemed, as a matter of Cayman Islands law, to have legal title to those shares as set against its name in the Register of Members.

23 **Disclosure**. The statements in the Registration Statement, the Time of Sale Prospectus and the Prospectus appearing under the headings "Risk Factors", "Dividends Policy", "Enforcement of Civil Liabilities", "Management", "Description of Share Capital", "Description of American Depositary Shares", "Shares and ADSs Eligible for Future Sale" and "Taxation", in each case to the extent that they constitute statements of Cayman Islands law or summaries of the Company's organisational documents, are accurate and complete in all respects.

24 **No Liability**. No holder of the Shares outstanding after completion of the offering contemplated by the Underwriting Agreement is or will be subject to any liability in the Cayman Islands in respect of any liability of the Company by virtue only of holding any such Shares.

25 **Proper Form.** Each of the Agreements is in proper form under the laws of the Cayman Islands for the enforcement thereof against the Company, and to ensure the legality, validity, enforceability or admissibility into evidence in the Cayman Islands of the Agreements.

This opinion is confined to the matters expressly opined on herein and given on the basis of the laws of the Cayman Islands as they are in force and applied by the Cayman Islands courts at the date of this opinion. We have made no investigation of, and express no opinion on, the laws of any other jurisdiction. We express no opinion as to matters of fact. Except as specifically stated herein, we make no comment with respect to any representations and warranties which may be made by or with respect to the Company in the Transaction Documents. We express no opinion with respect to the commercial terms of the transactions the subject of this opinion.

This opinion is rendered for your benefit and the benefit of your legal counsel (in that capacity only) in connection with the transactions contemplated by the Transaction Documents. It may be disclosed to your successors and assigns only with our prior written consent. It may not be disclosed to or relied on by any other party or for any other purpose.

Yours faithfully

Harney Westwood & Riegels

SCHEDULE 1

List of Documents Examined

1 the Certificate of Incorporation of the Company dated 27 May 2015 and the third amended and restated Memorandum and Articles of Association of the Company adopted by special resolutions passed on 26 May 2020 and effective immediately upon the closing of the IPO (the ***Memorandum and Articles of Association***);

2 a Certificate of Good Standing in respect of the Company issued by the Registrar of Companies dated 27 May 2020;

3 the Register of Writs and other Originating Process of the Grand Court of the Cayman Islands kept at the Clerk of Courts Office, George Town, Grand Cayman from the incorporation date of the Company to [●];

4 the Register of Directors and Officers and Register of Members and Register of Mortgages and Charges of the Company provided to us on [●];

5 a copy of the unanimous written resolutions of the shareholders of the Company dated 26 May 2020 approving the Company's entry into, and authorising the execution and delivery by the Company of, the Underwriting Agreement and the Deposit Agreement;

6 a copy of the minutes of a meeting of the board of directors of the Company dated 13 May 2020 approving the Company's entry into, and authorising the execution and delivery by the Company of, the Underwriting Agreement and the Deposit Agreement (together with the resolutions referred to in **Error! Reference source not found.** above, the ***Resolutions***),

(**Error! Reference source not found.** to **Error! Reference source not found.** above are the ***Corporate Documents***); and

7 copies of the executed Transaction Documents consisting of the following:-

(a) the underwriting agreement dated [●] entered into among (i) the Company and (ii) Morgan Stanley & Co. LLC and Jefferies LLC acting severally on behalf of the Underwriters (as defined in Appendix I) (the ***Underwriting Agreement***);

(b) the deposit agreement (the ***Deposit Agreement***) dated [●] entered into among the Company, JPMORGAN CHASE BANK, N.A. and all Holders and Beneficial Owners of American Depositary Receipts issued under the Deposit Agreement representing American Depositary Shares;

(c) the final prospectus relating to the Shares dated [●], in the form first filed by the Company pursuant to [Rule 424(b) under the Securities Act] (the ***Prospectus***);

(d) the preliminary prospectus supplement, together with the documents and pricing information set forth in Schedule II to the Underwriting Agreement, taken together (collectively, the ***Time of Sale Prospectus***); and

(e) the Registration Statement,

(items (a) – (b) above are the ***Agreements*** and items (a) – (e) above are the ***Transaction Documents***).

The Corporate Documents and the Transaction Documents are collectively referred to in this opinion as the ***Documents***.

SCHEDULE 2

Assumptions

1 **Validity under Foreign Laws.** That (i) each party to the Underwriting Agreement (other than the Company) has the necessary capacity, power and authority to enter into the Underwriting Agreement and perform its obligations thereunder, and each such party has duly executed the Underwriting Agreement; (ii) the Underwriting Agreement constitutes valid, legally binding and enforceable obligations of each of the parties thereto under the laws of New York State by which law it is expressed to be governed; (iii) all formalities required under the laws of New York State and any other applicable laws (other than the laws of the Cayman Islands) have been complied with; and (iv) no other matters arising under any foreign law will affect the views expressed in this opinion.

2 **Choice of Laws.** The choice of the laws of New York State selected to govern the Underwriting Agreement has been made in good faith and will be regarded as a valid and binding selection which will be upheld in the courts of that jurisdiction and all other relevant jurisdictions (other than the Cayman Islands) and the entry into and performance of the Underwriting Agreement will not cause any of the parties thereto to be in breach of any agreement or undertaking.

3 **Directors.** The board of directors of the Company considers the execution of the Underwriting Agreement and the transactions contemplated in the Transaction Documents to be in the best interests of the Company and no director has a financial interest in or other relationship to a party or the transactions contemplated by the Underwriting Agreement which has not been properly disclosed in the Resolutions.

4 ***Bona Fide* Transaction.** No disposition of property effected by the Transaction Documents is made for an improper purpose or wilfully to defeat an obligation owed to a creditor and at an undervalue.

5 **Solvency.** The Company was on the date of execution of the Underwriting Agreement able to pay its debts as they became due from its own moneys, any disposition or settlement of property effected by the Underwriting Agreement is made in good faith and for valuable consideration and, at the time of and following each such disposition of property by the Company pursuant to the Underwriting Agreement, the Company will be able to pay its debts as they become due from its own moneys.

6 **Authenticity of Documents.** All original Documents are authentic, all signatures, initials and seals are genuine, all copies of Documents are true and correct copies and the Transaction Documents conform in every material respect to the latest draft of the same produced to us and, where the Transaction Documents have been provided to us in successive drafts marked-up to indicate changes to such documents, all such changes have been so indicated.

7 **Corporate Documents.** All matters required by law to be recorded in the Corporate Documents are so recorded, and all corporate minutes, resolutions, certificates, documents and records which we have reviewed are accurate and complete, and all facts expressed in or implied thereby are accurate and complete.

8 **Court Search.** The Register of Writs and other Originating Process of the Grand Court of the Cayman Islands examined by us for the period from the date of incorporation of the Company to [*court search date*] at the Clerk of Courts Office, George Town, Grand Cayman on [*court search date*], constitutes a complete record of the proceedings for such period before the Grand Court of the Cayman Islands.

9 **No Steps to Wind-up**. The directors and shareholders of the Company have not taken any steps to have the Company struck off or placed in liquidation, no steps have been taken to wind up the Company and no receiver has been appointed over any of the property or assets of the Company.

10 **Resolutions**. The Resolutions remain in full force and effect, and the Resolutions are an accurate record of the relevant meetings and are factually accurate as to notice and quorum.

11 **Execution**. The Underwriting Agreement was either executed as a single physical document (whether in counterpart or not) in full and final form or, where the Underwriting Agreement was executed by or on behalf of any company, body corporate or corporate entity, the relevant signature page was attached to such agreement by, or on behalf of, the relevant person or otherwise with such person's express or implied authority.

12 **Unseen Documents.** Save for the Documents provided to us there are no resolutions, agreements, documents or arrangements which materially affect, amend or vary the transactions envisaged in the Documents and, in particular, that the entry into and performance of the Underwriting Agreement will not cause any of the parties thereto to be in breach of any agreement or undertaking.

13 **Proceeds of Crime.** No monies paid to or for the account of any party under the Underwriting Agreement represent or will represent criminal property or terrorist property (as defined in the Proceeds of Crime Law (2020 Revision) and the Terrorism Law (2018 Revision), respectively).

SCHEDULE 3

Qualifications

1 **Enforceability**. The term ***enforceable*** as used above means that the obligations assumed by the Company under the relevant instrument are of a type which the courts of the Cayman Islands enforce. It does not mean that those obligations will necessarily be enforced in all circumstances in accordance with their terms. In particular:

(a) **Insolvency.** Rights and obligations may be limited by bankruptcy, insolvency, liquidation, winding-up, reorganisation, moratorium, readjustment of debts, arrangements and other similar laws of general application affecting the rights of creditors;

(b) **Limitation Periods.** Claims under the Underwriting Agreement may become barred under the Limitation Law (1996 Revision) relating to the limitation of actions in the Cayman Islands or may be or become subject to defences of set-off, estoppel or counterclaim;

(c) **Equitable Rights and Remedies**. Equitable rights may be defeated by a *bona fide* purchaser for value without notice. Equitable remedies such as injunctions and orders for specific performance are discretionary and will not normally be available where damages are considered an adequate remedy;

(d) **Fair Dealing.** Strict legal rights may be qualified by doctrines of good faith and fair dealing - for example a certificate or calculation as to any matter might be held by a Cayman Islands court not to be conclusive if it could be shown to have an unreasonable or arbitrary basis, or in the event of manifest error;

(e) **Prevention of Enforcement.** Enforcement may be prevented by reason of fraud, coercion, duress, undue influence, unreasonable restraint of trade, misrepresentation, public policy or mistake or limited by the doctrine of frustration of contracts;

(f) **Penal Provisions**. Provisions, for example, for the payment of additional interest in certain circumstances, may be unenforceable to the extent a court of the Cayman Islands determines such provisions to be penal;

(g) **Currency.** A Cayman Islands court retains a discretion to denominate any judgment in Cayman Islands dollars;

(h) **Confidentiality**. Provisions imposing confidentiality obligations may be overridden by the requirements of legal process;

(i) **Award of Costs**. In principle the courts of the Cayman Islands will award costs and disbursements in litigation in accordance with the relevant contractual provisions but there remains some uncertainty as to the way in which the rules of the Grand Court will be applied in practice. Whilst it is clear that costs incurred prior to judgment can be recovered in accordance with the relevant contract, it is likely that post-judgment costs (to the extent recoverable at all) will be subject to taxation in accordance with Grand Court Rules Order 62; and

(j) **Inappropriate Forum.** The courts of the Cayman Islands may decline to exercise jurisdiction in relation to substantive proceedings brought under or in relation to the Underwriting Agreement in matters where they determine such proceedings may be tried in a more appropriate forum.

2 **Stamp Duty**. Cayman Islands stamp duty may be payable if the original Underwriting Agreement is executed in, brought to, or produced before a court of, the Cayman Islands.

3 **Severability.** The courts in the Cayman Islands will determine in their discretion whether or not an illegal or unenforceable provision may be severed.

4 **Several Remedies.** In certain circumstances provisions in the Underwriting Agreement that (i) the election of a particular remedy does not preclude recourse to one or more remedies, or (ii) the delay or failure to exercise a right or remedy will not operate as a waiver of any such right or remedy, may not be enforceable by the courts of the Cayman Islands.

5 **Foreign Statutes.** We express no opinion in relation to provisions making reference to foreign statutes in the Underwriting Agreement.

6 **Amendment.** A Cayman Islands court would not treat as definitive a statement in a contract that it could only be amended or waived in writing, but would be able to consider all the facts of the case (particularly where consideration had passed) to determine whether a verbal amendment or waiver had been effected and, if it found that it had, such verbal amendment or waiver would be deemed to have also amended the stated requirement for a written agreement.

7 **Good Standing.** The Company shall be deemed to be in good standing at any time if all fees (including annual filing fees) and penalties under the Companies Law have been paid and the Registrar of Companies has no knowledge that the Company is in default under the Companies Law.

8 **Court Search**. The Court Register is prepared manually and through inadvertent errors or delays in updating may not constitute a complete record of all proceedings and in particular may omit details of very recent filings. The Court Search of the Court Register would not reveal, amongst other things, an Originating Process filed with the Grand Court which, pursuant to the Grand Court rules or best practice of the Clerk of the Courts' office, should have been

entered in the Court Register but was not in fact entered in the Court Register (properly or at all), or any Originating Process which has been placed under seal or anonymised (whether by order of the Court or pursuant to the practice of the Clerk of the Courts' office).

9 **Conflict of Laws.** An expression of an opinion on a matter of Cayman Islands law in relation to a particular issue in this opinion should not necessarily be construed to imply that the Cayman Islands courts would treat Cayman Islands law as the proper law to determine that issue under its conflict of laws rules.

10 **Sanctions**. The obligations of the Company may be subject to restrictions pursuant to United Nations and European Union sanctions as implemented under the laws of the Cayman Islands.

11 **Economic Substance**. We have undertaken no enquiry and express no view as to the compliance of the Company with the International Tax Co-operation (Economic Substance) Law (2020 Revision).

Appendix I

1) Morgan Stanley & Co. LLC
   1585 Broadway
   New York, New York 10036

2) J.P. Morgan Securities LLC
   383 Madison Avenue
   New York, New York 10179

3) Jefferies LLC
   520 Madison Avenue
   New York, New York 10022

(collectively, the ***Underwriters***)

Exhibit 8.1

List of Subsidiaries

Name of Subsidiary	State or Other Jurisdiction of Incorporation
Legend Biotech Limited	British Virgin Islands
Legend Biotech HK Limited	Hong Kong
Nanjing Legend Biotech Co., Ltd.	People's Republic of China
Legend Biotech Ireland Limited	Ireland
Legend Biotech (Netherlands) BV	Netherlands
Legend Biotech USA Inc.	Delaware

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 annual report on Form 20-F of Legend Biotech Corp.;

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)) 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) [Reserved];

(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: April 2, 2021

/s/ Ying Huang
Name: Ying Huang
Title: Chief Executive Officer and Chief Financial 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 annual report on Form 20-F of Legend Biotech Corp.;

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)) 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) [Reserved];

(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: April 2, 2021

/s/ Lori Macomber
Name: Lori Macomber
Title: Vice President, Finance (*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 the Annual Report of Legend Biotech Corp. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ying Huang, Chief Executive Officer of the Company and 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: April 2, 2021
/s/ Ying Huang
Name: Ying Huang
Title: Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer)

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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 the Annual Report of Legend Biotech Corp. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lori Macomber, Vice President, Finance 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: April 2, 2021

/s/ Lori Macomber
Name: Lori Macomber
Title: Vice President,
Finance (Principal Financial Officer)

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the 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 of our report dated April 2, 2021, with respect to the consolidated financial statements of Legend Biotech Corporation included in this Annual Report (Form 20-F) for the year ended December 31, 2020.

/s/ Ernst & Young Hua Ming LLP
Shanghai, the People's Republic of China
April 2, 2021