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 2023 OF 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 Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Legend Biotech Corporation ("**Legend Biotech**"), 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 Biotech for the year ended 31 December 2023. For details, please refer to the attachment, which is the full Form 20-F as published on the SEC's website available at https://www.sec.gov/Archives/edgar/data/1801198/000180119824000021/0001801198-24-000021-index.html.

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, 19 March 2024

As at the date of this announcement, the executive Directors are Dr. Zhang Fangliang, 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*

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

FORM 20-F

☐ **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, 2023

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:
363,822,069 ordinary shares, par value $0.0001 per share, were issued and outstanding as of December 31, 2023

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

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

Our fiscal year end is December 31. References to a particular "fiscal year" are to our fiscal year ended December 31 of that calendar year. Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States.

This Annual Report contains translations of Renminbi ("RMB") amounts into U.S. dollars at specified rates solely for the convenience of the reader. We make no representation that the RMB or U.S. dollar amounts referred to in this Annual Report could have been or could be converted into U.S. dollars or RMB, as the case may be, at any particular rate or at all. Unless otherwise noted, translations of RMB amounts into U.S. dollars in this Annual Report are made based on an exchange rate of RMB 7.08 to $1.00, which is the exchange rate as of December 31, 2023 as published by the People's Bank of China.

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

- "ADSs" are to the American depositary shares, each of which represents two of our ordinary shares;
- "ADRs" are to the American depositary receipts that evidence the ADSs;
- "China" or "PRC" refers to the People's Republic of China, and solely in the context of describing PRC rules, laws, regulations and other legal and tax matters, excludes rules, laws, regulations and other legal and tax matters of the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan, however, the legal and operational risks discussed by the Company with respect to operating in the PRC throughout this filing also apply to Hong Kong and Macau; "Greater China" does not exclude the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan;
- "Ordinary shares" are to ordinary shares of our company, par value $0.0001 per share;
- "Renminbi" or "RMB" refers to the legal currency of the PRC;
- "Series A Preference Shares" are to the Series A preference shares, par value $0.0001 per share; and
- "US$," "U.S. dollars," "$," or "dollars" are to the legal currency of the United States.

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

MARKET, INDUSTRY AND OTHER DATA

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

TRADEMARKS AND SERVICE MARKS

"Legend Biotech," the Legend logo and other trademarks or service marks of the Company appearing in this Annual Report are the property of the Company. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report are without the ®, ™ and other similar symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. CARVYKTI is a registered trademark in the United States of Johnson & Johnson. Other trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. We do not intend our use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other person.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report 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 and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth, strategies and the industry in which we operate.

Forward-looking statements can be identified by words or phrases, such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements relating to:

- the ability to effectively manufacture, market and sell CARVYKTI;
- the market opportunity for and potential for commercial success of CARVYKTI;
- potential effects of treatment with CARVYKTI and resulting regulatory investigations or label updates;
- the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- our ability to achieve specified milestones under our collaboration with Janssen Biotech, Inc., a Johnson & Johnson company ("Janssen") for cilta-cel or under other collaboration and license agreements we have entered into;

- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract, retain and motivate such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of the product candidates we may develop, if approved;
- information about the prices and availability of labor, transportation and raw materials, including as a result of inflation, and our ability to obtain them in a timely manner;
- our exposure to and the potential impact of risks inherent in our foreign operations, including currency fluctuations, exchange controls and pricing restrictions;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- the effectiveness of our key information technology systems, networks, processes or related controls or those of our service providers;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our ability to consistently maintain effective internal control over financial reporting;
- changes in tax laws and the resolution of tax contingencies resulting in additional tax liabilities;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of United States or foreign laws and regulations on the Company’s operations, including the impact of tariffs; and
- the effect of epidemics and pandemics, rising inflation rates, geopolitical tensions, the failure and instability of financial institutions, or other world events' disruptions on our business, including, without limitation, our ability to manage the demand, supply and operational challenges associated with the actual or perceived effects of such disruptions.

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” in this Annual Report 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, 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 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 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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 20-F and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report and the documents that we refer to and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. Given these risks and uncertainties, you are cautioned not to place undue reliance on these forward-looking statements.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

ITEM 3. KEY INFORMATION

Our Holding Company Structure and China Operations

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

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

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

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

Recently, the PRC government has indicated an intent to exert more oversight and control over offerings that are conducted outside of the PRC and/or investment by non-PRC investors in issuers with operations in China, and initiated a series of regulatory actions and made a number of public statements, including cracking down on illegal activities in the securities market, enhancing supervision over companies with operations in China to be listed outside of the PRC, adopting

new measures to extend the scope of cybersecurity reviews, and expanding efforts in anti-monopoly enforcement. As a result, risks to our business arise from, among other things, the complex and evolving PRC legal system, frequent changes in laws, regulations and government policies, uncertainties, difficulties or delays in obtaining regulatory approvals or completing filing procedures for listing on a non-PRC stock exchange or conducting certain business activities and increasing oversight on cybersecurity and data privacy related to the PRC government's recently issued statements and instituted regulatory actions and could result in actions taken against the assets of our PRC subsidiaries, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline.

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

Permissions Required from the PRC Authorities for Our Operations

Each of our PRC subsidiaries is required to obtain, and has obtained, a business license issued by local counterparts of the State Administration for Market Regulation (the "SAMR"). As of the date of this Annual Report and to our knowledge, our PRC subsidiaries have obtained the requisite licenses and permits from the PRC government authorities that are material for their business operations in China. However, given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by government authorities, we cannot assure you that we have obtained all the permits or licenses required for conducting our business in the PRC.

In connection with our previous issuance of securities to investors in stock markets outside the PRC, under current PRC laws, regulations and regulatory rules, as of the date of this Annual Report, we and our PRC subsidiaries, (i) are not required to obtain permissions from the CSRC, (ii) are not required to go through cybersecurity review by the Cyberspace Administration of China (the "CAC"), and (iii) to our knowledge, we have not received or been denied such requisite permissions by any PRC authority. However, the PRC government has recently indicated an intent to exert more oversight and control over offerings that are conducted outside the PRC and/or investment by non-PRC investors in issuers with operations in China.

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

Dividends and other distributions

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

Legend Biotech is a holding company with no operations of its own. We conduct our operations through our subsidiaries, including our PRC subsidiaries. If the PRC government deems that any of our business operations carried out by our PRC subsidiaries should be restricted or prohibited from non-PRC investment in the future, we may be required to stop our business operations in the PRC and we could be subject to material penalties or be forced to relinquish our interests in the affected operations. Such events could result in a material change in our operations and a material change in the value of our securities, including causing the value of such securities to significantly decline. As we have incurred net losses and negative cash flow from operations historically, none of our subsidiaries have declared or paid any dividends or distributions to Legend Biotech or any investors as of the date of this Annual Report. Instead, we have primarily relied on upfront and milestone payments and interest-bearing borrowings from Janssen under our collaboration and license agreement (the "Janssen Agreement"), proceeds from public offerings and private placements of equity securities, and

capital contributions from GenScript to fund business operations of our operating subsidiaries. All the net cash proceeds we receive from financial activities are first deposited in the bank account of Legend Biotech. The funds deposited into Legend Biotech's accounts are then transferred through Legend Biotech's applicable subsidiaries to each operating subsidiary to meet its working capital needs primarily through capital contributions or intercompany loans. For the year ended December 31, 2022, Legend Biotech transferred $430.0 million through such capital contributions or intercompany loans. For the year ended December 31, 2023, approximately $1.27 billion was transferred into Legend Biotech Ireland Limited, Legend Biotech's wholly-owned subsidiary, making it a full treasury center for Legend Biotech.

According to the Foreign Investment Law of the PRC and its implementing rules, which jointly established the legal framework for the administration of non-PRC-invested companies, a non-PRC investor may, in accordance with other applicable laws, freely transfer into or out of China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of RMB or any non-PRC currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the PRC and other PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the PRC subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our PRC subsidiaries may allocate a portion of their after-tax profits based on PRC accounting standards to a discretionary reserve fund. See "—D. Risk Factors—Risks Related to Doing Business in China—Our business may be significantly affected by the newly enacted Foreign Investment Law and the "negative list".

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

A. [Reserved]

B. Capitalization and Indebtedness

Not Applicable.

C. Reasons for the Offer and Use of Proceeds

Not Applicable.

D. Risk Factors

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

Risk Factors Summary

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

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

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

- We are substantially dependent on the commercial success of CARVYKTI. If we are unable to successfully commercialize CARVYKTI or experience significant delays in doing so, our business will be materially harmed.
- We have limited experience as a commercial company and the manufacture, marketing and sale of CARVYKTI or future products may be unsuccessful or have less success than anticipated.
- The commercial success of CARVYKTI, and of any future products, will depend upon the degree of market acceptance by physicians, third-party payors and others in the medical community.
- If the market opportunities for our product or any future products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.
- Adverse side effects or other safety risks associated with CARVYKTI or any future products could limit the commercial profile of an approved label or result in significant negative consequences following marketing approval.
- We may not be able to successfully create our own manufacturing infrastructure for supply of our requirements of products for use in clinical trials and for commercial sale.
- We have limited sales experience and limited capabilities for marketing and market access. We expect to continue to invest significant financial and management resources to establish necessary capabilities and infrastructure to support our commercial needs. If we are unable to establish these commercial capabilities, we may be unable to generate sufficient revenue to sustain our business.
- We operate in a rapidly changing industry and face significant competition.
- Potential product liability risks.

Risks Related to Our Business

- Our ability to become and remain profitable may never be achieved due to the uncertainty of developing and commercializing complex therapies, and we may never achieve or maintain profitability.
- Our limited operating history, which has focused on research and development, makes it difficult to assess our future prospects.
- Our need for additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.

- Our inability to obtain or manufacture raw materials or key starting materials necessary for product manufacture, such as lentiviral vectors, would adversely affect the clinical development and commercialization of these products, which could, in turn, adversely affect our sales and profitability.

Risks Related to the Development of Our Product Candidates

- The uncertainties of the biopharmaceutical development process for novel and emergent treatment, including the uncertainty of outcomes of clinical trials, and the potential failure of product candidates to show safety or efficacy.
- Potential failure to obtain or maintain regulatory approvals for our product candidates.
- Our primary research and development efforts are focused on cell therapies, including chimeric antigen receptor T cell ("CAR-T") therapies and chimeric antigen receptor natural killer cell ("CAR-NK") therapies, which are emerging treatments that face significant challenges and hurdles.
- Our product candidates require significant preclinical study and clinical trials, which can be difficult to design and implement.
- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval.
- Our dependence on enrollment of patients in clinical trials for development of our product candidates.
- Risks associated with investigator-initiated clinical trials and studies that we do not fully control.
- Certain product opportunities may face limited market opportunities.
- Costs and difficulties in the manufacture of complex cell therapies.

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

Risks Related to Our Intellectual Property

- Our ability to obtain, maintain, defend and enforce intellectual property rights in our products and disparities and uncertainties in intellectual property rights throughout the world.

- Risks related to third party intellectual property rights, including the significant cost and complexity associated with intellectual property proceedings.

Risks Related to Doing Business in China

- Risks related to doing business in China, including the impact of extensive Chinese regulation on the pharmaceutical industry.
- The heightened level of government involvement in the Chinese economy and uncertainties regarding legal protections in the PRC legal system.
- PRC governmental authorities may take measures having influence on our operations, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.
- PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiaries.
- The PRC government may exert more control over offerings conducted outside the PRC and/or investment by non-PRC investors in issuers with operations in China, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. For example, the approval of, or filing or other procedures with, the CSRC or other governmental authority may be required in connection with issuing our equity securities outside of the PRC under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.
- PRC regulations relating to offshore investment activities by PRC residents and enterprises may increase our administrative burden and restrict our non-PRC and cross-border investment activity.
- Monetary, economic, political, environmental, social, and trade disputes between the U.S. and China.
- The heightened level of actions by the U.S. government in targeting Chinese companies and, in the biotech industry, the U.S. government seeking to implement heightened supply chain security for sourcing from China and limitations on the transfer of technology to recipients within 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 largest shareholder.
- The more limited protections afforded to shareholders as a result of our status as 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, potential tax consequences and risks from dilution of our ADSs and ordinary shares if we issue additional ADSs or other securities.

Risks Related to Commercialization of CARVYKTI and Our Other Product Candidates

We are substantially dependent on the commercial success of CARVYKTI. If we are unable to successfully commercialize CARVYKTI or experience significant delays in doing so, our business will be materially harmed.

We have only recently begun to commercialize cilta-cel and sell under the name CARVYKTI pursuant to the Janssen Agreement. Net trade sales for CARVYKTI for the year ended December 31, 2023 were approximately $500.0 million. Our ability to offset our losses and sustain our business, will be largely dependent upon sales of CARVYKTI . Our success as a company is substantially dependent on our ability to continue to generate revenue from the sales of CARVYKTI, which will depend on many factors, including but not limited to, our ability to:

- achieve and maintain full approval of CARVYKTI in the United States and in other jurisdictions;
- execute our sales and marketing strategies for CARVYKTI;
- maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to continue and successfully commercialize CARVYKTI;
- achieve, maintain and grow market acceptance of, and demand for, CARVYKTI;
- establish or demonstrate in the medical community the safety and efficacy of CARVYKTI and its potential advantages over and side effects compared to existing and future products;
- secure payor approval of CARVYKTI on acceptable terms;
- offer CARVYKTI at competitive prices as compared to alternative options, and our ability to achieve a suitable profit margin on our sales of CARVYKTI;
- adapt to additional changes to the label for CARVYKTI that could place restrictions on how we market and sell CARVYKTI, including as a result of adverse events that may be observed in other studies;
- obtain adequate and timely supply of CARVYKTI, which may in the future be adversely affected by factors relating to our manufacturing capabilities, global pandemics, epidemics or endemics, geopolitical tension, global supply chain disruptions, failure of financial institutions, rising inflation and other world events;
- comply with applicable legal and regulatory requirements;
- maintain the necessary state pharmaceutical distribution licenses and permits required for the sale of CARVYKTI and a pharmacovigilance system satisfying applicable legal and regulatory requirements;
- maintain arrangements with specialty pharmacies to dispense CARVYKTI to customers and to provide related patient and administrative support services;
- enforce intellectual property rights in and to CARVYKTI; and
- avoid third-party patent interference or intellectual property infringement claims.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we may not be able to generate material and continuing revenue from sales of CARVYKTI, which may materially impact the success of our business.

We may not be able to successfully establish manufacturing capabilities and infrastructure to supply our requirements of CARVYKTI and our product candidates for use in clinical trials and for commercial sale, and we may encounter difficulties successfully manufacturing CARVYKTI and our product candidates.

As part of our collaboration with Janssen, we have established a manufacturing facility in the United States which currently produces commercial supply of CARVYKTI for the U.S. and European markets, and we anticipate using this facility to supply other countries if we obtain approvals in such countries. We are in the process of establishing manufacturing capabilities in Belgium for commercial supply in the EU and U.S. markets, and possibly additional markets. We also have manufacturing facilities in the United States, Belgium and China which are currently supplying cilta-cel for our clinical trials.

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

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

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

We expect that operating our own commercial cell manufacturing facilities will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term cost margins. However, we have limited experience as a company in designing and operating a commercial manufacturing facility and may never be successful in effectively implementing our manufacturing capability. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce CARVYKTI or any future products in sufficient quantities to meet the requirements for the contemplated launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

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

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

In addition, any significant disruption in the supply chain for starting materials necessary for our manufacturing processes could adversely affect our commercialization efforts. We source key materials from third party suppliers. There are a small number of suppliers for certain key materials that are used to manufacture our product and product candidates. We must compete with other market participants for the limited supply of such materials, which may result in increased costs. Moreover, supply chain constraints with respect to such starting materials may impact the execution of our commercialization efforts. Any such supply chain constraints would necessarily limit the commercial benefits that could be achieved from a broader distribution.

We have not yet established manufacturing capacity at full commercial scale and may underestimate the cost and time required to do so, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our products and product candidates to levels that will allow for a margin in line with our expectations and return on investment in connection with commercialization.

To address market demand for CARVYKTI, we and our collaboration partner Janssen have engaged and are continuing to engage and pursue the use of CMOs in order to supplement our clinical and commercial manufacturing capabilities and infrastructure. For example, in April 2023 we and Janssen entered into a Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product with Novartis Pharmaceuticals Corporation (the "Novartis Clinical Supply Agreement"), to initiate technology transfer activities necessary for Novartis to manufacture cilta-cel for clinical development to supplement our manufacturing capabilities. We may be unable to enter into additional agreements with CMOs on acceptable terms or at all. Any planned use of CMOs with which we and Janssen have engaged or may engage could be delayed as we transfer our manufacturing technology to these CMOs, as these CMOs file for and await regulatory approval to manufacture CARVYKTI, and as these CMOs gain experience with our manufacturing technology and supply requirements. Furthermore, for any CMOs with which we and Janssen have engaged or may engage, production by these CMOs will be subject to the same risks and uncertainties as our manufacture of CARVYKTI. We may have less control over supply when compared with the facilities operated by us and Janssen, and the overall cost of goods for CARVYKTI may be higher as a result of such CMO engagements.

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

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

Having received FDA approval for CARVYKTI on February 28, 2022 and conditional approval from the European Commission on May 25, 2022, we remain at the early stages of commercializing CARVYKTI in the United States and Europe, with our collaborator Janssen, for the treatment of adults with relapsed or refractory multiple myeloma ("MM") who have received four or more prior lines of therapy (for commercialization in the United States), or three or more lines of therapy (for commercialization in Europe), in each case, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. While CARVYKTI has received marketing authorizations from a limited number of additional jurisdictions, it has not yet been commercially marketed outside the United States and Europe.

As CARVYKTI is our first approved product and the remainder of our product candidates are in clinical or preclinical development, we have limited experience as a commercial company and there is limited information about our ability to overcome many of the challenges encountered by companies commercializing products in the biopharmaceutical industry. To execute our business plan, in addition to successfully manufacturing marketing and selling of CARVYKTI, we, either individually or with a collaboration partner, will need to successfully:

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

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

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

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

significant product revenue and may not become profitable. The degree of market acceptance of CARVYKTI and of any future products will depend on a number of factors, including:

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

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts, and the efforts of any of our collaborators, to educate the medical community and payors on the benefits of our products may require significant resources and may never be successful. These efforts may require more resources than are required by the conventional technologies marketed by certain of our competitors. Any of these factors may cause CARVYKTI, or any future products, to be unsuccessful or less successful than anticipated.

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

Our projections regarding the number of people who have the potential to benefit from treatment with CARVYKTI or any future products are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases that our product candidates target. The number of patients may turn out to be lower or more difficult to identify than expected.

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

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

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

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

significant internal team or the support of a third party to perform these functions, including marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

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

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize. 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 Therapeutics, Inc., Arcellx, Inc., Autolus Therapeutics plc, bluebird bio, Inc., Bristol-Myers Squibb, Co., Caribou Biosciences, Inc., CARsgen Therapeutics Holdings Limited, Celyad Oncology, Gracell Biotechnologies, Innovent Biologics, IASO Biotechnology, Poseida Therapeutics Inc., Novartis AG and Sana Biotechnology, Inc.;

- academic medical centers pursuing independent development of BCMA CAR-T technologies; and

- additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Inc., Regeneron Pharmaceuticals, Inc., GSK plc, Bristol-Myers Squibb Co., Johnson & Johnson (the parent company of Janssen, our collaboration partner for cilta-cel), AbbVie and Pfizer Inc.

Other than CARVYKTI, our product candidates are in early stages of development. Our competitors with development-stage programs may obtain marketing approval from the FDA, the National Medical Products Association (the "NMPA"), the European Commission, Japan’s Pharmaceuticals and Medical Devices Agency (“PMDA”) or other comparable regulatory authorities for their product candidates more rapidly than we do with respect to our development-stage product candidates, and they could establish a strong market position for either a product or a specific indication before we are able to enter the market.

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

Our commercial opportunity—including with respect to CARVYKTI—could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize.

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

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

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

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we commercialize CARVYKTI, expand our clinical trials or if we commercialize additional product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Business

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have historically incurred substantial net losses, including net losses of $518.3 million and $446.3 million for the years ended December 31, 2023 and 2022, respectively. At December 31, 2023, we had an accumulated deficit of $1,484.7 million. We expect our net losses to continue as a result of:

- our ongoing and planned research and development of cilta-cel for the treatment of relapsed and lenalidomide-refractory multiple myeloma ("RRMM");
- our investment in manufacturing capabilities, including investments in our facilities in the United States, Europe and China;
- our ongoing and planned clinical development for our other product candidates;
- our ongoing and planned research and development activities;
- our discovery and development of additional product candidates and further expansion of our clinical product pipeline;
- regulatory or marketing approvals for any product candidates that successfully complete clinical trials;
- scaling up internal and external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establishing sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory or marketing approval;
- developing, maintaining, expanding and protecting our intellectual property portfolio;
- acquiring or in-licensing other product candidates and technologies;
- hiring additional clinical, quality control and manufacturing personnel;

- adding clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expanding our operations globally; and
- incurring additional legal, accounting, investor relations and other expenses associated with operating as a public company.

These net losses have had, and will continue to have, a negative impact on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would harm our business, financial condition, results of operations and cash flows.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year, due to factors including the timing of product clearance, approval, commercial ramp, clinical trials, any litigation that we may file or that may be filed against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive under them. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our common shares and may in the future raise substantial doubt about our ability to continue as a going concern.

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.

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

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

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

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, we will need to raise additional capital to complete the development and commercialization of cilta-cel and our other product candidates and in connection with our continuing operations and other planned activities. Our future capital requirements will depend on many factors, including:

- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for CARVYKTI and any other of our product candidates for which we receive marketing approval;
- the progress, results and costs of laboratory testing, manufacturing, and preclinical and clinical development for our current product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- the development requirements of other product candidates that we may pursue;
- the timing and amounts of any milestone or royalty payments we may be required to make under future license agreements;

- the costs of building out our infrastructure, including hiring additional clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our product candidates;
- the amount of revenue we receive pursuant to the Janssen Agreement and the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

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

Our operating results may be adversely affected by inflation.

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

Risks Related to the Development of Our Product Candidates

With the exception of CARVYKTI, which was approved by the FDA on February 28, 2022 and has received marketing authorizations from a limited number of additional jurisdictions, all of our product candidates are in clinical development or in preclinical development. If we are unable to continue to advance CARVYKTI and to advance our other product candidates through clinical development, obtain regulatory approval and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

While our first product, CARVYKTI, was approved by the FDA on February 28, 2022 for the treatment of adults with RRMM who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody and has received marketing authorizations from a limited number of additional jurisdictions, our success depends, in part, on our ability to continue to advance the development of CARVYKTI in earlier lines of MM treatment. In collaboration with Janssen, we have completed a Phase 1b/2 trial in RRMM patients in United States and Japan (CARTITUDE-1) and are currently conducting a Phase 2 trial of cilta-cel in RRMM patients in China (CARTIFAN-1). In November 2019, we and Janssen began enrolling an aggregate of approximately 157 patients in a Phase 2 multicohort trial of cilta-cel in the United States, EU, Israel and Saudi Arabia (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, EU, Australia, Japan and Israel was initiated in June 2020. This clinical trial is comparing treatment with

cilta-cel to treatment of standard triplet therapy in Revlimid-refractory MM. On January 27, 2023 we announced that CARTITUDE-4 met its primary endpoint of showing a statistically significant improvement in progression-free survival (PFS) compared to standard therapy at the study's first pre-specified interim analysis. The study has been unblinded following the recommendation of an independent data monitoring committee. Applications seeking expanded labeling consistent with the CARTITUDE-4 findings are under review by FDA and the CAT, although advisory committee meetings occurring in the first half of 2024 could recommend against approval of expanded labeling, and even if favorable recommendations are made, regulatory authorities may decide against approval for these applications. We also initiated the Phase 3 CARTITUDE-5 clinical trial during August 2021, targeting enrollment at approximately 650 patients, including sites in the United States, EU, Canada, Australia, Korea and Japan. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in newly diagnosed MM patients for whom hematopoietic stem cell transplant is not planned as an initial therapy. Furthermore, a Phase 3 CARTITUDE-6 clinical trial was initiated in October 2023, targeting enrollment at approximately 750 patients, including sites in EU, Australia, Korea, and Israel. This clinical trial will compare treatment with cilta-cel to treatment of autologous stem cell transplant (ASCT) in newly diagnosed MM patients. There is no assurance that these or any other future clinical trials for cilta-cel will be successful or will generate further positive clinical data, and we may not receive additional marketing approval from the FDA or other regulatory agencies for cilta-cel.

In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous CAR-T product candidates targeting various cancers, including Non-Hodgkins Lymphoma (NHL), acute lymphoblastic leukemia (ALL), gastric cancer, esophageal cancer, pancreatic cancer, colorectal cancer, hepatocellular carcinoma, small cell lung cancer, and non-small cell lung cancer. We are also developing allogeneic gamma delta CAR-T and allogeneic CAR-NK product candidates targeting BCMA for MM, which are currently in investigator-initiated Phase 1 clinical trials in China. Additionally, we are developing an autologous CAR-T product candidate targeting GPC3 for non-small cell lung cancer (NSCLC) and an autologous CAR-T product candidate targeting GCC for colorectal cancer that are in preclinical development. 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 or other regulatory agencies, for any of our product candidates. There can be no assurance that the FDA will permit the Investigational New Drug ("IND") applications for our product candidates to go into effect in a timely manner or at all. Without an IND, we will not be permitted to conduct clinical trials in the United States.

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

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

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

Our proprietary, next-generation cell preparation technologies, our modular approach for CAR-T, gamma delta CAR-T and CAR-NK and our manufacturing platform for our 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, gamma delta CAR-T and CAR-NK 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 product candidates. With the exception of our first product, CARVYKTI, which was approved by the FDA on February 28, 2022 for the treatment of adults with RRMM who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody and which has received marketing authorizations from a limited number of additional jurisdictions, we do not currently have any approved products, nor do we have any commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to reengineer or abandon a particular product candidate. Because cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA, the NMPA, the European Commission, the PMDA and other regulatory authorities have limited experience with cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a cells *ex vivo* and infusing the engineered cells into the patient;
- conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our product candidates;
- sourcing clinical and commercial supplies of the materials used to manufacture CARVYKTI and our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating and obtaining a sufficient supply of viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent vector and cell manufacturing process;
- establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;
- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our cell technologies and the potential side effect profile of each of our product candidates, such as potential adverse side effects related to cytokine release syndrome ("CRS");
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- establishing sales and marketing capabilities to successfully launch and commercialize CARVYKTI and any other of our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of a novel therapy if we receive approval; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our 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 six CAR-T cell therapy products that involve the genetic modification of patient cells have been approved in the United States and the European Union, and five 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 and the European Commission have recommended a 15-year follow-up observation period for all patients who receive treatment using gene therapies, and we may need to adopt such an observation period for our product candidates.

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

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

Our business is substantially dependent on our ability to further advance the development of CARVYKTI, obtain regulatory approval for cilta-cel in other jurisdictions and for additional indications, obtain regulatory approval of our other product candidates, and successfully commercialize CARVYKTI and, if approved, our other product candidates. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates in countries outside the United States without obtaining regulatory approval from comparable regulatory authorities in relevant jurisdictions, such as the NMPA in China, the European Commission, on the basis of the technical / scientific opinion issued by the European Medicines Agency ("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 European Commission, the PMDA and other regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's research and development and may vary among jurisdictions. It is possible that none of our existing clinical- or preclinical-stage product candidates or any future product candidates will ever obtain regulatory approval.

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

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes of our facilities, including an inability for regulatory authorities to conduct any required inspections of our facilities, whether due to geopolitical conflict, such as the ongoing Russia-Ukraine conflict and Israel-Hamas conflict, or travel restrictions;
- 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, such as 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 may result in our deciding to abandon a development program. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may impose warnings and restrictions on prescription and distribution, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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

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

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

A key element of our strategy is to use our expertise in tumor biology and cell programming and our proprietary and modular cell programming technologies to develop what we believe are safer and more effective CAR-T and CAR-NK cell therapies. Our focus is on the development of a pipeline of cell therapy product candidates for the treatment of cancers and the progression of these product candidates through clinical development. In addition to developing additional product candidates, we intend to develop platform technologies, including manufacturing technologies, armoring strategies and next-generation CAR 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 ("CTAs"), in China and the EU. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the NMPA, the PMDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the FDA, the NMPA, the PMDA or other regulatory authorities allowing clinical trials to begin.

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

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

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

Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. While we have received positive data from previously completed and ongoing clinical trials of cilta-cel in RRMM, we are still in the process of conducting additional clinical trials in the

United States, Japan, several countries in the EU, Canada, Australia, Argentina, Brazil, Israel, and Korea in order to seek regulatory approvals. Our other product candidates are in earlier stages of development. For that reason, we do not know whether these candidates will be effective and safe for the intended indications in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

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

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

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the understanding of risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population who meet inclusion criteria;
- the proximity of patients to study sites;
- the design of the clinical trial;
- clinical trial investigators' ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell-based immunotherapy;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment.

In particular, some of our clinical trials are designed to enroll patients with characteristics that are found in a very small population. Other companies are conducting clinical trials with cell therapies in MM and for other conditions that are targeted by our research, and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical programs. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participating in our clinical trials.

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

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

We are currently evaluating our product candidates in investigator-initiated clinical trials. In addition, part of our strategy is to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China, where such trials are initiated and conducted under the oversight of the China National Health Commission (the "NHC") as a

medical practice technology, rather than the NMPA as a medical product. The NMPA, generally speaking, will accept, review, and reject or approve a CTA only from the manufacturer of the investigational product as the sponsor of the CTA, rather than from a physician who intends to be the investigator and sponsor of the CTA. The NMPA distinguishes the former as registrational clinical trial, and the latter as non-registrational clinical trial, and normally will not consider the data generated from investigator-initiated non-registrational clinical trials, when it reviews the application for registrational clinical trial from the manufacturer.

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

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

Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this section relating to clinical trials initiated by us. While investigator-initiated trials may provide us with clinical data that can inform our future development strategy, we do not have full control over the protocols, administration, or conduct of the trials. As a result, we are subject to risks associated with the way investigator-initiated trials are conducted and there is no assurance the clinical data from any of our investigator-initiated clinical trials in China will be accepted by the FDA, EMA, PMDA or other comparable regulatory authorities outside of China for any of our product candidates. Third parties in such investigator-initiated clinical trials may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with clinical trial protocols or applicable regulations. Further, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our product candidates. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own, and they may elect to discontinue these trials, even if we believe they have scientific merit. As a result, our lack of control over the design, conduct and timing of, and communications with the FDA, NMPA, EMA and PMDA, other comparable regulatory authorities, and relevant Institutional Review Boards, Ethics Committees, and competent national authorities 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. Finally, the cross-border transfer of data generated by investigator-initiated and other trials in China is regulated by PRC law. We may not be able to transfer all or part of such data to other countries, which may impede our ability to use such data to further regulatory applications and in regulatory reporting in such other countries.

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

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

clinical trials in these situations. Similarly, a portion of our pipeline product candidates target the treatment of advanced or metastatic solid tumors that have failed prior lines of therapy. In some instances, solid tumors that are diagnosed in an early stage may be treated with surgery either alone or in combination with chemotherapy and/or radiation. However, solid tumors that become more advanced or metastatic are often more difficult to treat and current therapies are often inadequate for many patients.

While CARVYKTI has been approved by FDA and has received marketing authorizations from a limited number of additional jurisdictions as a later line therapy for patients with MM, there is no guarantee that cilta-cel will be approved for earlier lines of therapy, nor is there any guarantee that any of our other product candidates, even if approved, will be approved for earlier lines of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to or post gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. 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 CARVYKTI or our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval.

In clinical trials conducted by us and other companies involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures, encephalopathy and speech impairment. Adverse events with the worst grades and attributed to CAR-T cells were severe and life threatening in some patients. The life threatening events were related to respiratory dysfunction and neurotoxicity. Severe and life threatening toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three weeks, but several patients died in clinical trials involving CAR-T cells, including in our clinical trials. Furthermore, other patients experienced serious adverse events at later stages in treatment follow-up, such as cytopenias, infections and neurotoxicity.

In the Phase-1 LEGEND-2 clinical trial, CRS was observed in 91.9% of patients, with grade 3 or higher CRS observed in 9.5% of patients. Total CAR-T cell neurotoxicity of any grade was observed in one patient. No grade 3 or higher neurotoxicity events were reported. At a median follow up of approximately 48 months, there were 34 reported deaths during the Phase 1 LEGEND-2 clinical trial: 28 due to disease progression, one due to CRS and tumor lysis syndrome, one due to pulmonary embolism and potential acute coronary syndrome, one due to respiratory failure associated with subsequent therapy, one due to esophageal carcinoma, and two due to infection. In the Phase 1b/2 CARTITUDE-1 clinical trial, CRS was reported in 95% of patients, with grade 3 or higher CRS observed in 5% of patients. Total CAR-T cell neurotoxicity of any grade was observed in 21.6% of patients, with grade 3 or higher neurotoxicity observed in 12.3% of patients. At a median follow up of approximately 33 months, there were 35 reported deaths during the Phase 1b/2 CARTITUDE-1 trial: 17 due to disease progression, six due to treatment-related adverse events as assessed by the investigator, and 12 due to adverse events unrelated to treatment.

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

Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension,

clinical hold or termination of clinical trials by us, Institutional Review Boards, Ethics Committees, the FDA, the NMPA, the PMDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenue from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, for CARVYKTI or any other of our product candidates that receives marketing approval, if we or others later identify undesirable side effects caused by that product or product candidate, including during any long-term follow-up observation period recommended or required for patients who receive treatment using the product or product candidate or during additional clinical trials or required Risk Evaluation and Mitigation Strategy ("REMs"), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product or product candidate;
- regulatory authorities may require additional warnings on the label;
- if a REMs is not already required for such product or product candidate, we may be required to create a REMs or similar risk management plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

For example, in December 2023, the FDA approved a label update for CARVYKTI to include additional efficacy and safety information from longer-term follow-up (median duration of 28 months) of the CARTITUDE-1 study. In this CARVYKTI label update, the following sentence was added to the Boxed Warning of the U.S. Prescribing Information: “Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with CARVYKTI.” In addition, in November 2023, the FDA announced that it was investigating a serious safety signal of T-cell malignancies identified in patients who received treatment with BCMA-directed or CD19-directed autologous CAR-T cell immunotherapies. The FDA considered this information to be ‘new safety information’ and that it is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR-T cell immunotherapies, including CARVYKTI. In January 2024, the FDA announced that it has determined that new safety information should be included in the labeling of all BCMA- and CD19-directed genetically modified autologous CAR-T cell immunotherapies, including CARVYKTI.

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

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

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

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

- the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit eligible patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the NMPA, the PMDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, such as cytokine-induced toxicity and T cell aplasia, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the NMPA, the EMA, the PMDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA, the NMPA, the European Commission, the PMDA or regulatory authorities in other countries or jurisdictions to approve the BLA, marketing authorization application, new drug application ("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.

CARVYKTI and our product candidates are biologics and their manufacture 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 commercialization and clinical trials could be delayed or stopped.

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

We, like other manufacturers of biologic products, may encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems

include delays or breakdowns in logistics and shipping, difficulties with production costs and yields, quality control, and product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations.

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

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

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

Furthermore, for any CMOs with which we and Janssen have engaged or may engage, production by these CMOs will be subject to the same risks and uncertainties we encounter with respect to our manufacturing facilities and our manufacture of CARVYKTI.

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 autologous 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 ("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 product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of a T cell therapy treatment process. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated.

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

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

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

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

Risks Related to Our Business Operations

As a company with substantial operations 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 the EU and 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 U.S. dollar, euro, RMB 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 and restricted share units granted under our incentive equity plans;
- 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, failure of financial institutions, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

As of December 31, 2023, we had approximately 1,800 full-time employees. As our development and commercialization plans progress and strategic plans expand and develop, and as we mature as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and both current and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

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

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

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

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

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

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel, any of whom may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified managerial, financial, scientific, advisory, clinical, commercialization, manufacturing, and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees or advisors 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 marketing approvals;
- regulatory risks, including approvals and clearances that may be required by the Committee for Foreign Investment in the United States or antitrust authorities; 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, expose us to regulatory investigations, give rise to significant liability, subject us to costly and protracted litigation, cause significant reputational harm and interfere with our ability to operate our business effectively.

In the ordinary course of business, we collect, store, and transmit (collectively "process") sensitive information, including but not limited to intellectual property, proprietary business information, and personal information such as health-related data. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such sensitive 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 sensitive 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 evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware, (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, earthquakes, fires, floods, terrorism, war and telecommunication, electrical failures and other similar threats. 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. In addition, a breach or disruption of our systems could occur as a result of an intentional or unintentional action or lack of action by a person inside of our network with authorized access. 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 traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

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. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition, any such event that leads to unauthorized access, use, or disclosure of personal information, including sensitive 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 we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our ability to monitor third-party vendors and other collaborators, contractors and consultants; information security practices is limited, and these third parties may not have adequate information security measures in place. If the information technology systems of these third parties 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. While we may be entitled to damages if our third-party service providers fail to satisfy their data privacy or security-related obligations to us, any awards may be insufficient to cover our damages, or we may be unable to recover such award.

We are or may become subject to a variety of stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security, and our failure or failure of our third-party vendors, collaborators, contractors or consultants to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, disruptions of our business operations, reputational harm, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

In the ordinary course of business, we maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, personal data, and other sensitive information in connection with our commercialization and development activities and our employees. Our data processing activities may, subject us to the numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and safety security policies, contractual requirements and other obligations relating to data privacy and

security. Any actual or perceived failure by us, our third- party vendors, collaborators, contractors and consultants to comply with applicable data privacy and security obligations could result in government enforcement actions (e.g. investigations, fines , penalties, audits, inspections, and similar actions); litigation (including class-action claims), additional reporting requirements and oversight; bans on processing personal data; orders to destroy or not use personal data; 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.

Further, 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. 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.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. On April 2, 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.

The Cyber Security Law of the PRC, which became effective in June 2017, created China's national-level data protection for "network operators," which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Furthermore, the Opinions on Strictly Cracking Down on Illegal Securities Activities, which were issued by the General Office of the State Council and another authority on July 6, 2021, requires the speed-up of the revision of the provisions on strengthening the confidentiality and archives management related to overseas issuance and listing of securities, and improvement to the laws and regulations related to data security, cross-border data flow, and management of confidential information. The Data Security Law, which was promulgated by the Standing Committee of PRC National People's Congress (the "SCNPC"), on June 10, 2021 and became effective on September 1, 2021, outlines the main system framework of data security protection. The Personal Information Protection Law promulgated by the SCNPC on August 20, 2021 and which became effective on November 1, 2021 outlines the main system framework of personal information protection and processing.

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

On July 7, 2022, the CAC published the Measures on Security Assessment of Cross-border Transfer of Data, which became effective on September 1, 2022 and provides that a data processor is required to apply for security assessment for cross-border data transfer in any of the following circumstances: (i) where a data processor provides critical data abroad; (ii) where a Critical Information Infrastructure Operators or a data processor which processes personal information of more than 1,000,000 individuals provides personal information abroad; (iii) where a data processor has provided personal information in the aggregate of 100,000 individuals or sensitive personal information of 10,000 individuals abroad since January 1 of the previous year; or (iv) other circumstances prescribed by the CAC for which declaration for security assessment for cross-board transfer of data is required.

The draft Regulations for the Administration of Cyber Data Security (the "Draft Data Security Regulations"), published by the CAC on November 14, 2021 for public comments until December 13, 2021 reiterate that a data processor who processes personal information of more than one million individuals shall go through the cyber security review if it intends to be listed in a country other than Greater China, and if a data processor conducts any data processing activities that affect or may affect national security, an application for cyber security review shall also be made by such processor.

And the Draft Data Security Regulations require data processors processing important data or being listed outside China shall carry out data security assessment annually by itself or through a third-party data security service provider and submit assessment report to local agency of the CAC. The Draft Data Security Regulations provide a broad definition of data processing activities, including collection, storage, usage, processing, transfer, provision, publication, deletion and other activities, and the Draft Data Security Regulations also provide a broad definition of data processors as individuals and entities which autonomously determine the purpose and method during data processing activities. However, the Draft Data Security Regulations provide no further elaboration on what constitutes a situation that "affects or may affect national security" and are subject to further changes before being formally adopted and coming into effect.

As of the date of this Annual Report, the rules and implementations of the Measures for Cyber Security Review (2021) and the Measures on Security Assessment of Cross-border Transfer of Data are limited, and the Draft Data Security Regulations are still in draft forms and have not come into effect, and the PRC governmental authorities may have wide discretion in the interpretation and enforcement of these laws and regulations. It also remains uncertain whether the future regulatory changes would impose additional restrictions on companies like us. We cannot predict the impact of the Draft Data Security Regulations, if any, at this stage, and we will closely monitor and assess any development in the rulemaking process. If the enacted version of the Draft Data Security Regulations requires any clearance of cyber security review and other specific actions to be completed by companies like us, we face uncertainties as to whether such clearance can be timely obtained, or at all. If we are not able to comply with the cyber security and data privacy requirements in a timely manner, or at all, we may be subject to government enforcement actions and investigations, fines, penalties, or suspension of our non-compliant operations, among other sanctions, which could materially and adversely affect our business and results of operations. We have been making constant efforts to comply with the relevant data protection laws and regulations in the PRC and will endeavor to comply with any update in the applicable laws, regulations or guidelines as issued by any relevant regulatory authorities in the PRC. However, we cannot assure you that we are able to comply with any applicable privacy and data security laws, regulations and guidelines in a timely manner, or at all.

In addition, certain industry-specific laws and regulations affect the collection, use and transfer of personal data in China. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources (effective in July 2019), which require approval/filing from the Science and Technology Administration Department of the PRC State Council where human genetic resources are involved in any international collaborative project and additional approval, filing and backup for any export or cross-border transfer of the human genetic resources samples or associated data or for providing/offering access of the information on human genetic resources to non-PRC entities and the institutions established or actually controlled thereby. We cannot assure you that we have complied or will be able to comply with all applicable human genetic resources related regulations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of human genetic resources samples and associated data and administrative fines. As there are still uncertainties regarding the further enacting of new laws and regulations as well as the revision, interpretation and implementation of those existing laws and regulations, we cannot assure you that we will be able to comply with such regulations in all respects, and we may be ordered to make rectification and terminate any actions that are deemed illegal by the regulatory authorities and become subject to fines and/or other sanctions. As a result, we may be required to suspend our related businesses or face other penalties which may have material adverse effect on our business, operations and financial condition.

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 U.S. 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.

In May 2018, the General Data Protection Regulation (the "EU GDPR"), took effect in the European Economic Area (the "EEA"), where we have growing operations. Further, the United Kingdom has implemented a legislation similar to the EU GDPR, the ("UK GDPR"), including the UK Data Protection Act. The EU and UK GDPR govern the collection, use, disclosure, transfer or other processing of personal data of persons who are in the EU or in the UK. Among other things, the EU and UK GDPR impose requirements regarding the security of personal data and notification of data processing obligations to the competent national data protection authorities, establish a limited range of lawful bases on which personal data can be processed, expand 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 EU and UK GDPR, impose substantial fines for breaches and violations. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from the EEA, United Kingdom and other jurisdictions to the United States or other countries. The EEA, United Kingdom and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA and United Kingdom's standard contractual clauses, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations.

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 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), establish specific requirements related to the privacy, transmission, and security of individually identifiable health information, that constitutes protected health information. Enforcement of HIPAA and its regulations can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

Further, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents.

In addition, the California Privacy Rights Act of 2020 ("CPRA") expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and

local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely.

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 data privacy and 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, or are perceived to 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.

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, failures of financial institutions, 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.

Terrorist attacks and international hostilities and instability in any region could adversely affect our business.

Terrorist attacks, the outbreak of war, or the existence of international hostilities could damage the world economy, adversely affect the global supply chain and adversely affect both our ability to sell our products to certain regions or purchase supplies from such regions. In particular, the warfare and political turmoil in Ukraine could adversely impact our financial condition, result of operations and cash flows. In February 2022, Russian troops invaded Ukraine. Although the severity and duration of the ongoing military action are highly unpredictable, the Russia-Ukraine military conflict in Ukraine could materially disrupt our operations in Europe and/or increase their costs. In addition, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions being levied by the EU, the U.S. and other countries against Russia, Belarus and the two separatist republics in the Donetsk and Luhansk regions, with additional potential sanctions threatened and/or proposed. Russia's military incursion and the resulting sanctions could adversely affect the global economy and

financial markets and thus could affect our business, operations, operating results and financial condition as well as, potentially, the price of our ordinary shares and ADSs.

In the previous fiscal years ended December 31, 2022 and December 31, 2021, we identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise if we fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our reporting obligations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

On October 19, 2022, the Audit Committee (the "Audit Committee") of our board of directors ("Board"), after meeting with management to consider the relevant facts and circumstances, determined that the following financial statements should no longer be relied upon:

- our audited financial statements as of and for the years ended December 31, 2021, December 31, 2020 and December 31, 2019 (the "Affected Audited Financials"); and
- our unaudited financial statements for the interim period ended March 31, 2022 (the "Affected Unaudited Financials").

We amended and restated (the "Restatement") the Affected Audited Financials in Amendment No. 1 to our Annual Report on Form 20-F for the fiscal year ended December 31, 2021 and the Affected Unaudited Financials in our report on Form 6-K/A dated February 17, 2023.

As a result of the Restatement, we concluded that there was a material weakness (the "2021 Material Weakness") in our internal control over financial reporting as of December 31, 2021 relating to the lack of adequate review and monitoring of controls over complex agreements, specifically, the Janssen Agreement, and our disclosure controls and procedures were not effective.

Further, in connection with the audit of our financial statements for the fiscal year ended December 31, 2022, we concluded that there was a material weakness (the "2022 Material Weakness" and together with the 2021 Material Weakness, the "Material Weaknesses") in our internal control over financial reporting as of December 31, 2022 relating to ineffective information technology general controls ("ITGCs") in the area of privileged and regular user access and change management over key information technology ("IT") systems that support our financial reporting processes. As a result, the related process-level IT dependent controls and application controls were also ineffective.

For fiscal-year ended December 31, 2023, we remediated the previously identified Material Weaknesses. Related to the 2021 Material Weakness, we implemented the following: (i) additional responsive review and monitoring controls for complex agreements, including the Janssen Agreement, which includes additional review by the Chief Financial Officer and other senior finance staff over critical accounting judgements and estimates, reporting and disclosures; (ii) expanded the capabilities of existing financial reporting personnel through specific continuous training and education in the application of IFRS standards, with a focus on complex agreements, including the Janssen Agreement; (iii) hired additional financial reporting & technical accounting personnel as well as a Corporate Controller with relevant and appropriate IFRS accounting experience, including complex agreements. We also engaged additional external resources to aid and supplement our internal resources in executing this remediation plan. Related to the 2022 Material Weakness, we implemented the following: (i) we implemented a governance, risk and compliance tool ("GRC tool"), which automated previously manual processes within our ITGC environment and was fully effective as of December 31, 2023, and which facilitates a more robust, timely, and precise execution of ITGCs, with a particular emphasis over privileged and regular user access and change management controls over key IT systems that support our financial reporting processes. (ii) strengthened our IT governance, risk, and compliance oversight by adding additional personnel in in that function; (iii) developed and implemented additional training and awareness programs addressing ITGCs and policies, including educating control owners concerning the principles and requirements of each control, with a focus on user access; and (iv) strengthened the ITGC review processes, including user access reviews, by adding enhanced guidance on executing ITGCs and adding additional reviews. Based upon our successful implementation of the aforementioned new and enhanced controls, including testing and validating that the controls were operating effectively for a sufficient period of time, we have concluded that the Material Weaknesses were fully remediated as of fiscal year ended December 31, 2023.

As a public company, we must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. We are subject to reporting obligations under U.S.

securities laws, including the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). Section 404(a) of the Sarbanes-Oxley Act ("Section 404(a)"), requires that management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Pursuant to Section 404(b) of the Sarbanes-Oxley Act ("Section 404(b)"), our independent registered public accounting firm is required to issue an annual attestation report that addresses the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our Audit Committee be advised and regularly updated on management's review of internal control over financial reporting. The presence of material weaknesses, if identified, could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, which could require us to restate our operating results or result in our auditors issuing a qualified audit report. In order to maintain effective disclosure controls and procedures and internal controls over financial reporting, we must expend significant resources and provide significant management oversight. There can be no assurance that we will be effective in maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on the Nasdaq Stock Market LLC ("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 collaborators (including any licensees and licensors) 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. In addition, in November 2023, we entered into a License Agreement with Novartis Pharma AG (the "Novartis License Agreement"), pursuant to which we granted Novartis an exclusive worldwide license to certain of our intellectual property rights in order to develop, manufacture, commercialize and otherwise exploit certain CAR-T cell therapies targeting Delta-like ligand protein 3 ("DLL-3"), including our existing autologous CAR-T cell therapy candidate, which we refer to as "LB2102."

We may enter into additional collaborations (including licenses and related strategic agreements) for our other product candidates or technologies in development. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development, manufacturing or marketing of our products. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, including a material breach of agreement or an unforeseen material safety event. If the Janssen Agreement were to be terminated, we could encounter significant delays or other impairments in the commercialization of CARVYKTI and further developing cilta-cel, lose the opportunity to earn any future revenue we expected to generate under the agreement, incur unforeseen costs, and suffer damage to the reputation of our products, product candidates and as a company generally.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party contract research organizations ("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 non-renewal by our collaborators, or may not be fully complied with by our collaborators;
- in the case of a license granted by us, we lose control of the development of the product candidate licensed;
- in such cases we would have only limited control over the means and resources allocated by our partner for the commercialization of our product; and
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

Furthermore, even though Janssen is required to diligently develop and commercialize cilta-cel, it is possible that Janssen will seek to prioritize other products in its portfolio over cilta-cel, including products that may treat conditions that are the same as or are similar to the conditions for which cilta-cel has either received marketing approval or for which we are conducting research for potential future marketing approvals. The development and commercialization of DLL-3 by Novartis will be subject to the same risks and uncertainties described above.

In addition, we rely on data or other information generated or reported to us by our collaborators relating to, among other things, product development, marketing or regulatory approvals and commercialization efforts. Although we believe the information from our collaborators is reliable, we are unable to independently audit or verify the accuracy or completeness of all such data or information, and any inaccuracies may adversely affect our business.

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 an additional $335.0 million in milestone payments through the date of this Annual Report. Janssen may not execute its obligations as planned or may refuse to honor their commitments under the Janssen Agreement. The non-performance of Janssen, early termination of the Janssen Agreement, or our inability to find new or replacement partners may negatively impact our revenue and research and development activities and funding therefore. 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 our collaborators do not achieve our product development or commercialization objectives in the time frames we expect, we may not receive milestone, royalty or profit 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. The milestone payments in the Janssen Agreement are generally dependent on the accomplishment of various clinical, regulatory, sales and other product development objectives. We may enter into new additional collaboration agreements that also provide for milestone payments. For example, pursuant to the Novartis License Agreement, we are eligible to receive from Novartis up to an aggregate of $1.01 billion in milestone payments upon achievement of specified clinical, regulatory and commercial milestones. 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 our collaborators. If we or our collaborators 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;
- 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.

Furthermore, we and our collaborators may, from time to time, disagree about whether a particular milestone payment under an agreement has been earned. Although the Janssen Agreement, the Novartis License Agreement and applicable law provide remedies for either party's failure to perform its obligations, there can be no assurance that we will be paid milestones to which we believe we are entitled and any related dispute with our collaborators may result in a termination of the relevant agreement or otherwise impair our collaborations.

In addition, our share of any profits generated under the Janssen Agreement or any royalties we may receive under the Novartis License Agreement or under any other collaborations we may enter into in the future are dependent on the successful product development and commercialization of our product candidates.

Our failure to receive milestone payments or generate profits or royalties 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 certain services.

We rely on a limited number of services provided by Genscript pursuant to the agreements described in "Item 7 - Major Shareholders and Related Party Transactions - 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 will 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.

Any failure by Genscript to effectively manage the services that they provide to us could harm our business, financial condition and results of operations.

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

We have entered into, and may in the future enter into, collaboration agreements (including licenses and related strategic transactions) 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 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 collaborator (including any licensee or licensor) or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing collaborators for the development and commercialization of our product candidates, such as the Janssen Agreement or the Novartis License

Agreement, we have limited control over the time and resources that our collaborators may dedicate to the development and commercialization of our product candidates. These collaborations pose a number of risks, including the following:

- collaborators 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;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators 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;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, collaborations may not lead to development, regulatory approval, or successful commercialization of product candidates in the most efficient manner or at all. Some collaboration agreements are terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to regulatory approval and commercialization of a product candidate. We also face competition in seeking out collaborators. 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 (the "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 or another regulatory authority refusing 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 or another regulatory authority 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 or another regulatory authority. 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 CMOs as well as supply sources internal to the collaboration for vector supply. Our use of CMOs increases the risk of delays in production or insufficient supplies as we transfer our manufacturing technology to these CMOs and as they gain experience with our supply requirements. In addition, we purchase equipment and reagents critical for the manufacture of our product candidates from Hemacare, Miltenyi, Leukapheresis Collection Center and other suppliers on a purchase order basis. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing.

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

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of

extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the NMPA, the EMA, the PMDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain for a product candidate may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

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

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

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

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

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

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a REMs program (which is a requirement for FDA's approval of CARVYKTI) or equivalent foreign 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 European Commission, 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 European Commission, the PMDA or other regulatory authorities to monitor and ensure compliance with cGMP.

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

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

Any product candidate for which we obtain regulatory 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 ("DOJ") and equivalent regulatory authorities outside of the United States closely regulate compliance with all requirements governing prescription 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, DOJ and equivalent regulatory authorities outside of the United States 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 U.S. federal Food, Drug and Cosmetic Act (the "Food, Drug and Cosmetic Act") and other statutes, including the U.S. federal False Claims Act (the "False Claims Act") and other federal, state or foreign health care fraud and abuse laws as well as state or foreign consumer protection laws.

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

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

- suspension, variation 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 such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current

and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable healthcare laws, including, without limitation, the U.S. federal Anti-Kickback Statute (the "Anti-Kickback Statute"), the U.S. federal False Claims Act and similar foreign regulations, 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 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 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 Anti-Kickback Statute has been violated;
- U.S. federal civil and criminal false claims laws, including the False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, which, among other things, impose penalties, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or, decreasing an obligation to pay or transmit money or property to the federal government. Pharmaceutical and other healthcare companies have been found liable under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Further, pharmaceutical manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;
- HIPAA, which contains federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, obtaining, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, knowingly and willfully embezzling, stealing, or otherwise without authority converting to the use of any person other than the rightful owner, or intentionally misapplying any of the moneys, funds, securities, premiums, credits, property, or other assets of a healthcare benefit program, willfully preventing, obstructing, misleading, delaying or attempting to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a federal healthcare offense to a criminal investigator and in any matter involving a healthcare benefit program, knowingly and willfully falsifying, concealing or covering up by any trick, scheme, or device a material fact or making any materially false, fictitious, or fraudulent statements or representations, or making or using any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, and their

respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH, among other changes, also established four new tiers of civil monetary penalties; amends HIPAA to make business associates of covered entities directly liable for compliance with certain requirements of the federal HIPAA laws and gave state attorneys general new authority to bring civil actions for damages or injunctions on behalf of state residents in the appropriate district court of the United States for violations of the federal HIPAA laws and in the case of any successful action, the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State;

- the 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 (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), certain other healthcare providers (such as nurse practitioners and physicians assistants) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state laws and regulations and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the 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 Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

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

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

There has been heightened governmental scrutiny in the United States, China, the EU, Japan and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congressional leadership has each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside of the United States, particularly in countries within the EU, the pricing and reimbursement of certain pharmaceuticals is subject to governmental control. In these countries, pricing and reimbursement negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some EU countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Health Technology Assessment ("HTA"), of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some of the member states of the EU (the "EU Member States"), including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment (the "HTA Regulation"). The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025. If reimbursement of our product candidates 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 and our collaborator's ability to profitably sell any products or product candidates for which we or our collaboration may obtain marketing approval, including CARVYKTI.

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. There have been legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration 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 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional Congressional action is taken. 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 presidential executive orders, 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. For example, at the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. 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. Implementation of the new rebate safe harbor has been delayed until January 2032. It is unclear whether the rebate rule will ultimately be withdrawn or modified prior to the January 2032 effective date. The likelihood of implementation of, or willingness to defend, any of the other reform initiatives is uncertain. In addition, the IRA includes a provision requiring the Secretary of HHS to negotiate prices with drug companies for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). The number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The law establishes an upper limit for the negotiated price for a given drug or biologic and specifies factors the Secretary of HHS is required to consider when negotiating these upper pricing limits. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA also imposes rebates under Medicare Part B and Medicare Part D that penalize manufacturers for price increases that outpace inflation. Further in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price of pharmaceutical products. Failure by us or our collaborators to obtain or maintain adequate coverage and reimbursement for any approved products, including CARVYKTI, could materially and adversely affect the revenue or sales of such products.

In December 2021 the European Parliament adopted the HTA Regulation which, when it enters into application in 2025, will be intended to harmonize the clinical benefit assessment of HTA across the EU. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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 marketing 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.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, we may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

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 our operations in China, we have not completed all required safety-related procedures in a timely manner, which could subject us to fines and other administrative penalties.

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

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

Risks Related to Our Intellectual Property

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

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, China, the EU, 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, our patent portfolio for such products is currently comprised primarily of applications as our patent portfolio is developing. 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 (the "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 patents and 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 (the "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 and CAR-NK 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 immune cells such as T cells and NK cells the production of CAR-T and CAR-NK 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., European 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 (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, on June 1, 2021, an amendment to the PRC Patent Law went into effect introducing patent extensions to eligible innovative drug patents and on January 20, 2024, the implementing rules under this amendment became effective. As such, 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 the amendments 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.

In European countries, as in other countries, intellectual property laws are constantly evolving. As an example, the Unitary Patent and the Unified Patent Court became operational on June 1, 2023 and introduces uncertainties in the pharmaceutical patent landscape within all participating European countries. We cannot guarantee the enforceability of patents in this new patent and court system and face new centralized challenges to patents that could render patents unenforceable across participating member states, introducing a new risk to our patent portfolio in Europe. We cannot guarantee that other changes to European 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 product 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 product candidates, patents protecting such product candidates might expire before or shortly after such product 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 product 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 (the "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 the 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. Except for the Chinese trademark for cilta-cel, we have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

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

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

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

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

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

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product

candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Doing Business in China

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

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

A material portion of our research and development operations and our manufacturing facilities for China are located 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" of this Annual Report for a discussion of the regulatory requirements that are applicable to our current business activities in China. For example, approval from the relevant science and technology departments is required in international collaboration projects using China's human genetic resources except for in certain circumstances stipulated in the HGR Regulation. Due to certain restrictions of practical operations which are beyond our control, we cannot assure you that we have obtained all required approvals under China's human genetic resources laws and regulations in a timely manner, or at all. We are paying attention to regulatory trends and are in the process of applying for and obtaining such approvals from the relevant regulatory authority. The failure to obtain such approval could cause relevant international collaboration projects to be suspended by governing authorities, may result in fines and other penalties, and also may constitute a breach under our agreements with certain CROs. According to PRC laws and regulations, 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 such activities, confiscate the human genetic resources illegally collected and preserved and illegal gains, impose fines and restrictions on business activities such entities and their responsible persons, and even 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 and regulations, 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. In addition, with respect to our collaboration partner, any 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 of our collaborators 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 product 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, and even administrative penalties. 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 ("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 ("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 (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 non-PRC entities or individuals or such entities established or actually controlled thereby, or “Foreign Persons,” from collecting or preserving China HGR in China, or providing China HGR abroad, whereas activities of collection and preservation of organs, tissues and cells for purposes of clinical diagnosis and treatment, service of blood collection and provision, investigation of illegal activities, doping test and funeral service, are required to be conducted in accordance with other relevant laws and regulations. The HGR Regulation permits Foreign Persons’ limited use of China HGR “to carry out scientific research activities,” which must be conducted through collaboration with Chinese scientific research institutions, higher education institutions, medical institutions, or enterprises, collectively, the “Chinese Entities.” Such activities must be approved by MOST, and the application for approval must be filed jointly by the Foreign Person and the relevant Chinese Entity. The only exception to the approval requirement is “international collaboration in clinical trials” that do not involve the outbound transfer of China HGR materials such as organs, tissues, or cells comprising the human genome, genes, or other genetic substances, collectively, China HGR Materials. Such clinical trial collaboration, however, must still be pre-registered with MOST. There remain significant uncertainties as to how provisions of the HGR Regulation might be interpreted and implemented. Short-term storage of samples of laboratory testing by foreign laboratories or foreign-invested laboratories may also be interpreted as preserving China HGR, thus being subjected to MOST application, approval or pre-registration processes.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC (the "Biosecurity Law") 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.

The Chinese economy differs from the economies of most developed countries in many respects, including a higher level of government involvement, and the ongoing development of a market-oriented economy.

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

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

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

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

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

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

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

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

significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in China against us or our management named in the Annual Report based on foreign laws. It may also be difficult for regulators outside of the PRC or you to conduct investigations or collect evidence within China.

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

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

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

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded, at least in part, by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Currently, as the term “state secret” is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of product 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. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. As we commence with commercialization of product 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 (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 (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 subsidiaries 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 above mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement. If we are required under the PRC Enterprise Income Tax Law to pay income tax for any dividends we receive from our subsidiaries in China, or if our Hong Kong subsidiary is determined by PRC government authority as receiving benefits from reduced income tax rate due to a structure or arrangement that is primarily tax-driven, it would materially and adversely affect the amount of dividends, if any, we may pay to our shareholders.

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

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

Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC or non-PRC individuals, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in the PRC.

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

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

Governmental control of currency conversion may limit our ability to utilize our revenues effectively and affect the value of our ADSs.

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

In light of the recent flood of capital outflows of China due to the weakening of RMB, the PRC government has imposed more restrictive foreign exchange policies and stepped up scrutiny of major outbound capital movement including overseas direct investment. More restrictions and substantial vetting process are put in place by SAFE to regulate cross-border transactions falling under the capital account. If any of our shareholders regulated by such policies fails to satisfy the applicable overseas direct investment filing or approval requirement timely or at all, it may be subject to penalties from the relevant PRC authorities. The PRC government may at its discretion further restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the ADSs.

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

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions in China and by China's foreign exchange policies. Since June 2010, the RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. On November 30, 2015, the Executive Board of the International Monetary Fund, completed the regular five-year review of the basket of currencies that make up the Special Drawing Right (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 cross-border investment activity, our investment activity outside the PRC and our investments in the PRC. 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 ("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 ("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 ("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 subsidiaries of such SPV in China may be prohibited from distributing their 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 ("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 subsidiaries' 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 subsidiaries, we may make loans or additional capital contributions to our PRC subsidiaries, subject to satisfaction of applicable governmental registration and approval requirements.

Any loans we extend to our PRC subsidiaries, 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 subsidiaries by means of capital contributions. According to the relevant PRC regulations on foreign-invested enterprises in China, these capital contributions are subject to registration with the SAMR or its local counterparts. In addition, the PRC government also restricts the convertibility of foreign currencies into RMB and use of the proceeds. On March 30, 2015, SAFE promulgated the Notice on Reforming the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises ("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 ("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 subsidiaries. On October 23, 2019, SAFE promulgated the Circular to Further Facilitating Cross-border Trade and Investment ("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 subsidiaries 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 subsidiaries or future capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approvals, our ability to fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

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

Under the applicable regulations and SAFE rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in a public company listed outside of the PRC are required to register with SAFE and complete certain other procedures. In February 2012, SAFE promulgated the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plan or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE in March 2007. Pursuant to the Stock Option Rules, if a PRC resident participates in any stock incentive plan of a public company listed outside of the PRC, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock incentive plan and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents' foreign exchange income received from the sale of stock and dividends distributed by the public company listed outside of the PRC must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other share-based incentives of ours are subject to the Stock Option Rules. However, we do not have control over our PRC resident participants and cannot compel them to comply with SAFE registrations.

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

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

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

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

domestic company by foreign entities as defined under the M&A Rules. However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel.

Furthermore, the recently issued Opinions on Strictly Cracking Down on Illegal Securities Activities emphasized the need to strengthen the supervision on listings outside of the PRC by companies with operations in China and provided that the special provisions of the State Council on issuance and listing of shares outside of the PRC by those companies limited by shares will be revised. There are still uncertainties regarding the interpretation and implementation of these Opinions, and further explanations or detailed rules and regulations with respect to these Opinions may be issued in the future which could impose additional requirements on us.

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the "Overseas Listing Trial Measures"), which will come into effect on March 31, 2023. Pursuant to the Overseas Listing Trial Measures, (i) PRC domestic companies that seek to offer or list equity securities overseas, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC; (ii) if a company outside of the PRC satisfies both of the following conditions, its offering and listing outside of the PRC will be deemed an indirect offering by a PRC domestic company: i) more than 50% of such overseas company's consolidated revenues, profit, total assets or net assets that are derived from its audited consolidated financial statements for the most recently completed fiscal year are attributable to PRC domestic companies, and ii) any of the following circumstances applies: key components of its operations are carried out in the PRC; its principal places of business are located in the PRC; or the majority of the senior management members in charge of operation and management are PRC citizens or residents. The determination will be made on the basis of "substance over form"; and (iii) where a PRC domestic company seeks to indirectly offer and list securities in a market outside of the PRC, such company is required to designate a major domestic operating entity responsible for all filing procedures with the CSRC; where a company makes an application for initial public offerings or listings in a market outside of the PRC, such company is required to submit filings with the CSRC within three business days after such application is submitted, and where an issuer conducts follow-on offerings in the same market outside of the PRC where it has previously offered and listed securities, the issuer shall submit filings with the CSRC within three business days after the follow-on offering is completed. If a PRC domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such PRC domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

However, since the Overseas Listing Trial Measures was newly promulgated, the interpretation, application and enforcement of the Overseas Listing Trial Measures remain unclear. It remains uncertain whether the filing requirements under the Overseas Listing Trial Measures are applicable to securities offerings by us. If the filing procedure with the CSRC under the Overseas Listing Trial Measures is required for any future follow-on offerings or any other capital raising activities by us, it is uncertain whether we can or how long it will take us to obtain such approval or complete such filing procedures. Given the substantial uncertainties surrounding the latest CSRC filing requirements at this stage, we cannot assure you that we will be able to complete the filings and fully comply with the relevant new rules on a timely basis, if at all.

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

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

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

The Anti-Monopoly Law promulgated by the Standing Committee of the National People's Congress (the "NPC"), in August 2007, was amended in June 2022 and became effective in August 2022. The Anti-Monopoly Law requires that the SAMR should be notified in advance of any merger, share or asset acquisition, or acquisition of control (including through the provision of influence) by contract or other means if certain thresholds are triggered. Transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by the SAMR before they can be completed.

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 SAMR, 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 ("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 ("SAT Bulletin 37"), which came into effect on December 1, 2017. The Bulletin 37 further clarifies the practice and procedure of the withholding of nonresident enterprise income tax. Where a non-resident enterprise transfers taxable assets indirectly by disposing of the equity interests of a holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such Indirect Transfer to the relevant tax authority. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the holding company outside of the PRC if it lacks a reasonable commercial purpose and was established for

the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer other than transfer of shares of ADSs acquired and sold on public markets may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes.

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

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. 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 holding company and our PRC subsidiaries, Legend Nanjing and Legend Hainan, are currently considered to be foreign invested entities. Legend Hainan was established in October 2021. As of the date of this Annual Report, Legend Hainan is not engaged in substantive business operations in the PRC.

The latest version of the "negative list," namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2021) or the Negative List, which was promulgated by the MOFCOM and the NDRC, became effective on January 1, 2022. The Negative List provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies.

As of the date of this Annual Report, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" specified in the Negative List and the application of this regulation remains unclear. The Encouraged Industry Catalogue for Foreign Investment (2022) (the "2022 Encouraged Industry Catalogue"), which was promulgated by the MOFCOM and the NDRC, became effective on January 1, 2023, provides that foreign investment is encouraged in the development and production of cell therapy drugs except in areas where foreign investment is prohibited. Further, on November 30, 2021, the CDE published the Technical Guidelines for Non-clinical Research and Evaluation of Gene Therapy Products (Trial) (the "Technical Guidelines for Gene Therapy Products"), and Technical Guidelines for Non-clinical Research of Gene Modified Cell Therapy Products (Trial) (the "Technical Guidelines for Gene Modified Cell Therapy Products"), which became effective as of the date of promulgation. The Technical Guidelines for Gene Therapy Products provides that it is applicable to gene therapy products other than genetically modified cells therapy products, and genetically modified cells therapy products, such as CAR-T cell therapy products, shall refer to the Technical Guidelines for Gene Modified Cell Therapy Products, which was formulated according to the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial).

Legend Nanjing is engaged in the research and development of CAR-T cell therapies. We believe the CAR-T cell therapies, as they are currently being researched and developed by Legend Nanjing, do not involve the use of human stem cells or genetic diagnosis and treatment, and as such should not fall into the category of "human stem cell or gene diagnostic and therapeutic technologies" under the Negative List. Moreover, relevant governmental authorities also confirmed that 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 any of our PRC subsidiaries are deemed by relevant PRC regulatory agencies as falling into the category of "human stem cell or gene diagnostic and therapeutic technologies" under the Negative List, such PRC subsidiary would be prohibited from engaging in the research or development of such CAR-T cell therapies or other technologies. In that event, we may have to stop investing in our PRC subsidiaries or consider restructuring our PRC subsidiaries as PRC domestic entities and our variable interest entity. Our PRC subsidiaries may also have to forfeit their 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. We may be subject to fines due to the lack of registration of our leases.

In China, we lease certain premises used in our operations from third parties. We cannot guarantee that all lessors can provide 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, and our financial condition and results of operations may be adversely affected.

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

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

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

At various times during recent years, the United States and China have had significant disagreements over monetary, economic, political, environmental and social issues, and future relations between these two countries may deteriorate.Various Chinese entities, including certain biotechnology companies and CMOs in China, have been or may become, the subject of trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit the ability to work with such entities. 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. For example, President Biden recently issued an Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern that seeks to prohibit or restrict specific types of commercial transactions involving "bulk sensitive personal data," including (1) personal identifiers; (2) personal financial data; (3) personal health data (as defined under HIPAA); (4) precise geolocation data; (5) biometric identifiers; and (6) human genomic data, between U.S. persons and "countries of concern," including China. If there is no lawful manner for us to transfer such data to China, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as the United States) at significant expense and increased exposure to regulatory actions.

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

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

Genscript is currently our majority shareholder and three of the ten members of our Board are employees of Genscript. 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. See "Item 7—Major Shareholders and Related Party Transactions" for further information on our related party agreements with Genscript.

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

To comply with the requirements imposed on us as a public company, we have incurred, and expect to continue to incur, significant legal, insurance, accounting and other expenses that we did not as a private company. The increased costs

may require us to reduce costs in other areas of our business. In addition, our board of directors, management and administrative staff are required to perform additional tasks. For example, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. We have invested, and intend to continue to invest, resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from research and development activities. These laws, regulations and standards are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, enforcement proceedings and higher costs necessitated by ongoing revisions to disclosure and governance practices, which could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

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

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

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

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

We are entitled to rely on a provision in the Nasdaq's corporate governance rules that allows us to follow Cayman Island's corporate law with regard to certain corporate governance matters. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on the Nasdaq. For example, 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 or compensation committee. Currently, our board of directors consists of a majority of independent directors and we have a nominating and corporate governance and compensation committee. We currently rely on foreign private issuer exemptions to Nasdaq Rules 5605(d) and 5605(e), as currently only two of the three members of each of our compensation committee and nominating and corporate governance committee are independent directors. Additionally, we

may in the future rely on additional foreign private issuer exemptions, including exemptions allowing for less than a majority of our board of directors to consist of independent directors, and so fewer board members would be exercising independent judgment and the level of board oversight on the management of our company may decrease as a result.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a "foreign private issuer", and therefore is not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2024. In the future, we would lose our "foreign private issuer" status if more than 50% of our outstanding voting securities become directly or indirectly held of record by U.S. Holders and any one of the following is true: (i) the majority of our directors or executive officers are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States. If we lose our "foreign private issuer" status, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We would also have to comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements under the listing rules of Nasdaq. As a U.S. listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we do not incur as a foreign private issuer. In addition, members of our management would likely have to divert time and resources from other responsibilities to ensuring these additional regulatory requirements are fulfilled.

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 Third Amended and Restated Memorandum and Articles of Association, the Companies Act (As Revised) 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 duties 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 duties 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 Third Amended and Restated 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 differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. As a foreign private issuer, we are permitted to defer to home country practice with respect to certain corporate governance matters under the Nasdaq listing rules. For example, 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 or compensation committee. We currently rely on foreign private issuer exemptions to Nasdaq Rules 5605(d) and 5605(e), as currently only two of the three members of each of our compensation committee and nominating and corporate governance committee are independent directors. As a result of these foreign private issuer exemptions available to us, 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 or one that was fully subject to the Nasdaq corporate governance rules. For a discussion of significant differences between the provisions of the Companies Act (As Revised) of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, please refer to Exhibit 2.4 filed with this Annual Report.

Provisions in our Third 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 Third 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 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 can fix the price, rights, preferences, privileges, and restrictions of the other classes of shares without any further vote or action by our shareholders. The issuance of such shares may delay or prevent a change of control transaction. As a result, the market price of our ADSs and the voting and other rights of our shareholders may be adversely affected. An issuance of other classes of shares may result in the loss of voting control to other shareholders.

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

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

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

Raising additional capital may cause dilution to our holders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

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

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

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

additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders, and may cause the market price of our ADSs to decline.

Risks Related to Our Securities

The trading price of our ADSs may be volatile.

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

- the manufacturing and commercialization of CARVYKTI;
- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- 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, product candidates or CAR-T cells in general, including updates required to be made to the Boxed Warning for CARVYKTI;
- 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.

Sales of a substantial number of our ordinary shares or ADSs could cause the market price of our ADSs to drop significantly, even if our business is doing well.

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

Additionally, certain holders of ordinary shares, or their transferees, have rights, subject to some conditions, to require us to file (or, if filed, keep in effect) one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once the resale of these shares is registered, they can be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

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

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

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

The deposit agreement governing the ADSs representing our shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to

bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement, our shares or the ADSs or the transactions contemplated thereby. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If a holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, such holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

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

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

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

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to ADS holder in the United States unless we register the rights and the securities to which the rights relate under the Securities Act of 1933, as amended (the "Securities Act") or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to ADS holder unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution.

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

We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, holders of our ordinary shares and ADSs should not rely on an investment in these securities to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or out of the credit standing in our company's share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our shareholders may, subject to our Third Amended and Restated Memorandum and Articles of Association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of

directors. As a result, capital appreciation, if any, on our ADSs and ordinary shares will be the sole source of gains for the foreseeable future for the holders of these securities. These factors could harm the value of our ADSs.

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

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than certain rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares or ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares or ADSs.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ADSs, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from our initial public offering, follow-on offerings, and other fundraising activities in our business. Based on our operating history and the composition of our income and valuation of our assets, including goodwill, we do not believe we were a PFIC for our taxable year ending December 31, 2023. 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, 2023, and also expresses no opinion with regard to our expectations regarding our PFIC status for the current or future taxable years.

The tax consequences that would apply if we are classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund ("QEC") 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 QEC election. Prospective investors should assume that a QEC election will not be available.

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

If a U.S. Holder (as defined below under “Material Income Tax Considerations—Material U.S. Federal Income Tax Considerations for U.S. Holders”) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, including ordinary shares represented by ADSs, such U.S. Holder may be treated as a “United States shareholder” with respect to each controlled foreign corporation in our group (if any). A non-U.S. corporation generally will be classified as a controlled foreign corporation for U.S. federal income tax purposes if United States shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. The determination of controlled foreign corporation status is complex and includes attribution rules, the application of which is not entirely certain. Because our group includes at least one U.S. subsidiary, attribution rules could cause all of our non-U.S. subsidiaries to be treated as controlled foreign corporations.

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. Many of the countries in which we do business are expected to adopt changes to tax laws, including as a result of the Base Erosion and Profit Shifting Project of the Organisation for Economic Co-operation and Development (the "OECD"), Shifting, Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. The OECD has published a package of measures for reform as a product of the Base Erosion and Profit Shifting Project, which include the reallocation of global profits of large multinational companies to market jurisdictions based on customer location as well as the introduction of a global minimum tax. Many of the package's proposed measures require amendments to the domestic tax legislation of various jurisdictions. In the United States, the Inflation Reduction Act of 2022 imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. 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.

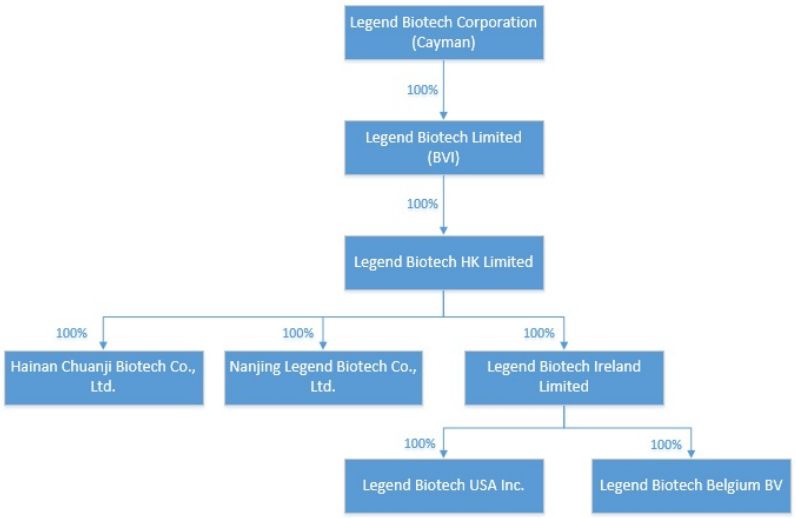
The market price of our ADSs may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result 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 (As Revised) of the Cayman Islands. Legend Biotech is a Cayman Islands holding company incorporated as a Cayman Islands exempted company and not a Chinese operating company. We operate through our operating subsidiaries located primarily in the United States, PRC and EU. Our operations in the PRC, in addition to our business presence elsewhere in the world, are enabled by our subsidiaries based therein.

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



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 Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, PO Box 10240, Grand 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, 2023, 2022, and 2021 amounted to $104.0 million, $70.3 million, and $44.5 million, 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 2024 to be financed from our cash and cash equivalents on hand. Primarily, these capital expenditures will be made in the United States, EU and China, where our principal manufacturing and 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.

B. Business Overview

We are primarily a global, clinical-stage biopharmaceutical company engaged in the discovery, development, manufacturing and commercialization of novel cell therapies for oncology and other indications. Our team of approximately 1,800 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 CAR-T cell therapy we are jointly developing

with our strategic partner, Janssen, for the treatment of multiple myeloma ("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 ("RRMM") patients with a manageable safety profile.

On February 28, 2022, cilta-cel was approved by the U.S. Food and Drug Administration (the "FDA") under the trademark CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. We have established a sales, marketing and operational infrastructure to support the launch of CARVYKTI in the United States. On May 25, 2022, the European Commission granted conditional marketing authorization of CARVYKTI for the treatment of adults with RRMM who have received at least three prior therapies, including a proteasome inhibitor ("PI"), an immunomodulatory agent ("IMiD") and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy. On September 26, 2022, Japan's Ministry of Health, Labour and Welfare approved CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma, limited to cases meeting both of the following conditions: patients have no history of CAR-positive T cell infusion therapy targeting B-cell maturation antigen ("BCMA"); and patients who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy.

Cilta-cel has been granted breakthrough therapy designation by the FDA, Priority Medicines ("PRIME"), designation, enabling accelerated assessment, by the European Medicines Agency ("EMA"), and breakthrough therapy designation by the CDE. In January 2021, the Committee for Medicinal Products for Human Use ("CHMP"), of the EMA accepted a request for an accelerated assessment of the marketing authorization application. 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.

On June 5, 2023, we announced study closeout results from the CARTITUDE-1 clinical trial, studying cilta-cel in the treatment of RRMM, which were presented at the 2023 ASCO Annual Meeting.

In our Phase 1b/2 CARTITUDE-1 trial, longer-term results in 97 patients with RRMM continued to show a high overall response rate ("ORR") of 98%. After 27.7 months of follow-up, 83% of patients treated with cilta-cel achieved a stringent complete response, or sCR, which was higher than the 67% sCR rate reported at a median of approximately 1 year of follow up. Furthermore, 95% of patients achieved a very good partial response ("VGPR"), or better. At study closeout with a median follow-up of 33.4 months, median duration of response (DOR) was 33.9 months, median progression-free survival (PFS) was 34.9 months and median overall survival (OS) was not reached. An estimated 62.9% of patients were alive at the 3-year follow-up. Of the 61 patients evaluable for minimal residual disease ("MRD"), 91.8% were MRD-negative at the 10-5 cutoff threshold. The 30 month PFS rates in patients with 12-month sustained MRD negativity and 12-month sustained MRD-negative ≥CR were 75% and 79%, respectively. The longer-term data showed no new events of CRS reported since the median approximate 1 year follow up. One new case of signs and symptoms of parkinsonism, previously termed movement and neurocognitive treatment-emergent adverse events ("AEs"), was observed at the 27.7-month median follow-up with no additional cases at study closeout.

We also presented longer-term data from our Phase 2 multicohort CARTITUDE-2 trial at various scientific congresses in 2023. The CARTITUDE-2 trial was designed to evaluate the safety and efficacy of cilta-cel in various clinical settings for patients with MM. Updated data from Cohort A of the trial was presented at the 65th American Society of Hematology Meeting in 2023. Cohort A examined the efficacy and safety of cilta-cel in 20 patients with progressive multiple myeloma after 1-3 prior lines of therapy and who are lenalidomide-refractory. At a longer median follow-up of approximately 30 months, patients experienced early and deep responses with a manageable safety profile consistent with the CARTITUDE-1 trial. MRD negativity among MRD-evaluable patients at the 10-5 sensitivity threshold was 100% (17/17 patients). ORR was 95%, which included 90% of patients achieving complete response ("CR") or better and 95% achieving VGPR or better. The median time to first response was one month and the median time to best response was 3.25 months. The 24-month PFS and OS rate was 75%.

Cohort B included 19 patients with early relapse after initial therapy with a PI, and IMiD, defined as progression within 12 months after autologous stem cell transplant ("ASCT") or from the start of anti-MM therapy for patients who have not had ASCT. Data showed early and deep responses with a manageable safety profile. At a median follow-up of 28 months, MRD negativity among MRD-evaluable patients was 93% (14/15 patients). ORR was 100%, which included 90% of patients achieving CR or better and 100% of patients achieving VGPR or better. The median time to first response was .95 months and the median time to best response was 5.1 months. The 24-month PFS and 24-month OS rates were 73% and 84%, respectively.

Data from Cohort C of the CARTITUDE-2 trial was also presented at the 20th International Myeloma Society Annual Meeting and Exposition in 2023. Cohort C included 20 patients with prior exposure to a proteasome inhibitor ("PI"), immunomodulatory drug ("IMiD"), anti-CD38 monoclonal antibody (mAb), and non-cellular BCMA-targeting therapy including an antibody-drug conjugate ("ADC") or bispecific antibody ("BsAb"). At a median follow-up of 18 months, ORR was 60% for the full cohort of ADC and BsAb exposed patients, which included 55% of patients achieving VGPR or better. Median duration of response was 12.3 months and median PFS was 9.1 months for the full cohort.

The safety profile seen in CARTITUDE-2 Cohorts A, B, and C were consistent with data previously reported from CARTITUDE-1. CRS occurred in 95% of patients in Cohort A, 84% of patients in Cohort B, and in 60% of patients in Cohort C, which were mostly grades 1/2 with median time to onset of 7 to 8 days post-infusion and median duration of approximately 3 to 5.5 days.

Additionally, CARTITUDE-4, our Phase 3 trial evaluating cilta-cel versus pomalidomide, bortezomib, and dexamethasone (PVd) or daratumumab, pomalidomide, and dexamethasone (DPd) for the treatment of adult patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy, met its primary endpoint of showing a statistically significant improvement in PFS compared to standard therapy at the trial's first pre-specified interim analysis. At a median follow-up of 15.9 months, the median progression-free survival was not reached in the cilta-cel group and was 11.8 months in the standard-care group (hazard ratio, 0.26; 95% confidence interval 0.18 to 0.38; P<0.001). The trial has been unblinded following the recommendation of an independent data monitoring committee. Progression-free survival at 12 months was 75.9% in the cilta-cel group and 48.6% in the standard care group. More patients in the cilta-cel group than in the standard-care group had an overall response (84.6% vs. 67.3%), a complete response or better (73.1% vs. 21.8%), and an absence of minimal residual disease (60.6% vs. 15.6%). Death from any cause for the cilta-cel group and standard care group was reported in 39 patients and 46 patients, respectively. Most patients reported grade 3 or 4 adverse events during treatment. Among the 176 patients who received cilta-cel in the as-treated population, 134 (76.1%) had CRS (grade 3 or 4, 1.1%; no grade 5), 8 (4.5%) had ICANS (all grade 1 or 2), 1 had movement and neurocognitive symptoms (grade 1), 16 (9.1%) had cranial nerve palsy (grade 2, 8.0%; grade 3, 1.1%), and 5 (2.8%) had CAR-T–related peripheral neuropathy (grade 1 or 2, 2.3%; grade 3, 0.6%).

In 2023, we also released five-year follow-up data from LEGEND-2, the longest follow-up for any BCMA-targeted CAR-T cell therapy study investigating LCAR-B38M, the same CAR construct to cilta-cel, showed a median OS of 55.8 months, with 16.2% of patients with heavily pretreated MM remaining disease-free. At the data cut-off, median follow-up in the LEGEND-2 study was 65.4 months. Seventy-four patients received LCAR-B38M, with a median of three prior lines of therapy; 35.7% of patients had high risk cytogenic profiles. In the study, the ORR was 87.8%, and 73% of patients achieved a CR. The median duration of response in the study was 23 months, and median PFS was 18 months at maturity, consistent with previously reported data. The rate of MRD-negative CR was 67.6%. No new CAR-T cell-related toxicities were reported in the analysis.

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 ("IND"), process as part of the encouragement of innovation by the National Medical Products Administration ("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. We believe 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, EU and China. Furthermore, we will seek to make our products, if approved, widely available to cancer patients throughout the United States, Europe and Asia independently or through partnerships.

Taken together, we believe that our fully integrated approach will enable us to rapidly expand the use of CAR-T cell therapies.

Our lead product, cilta-cel, is an autologous CAR-T cell therapy that targets the BCMA, which is a highly expressed protein in a number of hematologic malignancies including MM. Autologous cells refer to the patient's own cells. Following FDA's approval of CARVYKTI, we are continuing to develop cilta-cel for potential further improvements in the treatment of MM. MM is a highly aggressive disease representing approximately 10% of all hematologic malignancies and 20% of deaths of hematologic malignancies worldwide. The American Cancer Society projects that 35,780 new cases of MM and 12,540 deaths will occur in the United States in 2024. 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, median overall survival ("mOS") in patients who have received at least three prior lines of therapy and are refractory to both an immunomodulatory drug and a proteasome inhibitor is only 13 months. The reported ORR for approved therapies for the population of heavily pre-treated and refractory patients with MM is 30% or less. Therefore, we believe there is a high unmet need for a therapy that provides an improved efficacy profile for a prolonged period of time.

We believe that cilta-cel has the potential to transform the treatment of MM. Following the results from our Phase 1 clinical trial in China, which we refer to as LEGEND-2, we are conducting a Phase 2 registrational trial of cilta-cel in RRMM patients in China, which we refer to as CARTIFAN-1. Based on available data from CARTIFAN-1, we submitted a New Drug Application ("NDA") to China's Center for Drug Evaluation ("CDE"), in December 2022.

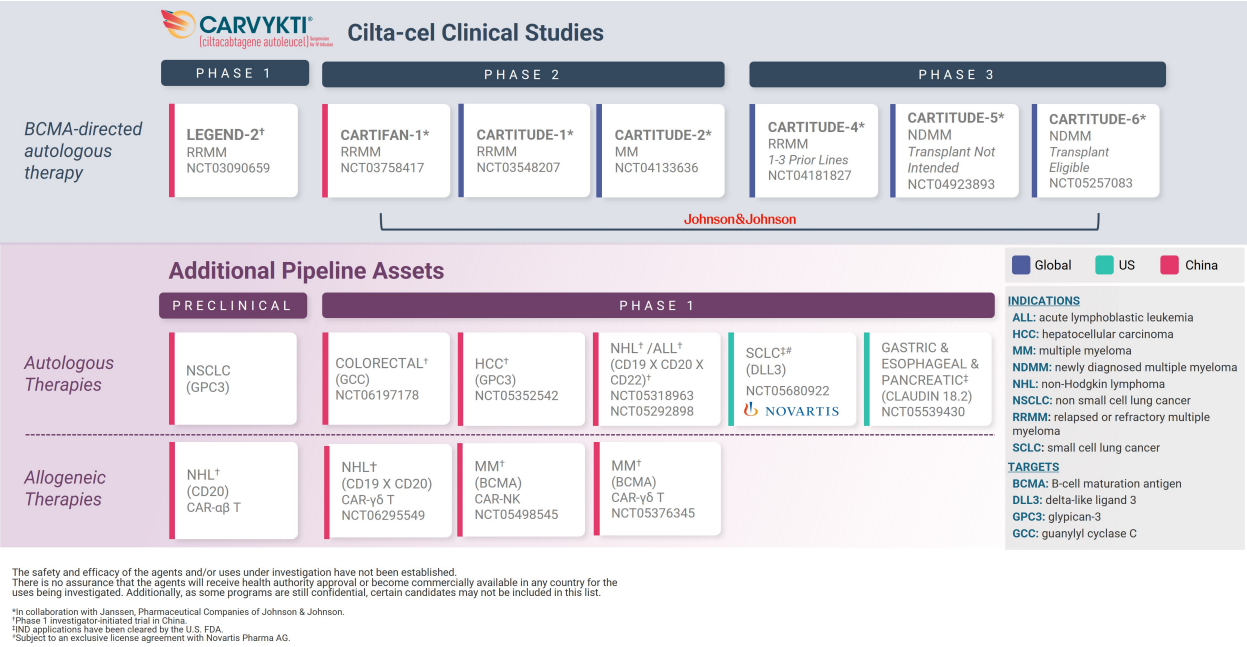
In conjunction with our collaboration partner Janssen, we completed the rolling submission of a cilta-cel Biologics License Application ("BLA") to the FDA in March 2021, submitted a cilta-cel marketing authorization application to the EMA in April 2021, and a cilta-cel NDA to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") in December 2021. On February 28, 2022, FDA approved cilta-cel under the name CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. On May 25, 2022, the European Commission granted conditional marketing authorization of CARVYKTI for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. On September 26, 2022, Japan's Ministry of Health, Labour and Welfare approved CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma, limited to cases meeting both of the following conditions: patients have no history of CAR-positive T cell infusion therapy targeting BCMA; and patients who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy.

In addition to the trials we are conducting to support our initial regulatory submissions, we are conducting multiple clinical trials to evaluate cilta-cel as an earlier line of therapy for MM. In November 2019, we and our strategic partner Janssen began enrolling an aggregate of approximately 160 patients in a Phase 2 multicohort trial of cilta-cel in the United States, EU, Israel and Saudi Arabia, which we refer to as CARTITUDE-2, in patients with MM in various clinical settings such as in early relapse patients or as a front-line therapy. Based on those results, we intend to explore expanding our investigation in those patient populations to potentially support regulatory approval submissions upon the agreement of regulatory agencies. In addition, the Phase 3 CARTITUDE-4 clinical trial, which includes approximately 400 patients in the United States, Europe, Australia, Japan, the Republic of Korea and Israel, completed enrollment during October 2021. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in Revlimid-refractory MM. On January 27, 2023 we announced that CARTITUDE-4 met its primary endpoint of showing a statistically significant improvement in PFS compared to standard therapy at the study's first pre-specified interim analysis. These results were published in the New England Journal of Medicine. At a median follow-up of 15.9 months, the median progression free survival was not reached in the cilta-cel group and was 11.8 months in the standard-care group (hazard ratio, 0.26; 95% confidence interval 0.18 to 0.38; $P<0.001$). The trial has been unblinded following the recommendation of an independent data monitoring committee. Furthermore, we initiated the Phase 3 CARTITUDE-5 clinical trial during August 2021, targeting enrollment at approximately 650 patients, including sites in the United States, Europe, Canada, Australia, Korea and Japan. This clinical trial is comparing treatment with cilta-cel to treatment of standard triplet therapy in newly diagnosed MM patients for whom hematopoietic stem cell transplant is not planned as an initial therapy. Through a collaboration with the European Myeloma Network, we and Janssen initiated a Phase 3 CARTITUDE-6 clinical trial in October 2023, targeting enrollment at approximately 750 patients, including, but not limited to, sites in EU, Australia, Korea, and Israel. This clinical trial will compare treatment with cilta-cel to treatment of autologous stem cell transplant (ASCT) in newly diagnosed MM patients.

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% of development, production and commercialization costs and retain or bear 70% of pre-tax profits or losses. We received an upfront payment of $350.0 million from Janssen in 2018, and an additional $335.0 million in milestone payments through December 31, 2023.

In addition to cilta-cel, we have a broad portfolio of earlier-stage autologous CAR-T product candidates targeting various cancers, including Non-Hodgkins Lymphoma ("NHL"), acute lymphoblastic leukemia ("ALL"), gastric cancer, esophageal cancer, pancreatic cancer, colorectal cancer, hepatocellular carcinoma, small cell lung cancer, and non-small cell lung cancer. We are also developing an allogeneic gamma delta CAR-T product candidate and an allogeneic CAR-NK product candidate targeting BCMA for MM, which are currently in investigator-initiated Phase 1 clinical trials in China. Our pipeline of product candidates is summarized in the table below.



In November 2023 we entered into the Novartis License Agreement. The Novartis License Agreement grants Novartis the exclusive worldwide rights to develop, manufacture and commercialize these cell therapies, and Novartis may apply its T-Charge™ platform to their manufacture. We received a $100 million upfront payment in January 2024 and will be eligible for an aggregate $1.01 billion additional clinical, regulatory and commercial milestone payments as well as tiered royalties.

We are led by Ying Huang, Ph.D., our Chief Executive Officer and a member of our Board of Directors, who was most recently a Managing Director and Head of Biotech Equity Research at BofA Securities, Inc., and earlier in his career, he was a Principal Scientist at Schering-Plough (now Merck), and also Lori Macomber, our Chief Financial Officer. 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 in cell therapy, advancing the treatment of cancers. Our strategy to achieve this goal is as follows:

- **Advance cilta-cel through registrational trials and obtain approval for the treatment of MM globally**. We believe we have demonstrated that cilta-cel can deliver deep and durable anti-tumor responses, resulting in increased survival in RRMM patients. During 2022, cilta-cel received approval from the FDA, conditional approval from the European Commission, and approval from Japan's Ministry of Health, Labour and Welfare. While these approvals were for later-stage patients, 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. While we have encountered legal and regulatory challenges in transferring clinical data from China to other jurisdictions, 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 further regulatory approvals 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.** Our manufacturing facility in the United States that we operate with Janssen currently supplies CARVYKTI for the U.S and EU markets, and we anticipate using such facility to supply other countries if we obtain approvals in such countries. Cilta-cel for our clinical trials is currently supplied by our U.S. facility, one of our Belgium facilities and our facility in China. We intend to further expand the commercial-scale manufacturing capacities at our U.S. facility and are in the process of establishing manufacturing capabilities in Belgium for commercial supply in the EU and U.S. markets, and possibly additional markets. Moreover, with Janssen, we have engaged, and are continuing to engage and pursue the use of third party CMOs to supplement our clinical and commercial capabilities and infrastructure, including the Novartis Clinical Supply Agreement.
- **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 non-Chinese 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 ("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 ("TCRs") that recognize antigens on a patient's tumors. Other immune cell types can be engineered to express CAR constructs as well, including NK cells. 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 and CAR-NK Cell Therapies

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

- **Selecting an appropriate tumor antigen target:** The antigen targets that are recognized by CAR-T or CAR-NK 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 cell 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 and CAR-NK cell therapy. The affinity and flexibility of the antigen binding domain(s) are important in enhanced tumor-specific recognition, and co-stimulation during cell activation regulates metabolism, survival and functions of T cells. A common side effect with CAR-T and CAR-NK cell therapy is excessive cell activation when encountering its target antigen. Such over activation can result in cytokine release syndrome ("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 and CAR-NK cell therapy 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 and CAR-NK cell therapy 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 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 and CAR-NK 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 and CAR-NK cell therapies. The difference in regulations governing the manufacturing of cell 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 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 product candidates to patients. We are leveraging our in-house antibody generation, coupled with our CAR-T and CAR-NK specific functional screening capability, to add one or multiple binding sites on immune 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 have built a manufacturing facility in the United States and China and are in the process of establishing manufacturing capabilities in Belgium for commercial supply in the EU and U.S. markets, and possible additional markets. We will, moreover, continue to evaluate the use of third party CMOs to assist us in meeting commercial demand. 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 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 cell therapy. 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 cell therapy and related fields.

In-house antibody and CAR screening capability

There is considerable variability in CAR-T and CAR-NK 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 and CAR-NK 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 or CAR-NK 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. While we have encountered legal and regulatory challenges in transferring clinical data from China to other jurisdictions, we continue to believe that this approach is beneficial. 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 continue to invest in our manufacturing facilities in the United States, EU and China and continue to develop our commercial capabilities to support our product sales, including product promotion, healthcare provider education, and medical and scientific exchange.

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 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 305 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 ("CMC"), team with extensive CAR-T process development and commercialization experience, many of whom have direct experience with commercial launch and manufacturing supply of marketed CAR-T products. We have current good manufacturing practices ("cGMP"), compliant manufacturing facilities in the United States and China that supply the clinical material for our trials for our pipeline programs, and our facility located in the United States also manufactures for commercial supply in the U.S. market. We are also in the process of establishing manufacturing facilities in the EU for future supply.

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

Our Programs

Cilta-cel for the Treatment of Multiple Myeloma

Cilta-cel is a CAR-T cell therapy that we are developing for the treatment of MM. In a Phase 1 first-in-human clinical trial (LEGEND-2), 74 RRMM patients were treated with LCAR-B38M CAR-T cells. With a median follow-up time of 65.4 months, the ORR was 87.8% including a CR rate of 73%. The median duration of response was 23.3 months and the median PFS was 18 months. Median OS was 55.8 months. At a median follow-up of 47.8 months, expected adverse events were reported in all patients in LEGEND-2, with CRS reported in 91.9% of patients, with grade 3 or higher CRS observed in 9.5% of patients. Total CAR-T cell neurotoxicity of any grade was observed in 1 patient. No grade 3 or higher neurotoxicity events were reported, and no new CAR-T cell-related adverse events were reported since the 48-month follow-up. At a median follow-up of 47.8 months, there were 34 reported deaths during the Phase 1 LEGEND-2 clinical trial: 28 due to disease progression, one due to CRS and tumor lysis syndrome, one due to pulmonary embolism and potential acute coronary syndrome, one due to respiratory failure associated with subsequent therapy, one due to esophageal carcinoma, and two due to infection. At a median follow-up of 65.4 months, 33 patients were alive of whom 12 were disease free at 5 years or greater after infusion.

Patients were measured for whether they achieved a CR, VGPR or a partial response ("PR") in accordance with the International Myeloma Working Group (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 ("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 ("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 recommended Phase 2 dose and, for the Phase 2 portion, the primary endpoint was to evaluate efficacy by ORR. Secondary endpoints included efficacy, duration of and timing to response, progression-free survival, overall survival, pharmacokinetic and pharmacodynamic markers, and presence of anti-JNJ-4528 antibodies. In the United States, 97 patients were treated with cilta-cel in the combined Phase 1b/2 CARTITUDE-1 trial. At a median follow-up of 27.7 months (data as of January 11, 2022), the overall response rate was 97.9% with a sCR rate of 82.5%. At study closeout (median follow-up of 33.4 months; data as of October, 14, 2022), the median DOR was 33.9 months. The median PFS was 34.9 months for all patients and 38.2 months for patients with a complete response (CR) or better. The PFS rates for all patients at 30 months and 36 months were 54.2% and 47.5%, respectively. Median OS was not reached and an estimated 62.9% of patients were alive at the 3-year follow-up. At the 27.7 month median follow-up, the most common hematologic adverse events observed were neutropenia (95.9%), anemia (81.4%), thrombocytopenia (79.4%), leukopenia (61.9%) and lymphopenia (53.6%). With respect to adverse events of special interest, no new events of CRS were reported since the median approximate 1 year follow up. One new case of signs and symptoms of parkinsonism, previously termed movement and neurocognitive treatment-emergent AEs, was observed at the 27.7-month median follow-up. At a median follow-up of 33.4 months, there were no new neurotoxicity events were reported since the 27.7 month follow-up. A total of 26 second primary malignancies ("SPMs") were reported during the study in 20 patients. Four new patients developed 6 new cases of SPMs since the 27.7 month median follow-up, including 2 cases of basal cell carcinoma, and 1 case each of myelodysplastic syndrome, B-cell lymphoma, melanoma, and prostate cancer. A total of 35 deaths occurred during the study with 17 due to progressive disease, 12 deaths due to adverse events unrelated to treatment, and 6 deaths due to adverse events related to treatment.

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 marketing authorization application. 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. On February 28, 2022, cilta-cel was approved by FDA under the trademark CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. On May 25, 2022, the European Commission granted conditional marketing authorization of CARVYKTI for the treatment of adults with relapsed and refractory MM who have received at least three prior therapies, including a PI, an IMiD and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy. On September 26, 2022, Japan's Ministry of Health, Labour and Welfare approved CARVYKTI for the treatment of adults with relapsed or refractory multiple myeloma, limited to cases meeting both of the following conditions: patients have no history of CAR-positive T cell infusion therapy targeting BCMA; and patients who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy. In December 2022, a cilta-cel NDA was submitted to the CDE in China 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.

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% of development, production and commercialization costs and retain or bear 70% of pre-tax profits or losses. We received an upfront payment of $350.0 million from Janssen in 2018, and an additional $335.0 million in milestone payments through December 31, 2023.

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 10% of all cases and 20% of deaths of hematological malignancies. In 2018, there were 25,962 new cases of MM and 13,648 deaths in the United States, 48,297 new cases of MM and 30,860 deaths in Europe and 20,066 new cases of MM and 14,655 deaths in China. For 2024, the American Cancer Society estimates that about 35,780 new MM cases will be diagnosed and about 12,540 deaths are expected to occur in the United States.

Most people in the United States who are diagnosed with MM are 65 years old or older, with less than one percent of cases diagnosed in people younger than 35 years old. From 2013 to 2019, MM had a five-year relative survival rate of approximately 59.8% in the United States. 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 ("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% 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% 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.

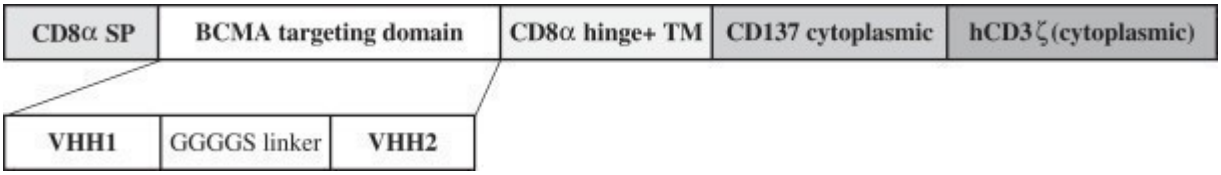
Tissue distribution of BCMA, as determined using quantitative analysis of transcription levels, shows that BCMA is generally expressed only in lymphoid cells and not in other tissues in the body. The expression level of BCMA in plasmacytomas, or MM tumors, is hundreds to thousands of times higher than 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% in a series of 24 RRMM patients and an ORR of 81% 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.

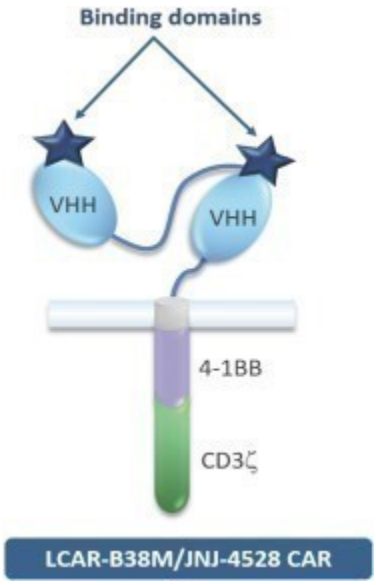
Our Solution, Cilta-cel

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



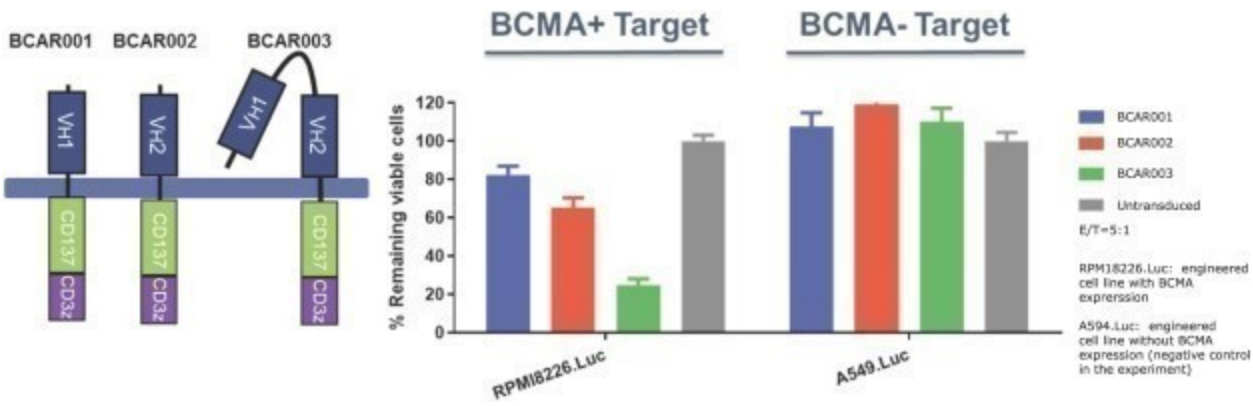
Same antigen dual binding domain CAR

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

- having two antigen-binding domains takes advantage of the concept of higher binding avidity—two points of contact between the CAR and the tumor antigen results in binding much less likely to be reversible than single point of contact with either antigen;
- dual antigen-binding domains could also allow CARs to cross-link epitopes on different molecules, which facilitates the gathering of more CARs in the immune synapse for T cell activation, increases downstream signal strength of T cells, and therefore, enhances overall CAR-T functionality; and
- inclusion of antigen-binding domains that recognize antigenic sites independently could lead to an increased ratio of on-off target binding, resulting in higher specificity thereby resulting in less off-target effects.

We conducted a preclinical study in which the anti-tumor killing effect of a single binder BCMA CAR (BCAR001 and BCAR002) was compared to a dual-binding BCMA CAR (BCAR003). As depicted below, the data from the study demonstrated that, at the same effector-to-target ratio (E/T 5:1), anti-tumor killing activity of a CAR containing a dual-binder was superior to those containing just one binder in cell lines with BCMA expression.

Preclinical data demonstrates higher specific cytolytic activity of dual-binder BCMA CAR over single-binder BCMA CAR



Completed Clinical Results LEGEND-2 (China)

LEGEND-2 is a first-in-human investigator-initiated phase 1 study in China to evaluate the safety of LCAR-B38M CAR-T cells as well as provide initial proof-of-concept efficacy in patients with relapsed or refractory multiple myeloma. Patient enrollment in this study began in 2016 and accrued a total of 74 patients across four academic sites in China. Data from the four academic sites was previously reported in a 2022 Journal of Hematology & Oncology publication, and most recently at the 2023 American Society of Clinical Oncology Annual Meeting. At a median follow-up of 65.4 months, the overall median mPFS was 18 months with a 5-year PFS rate of 21.70%. The mOS was 55.8 months with a 5-year OS rate of 49.11%. In this study, LCAR-B38M displayed a safety profile that was generally consistent with other safety reports of BCMA-targeting CAR-T therapies. CRS and cytopenias were the most observed AEs in this study and no new CAR-T cell related toxicities were reported since the 48-month follow-up.

Ongoing Clinical Development

We obtained approval to conduct confirmatory clinical trial, CARTIFAN-1, through multiple centers in China in March 2018. Following the submission of an IND, which was cleared by the FDA in May 2018, we and Janssen are conducting the CARTITUDE-1, CARTITUDE-2, CARTITUDE-4, CARTITUDE-5 and CARTITUDE-6 (in collaboration with the European Myeloma Network (the "EMN")) trials.

CARTIFAN-1 (China)

We are 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. In December 2022, we submitted a cilta-cel NDA to CDE in China based on available data from CARTIFAN-1.

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% 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 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 0.71×10^6 CAR+ viable T cells/kg (range $0.51 – 0.95 \times 10^6$).

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 the 2023 ASCO Annual Meeting.

As of January 11, 2022 (median follow-up of 27.7 months), 97 patients with RRMM continued to show a high ORR of 97.9%, with 82.5% of patients achieving a sCR. At a median follow-up of 33.4 months (data as of October 14, 2022), median DOR was 33.9 months. The median PFS for all patients and patients with CR or better was 34.9 months and 38.2 months, respectively. The PFS rates for all patients at 30 months and 36 months were 54.2% and 47.5%, respectively. Median OS was not reached, and an estimated 62.9% of patients were alive at the 3-year follow-up. At the 27.7 month median follow-up, the most common hematologic adverse events of any grade were neutropenia (95.9%), anemia (81.4%), thrombocytopenia (79.4%), leukopenia (61.9%) and lymphopenia (53.6%). One new case of signs and symptoms of parkinsonism, previously termed movement and neurocognitive treatment-emergent AEs, was observed at the 27.7-month median follow-up and the longer-term data showed no new neurotoxicity events since the 27.7-month follow-up. A total of 26 second primary malignancies (SPMs) were reported in 20 patients. Four new patients developed six new cases of SPMs since the 27.7 month median follow-up, including 2 cases of basal cell carcinoma, and 1 case each of myelodysplastic syndrome, B-cell lymphoma, melanoma, and prostate cancer. A total of 35 deaths occurred during the study with 17 due to progressive disease, 12 deaths due to adverse events unrelated to treatment, and 6 deaths due to adverse events related to treatment.

RESULTS

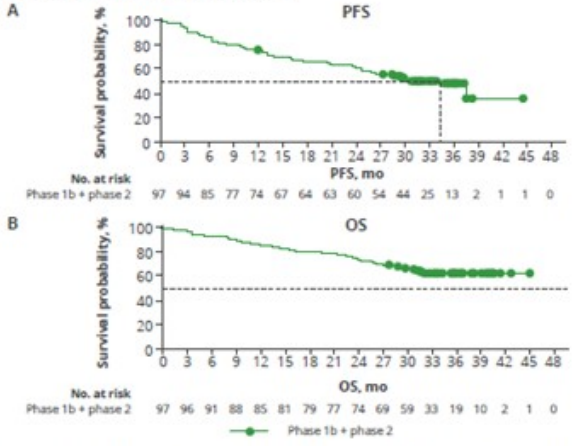
Study population

- As of October 14, 2022, 97 patients were treated with cilta-cel, with a median follow-up of 33.4 months (range, 1.5–45.2)
- Patient demographics and baseline characteristics have been previously described[1,2]
  - 42% of patients were penta-drug refractory, 88% were triple-class refractory, and 99% were refractory to last LOT
  - Patients received a median of 6 (range, 3–18) prior LOT

Efficacy

- The primary endpoint as assessed by independent review committee was previously reported:
  - ORR was 97.9% (95% CI, 92.7–99.7), and 82.5% (95% CI, 73.4–89.4) of patients achieved stringent complete response (sCR)[2]
- At study closeout:
  - Median DOR was 33.9 months (95% CI, 25.5–NE [not estimable])
  - Median PFS was 34.9 months (95% CI, 25.2–NE; **Figure 2A**)
  - Median OS was not reached (**Figure 2B**); an estimated 62.9% of patients were alive at 3-year follow-up

FIGURE 2: Time-to-event outcomes



- 62 patients had samples evaluable for MRD at any time, and 49 patients had samples evaluable for 12-month sustained MRD
  - Of these 49 evaluable patients, 26 had sustained MRD negativity for ≥12 months (**Table 1**)
    - Of the 26 patients, 20 had sustained MRD-negative complete response (CR) or better
- At 24 months post cilta-cel infusion, 18 patients remained MRD negative with ≥CR

TABLE 1: PFS by CR and sustained MRD negativity

Subgroups	mPFS (95% CI), mo	30-mo PFS rate	36-mo PFS rate
All patients	34.9 (25.2–NE)	54.2%	47.5%
≥CR[a]	38.2 (34.9–NE)	66.8%	59.8%
12-mo sustained MRD negativity[b]	NR (NE–NE)	74.9%	NE
12-mo sustained MRD-negative ≥CR[b]	NR (NE–NE)	78.5%	NE

[a]Patients had ≥CR at any time during the study, assessed by computerized algorithm. [b]Patients who were MRD evaluable had a baseline clone identified, sufficient follow-up for assessment, and ≥2 MRD-negative assessments 12 months apart, with no MRD-positive samples in that interval. mPFS, median progression-free survival; NR, not reached.

Safety

- No new neurotoxicity events were reported since the 27.7-month follow-up[2]
- A total of 26 second primary malignancies (SPMs) were reported in 20 patients
  - 4 new patients developed SPMs since 27.7-month median follow-up, with 6 new cases, including basal cell carcinoma (n=2) and 1 case each of myelodysplastic syndrome, B-cell lymphoma, melanoma, and prostate cancer
- A total of 35 deaths occurred (**Table 2**)
  - 5 new deaths unrelated to cilta-cel were reported since the 27.7-month median follow-up, including progressive disease (n=3), pneumonia (n=1), and sepsis (n=1)

TABLE 2: Study deaths

	Patients (N=97)	Time of death post cilta-cel infusion, days
Total deaths during the study	35	45–980
Due to progressive disease	17	253–980
AEs unrelated to treatment	**12**	
Pneumonia	2	109; 887
AML[a]	3	418; 582; 718
Ascites[b]	1	445
MDS	1	803
Respiratory failure	3	733; 793; 829
Septic shock and/or sepsis	2	917; 945
AEs related to treatment	**6**	
Septic shock and/or sepsis	2	45; 162
CRS/HLH	1	99
Lung abscess	1	119
Respiratory failure	1	121
Neurotoxicity	1	247

[a]One patient with AML also had MDS and a cytogenetic profile consistent with MDS (del(20q) [present before cilta-cel infusion], loss of 5q); another patient who died from AML had both prostate cancer and squamous cell carcinoma of the scalp. [b]Patient died from ascites (unrelated to cilta-cel as assessed by the investigator) due to noncirrhotic portal fibrosis and nonalcoholic steatosis that was present for many years preceding the study. AE, adverse event; AML, acute myelogenous leukemia; CRS, cytokine release syndrome; HLH, hemophagocytic lymphohistiocytosis; MDS, myelodysplastic syndrome.

REFERENCES:

1. Berdeja JG, et al. *Lancet* 2021;398:314-24. 2. Martin T, et al. *J Clin Oncol* 2023;41:1265-74. 3. Mateos M-V, et al. *Leukemia* 2022;36:1371-76. 4. Gandhi UH, et al. *Leukemia* 2019;33:2266-75. 5. CARVYKTI (ciltacabtagene autoleucel). Package insert. Janssen Biotech, Inc.; 2023. 6. CARVYKTI® (ciltacabtagene autoleucel). European Medicines Agency. Orphan maintenance assessment report. June 7, 2022. Accessed March 23, 2023. https://www.ema.europa.eu/en/documents/orphan-maintenance-report/carvykti-orphan-maintenance-assessment-report-initial-authorisation_en.pdf. 7. ClinicalTrials.gov. (NCT05201781).

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

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

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

We and Janssen began enrolling patients in November 2019 in a multi-cohort, open-label Phase 2 trial of JNJ-4528 in the United States, Europe, Israel and Saudi Arabia which we refer to as CARTITUDE-2. CARTITUDE-2 consists of the following eight cohorts, with enrollment of approximately 169 patients:

- Cohort A: Treatment of patients with progressive MM with cilta-cel after one to three prior lines of therapy
- Cohort B: Treatment of MM patients with cilta-cel with early relapse after a front-line therapy
- Cohort C: Treatment of RRMM patients with cilta-cel that have failed therapy with a proteasome inhibitor, immunomodulatory therapy, an anti-CD38 monoclonal antibody, and anti-BCMA therapy
- Cohort D: Treatment of MM patients with cilta-cel and lenalidomide who have not achieved a CR after ASCT
- Cohort E: Treatment of newly diagnosed MM patients, transplant was not planned, high risk disease
- Cohort F: Treatment of newly diagnosed MM patients with standard risk disease
- Cohort G: Treatment of newly diagnosed MM patients, transplant not planned
- Cohort H: Treatment of newly diagnosed MM patients, transplant eligible

The primary endpoint for Cohorts A-F of this trial is the percentage of patients with negative MRD one year after treatment, and the primary endpoint for Cohorts G-H is the percentage of participants with sustained MRD-negative CR. 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.

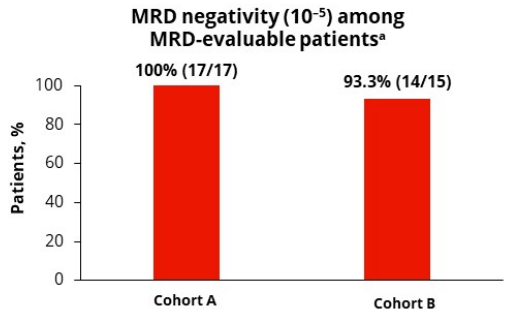
Cohort A of the trial evaluated the efficacy and safety of cilta-cel in 20 patients with progressive MM after 1-3 prior lines of therapy and were refractory to lenalidomide. As of April 2023 (median follow-up of 29.9 months), the ORR was 95% with a CR or better rate of 90%. Median time to first response was 0.99 months and the median time to best response was 3.25 months. The median DOR was not reached at a median follow-up of 17.1 months. At a median follow-up of 29.9 months, the 24-month DOR rate was 73.3%, the 24-month PFS rate was 75.0%, and the 24-month OS rate was 75.0%. All patients with MRD-evaluable samples at 10^{-5} threshold (n=17) were MRD negative. Hematologic adverse events included neutropenia (95%), thrombocytopenia (80%), anemia (75%), lymphopenia (80%) and leukopenia (60%). CRS of any grade occurred in 95% of patients and CAR T-cell neurotoxicity of any grade occurred in 30% of patients. Three patients (15%) had immune effector cell associated neurotoxicity syndrome (“ICANS”). There were no cases of movement and neurocognitive treatment emergent adverse events or parkinsonism observed. Five deaths occurred post cilta-cel infusion: one due to COVID-19 pneumonia (treatment related), one due to sepsis (not treatment related), and three due to progressive disease.

Cohort B of the trial evaluated the efficacy and safety of cilta-cel in 19 patients with early relapse MM after a front-line therapy. As of April 2023 (median follow-up was 27.9 months), the overall response rate was 100%, which included 89.5% of patients achieving ≥ CR. The median time to first response was 0.95 months and median time to best response was 5.1 months. Of the 15 patients with MRD-evaluable samples, 14 (93.3%) were MRD negative at the 10^{-5} threshold. The hematologic treatment emergent adverse events (“TEAEs”) that were observed included neutropenia (94.7%), thrombocytopenia (57.9%), anemia (57.9%), lymphopenia (47.4%), and leukopenia (31.6%). CRS of any grade occurred in 16 (84.2%) patients, and ICANS of any grade occurred in one patient. One patient experienced Grade 3/4 movement and neurocognitive TEAEs on day 38 post cilta-cel infusion.

CARTITUDE-2 Cohorts A & B: MRD Negativity (Primary Endpoint)

(~29-month median follow-up)

Most patients achieved MRD negativity at a threshold of 10^{-5}



Sustained MRD negativity[b]	Cohort A	Cohort B
Patients evaluable for sustained MRD negativity ≥6 mo[c]	**n=11**	**n=13**
Sustained MRD negativity (10^{-5}) ≥6 mo,[d] n (%)	8 (72.7)	10 (76.9)
Patients evaluable for sustained MRD negativity ≥12 mo[e]	**n=14**	**n=13**
Sustained MRD negativity (10^{-5}) ≥12 mo,[f] n (%)	7 (50.0)	8 (61.5)

Per protocol, bone marrow aspirate samples for MRD evaluation were collected at time of suspected CR/sCR; for all dosed patients at months 2, 6, 12, 18, and 24; and yearly thereafter for patients in CR/sCR.

[a]Patients who were MRD evaluable had a clone identified and had at least 1 postbaseline MRD sample that included sufficient cells for evaluation at the 10^{-5} testing threshold (for NGS) or patients who had at least 1 postbaseline sample with the result of either positive or negative (for NGF). [b]Post hoc analysis. [c]Patients who achieved overall MRD negativity and had at least an evaluable MRD sample at the 10^{-5} testing threshold on or after 6 months after their first MRD negativity or progressed, started subsequent therapy, or died due to progressive disease within 6 months after their first MRD negativity. [d]MRD negative confirmed by at least 6 months apart without MRD positive in between. Percentage is calculated with number of patients evaluable for sustained MRD negativity ≥6 months as denominator. [e]Patients who achieved overall MRD negativity and had at least an evaluable MRD sample at the 10^{-5} testing threshold on or after 12 months after their first MRD negativity or progressed, started subsequent therapy, or died due to progressive disease within 12 months after their first MRD negativity. [f]MRD negative confirmed by at least 12 months apart without MRD positive in between. Percentage is calculated with number of patients evaluable for sustained MRD negativity ≥12 months as denominator. CR, complete response; MRD, minimal residual disease; NGF, next-generation flow; NGS, next-generation sequencing; sCR, stringent CR.

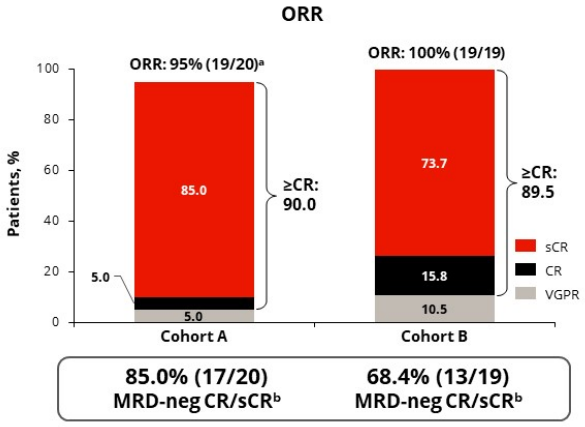
Presented by J Hillengass at the 65th American Society of Hematology (ASH) Annual Meeting; December 9–12, 2023; San Diego, CA, USA

** Presented by J Hillengass at the 65th American Society of Hematology (ASH) Annual Meeting; December 9–12, 2023; San Diego, CA, USA*

CARTITUDE-2 Cohorts A & B: Response (Secondary Endpoints)

(~29-month median follow-up)

Cilta-cel led to deep and durable responses



Treatment response among responders	Cohort A (N=19)	Cohort B (N=19)
Time (mo) to first response,[c] median (range)	0.99 (0.7–3.3)	0.95 (0.9–9.7)
Time (mo) to best response, median (range)	3.25 (0.9–13.6)	5.1 (0.9–11.8)
Duration of response		
24-mo DOR rate, % (95% CI)	73.3 (47.2–87.9)	70.5 (42.5–86.7)

[a]1 patient had a minimal response. [b]Only MRD assessments (10^{-5} testing threshold) within 3 months of achieving CR/sCR until death/progression/subsequent therapy (exclusive) are considered. [c]≥PR. cilta-cel, ciltacabtagene autoleucel; CR, complete response; DOR, duration of response; MRD, minimal residual disease; ORR, overall response rate; PR, partial response; sCR, stringent CR; VGPR, very good partial response.

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CARTITUDE-2 Cohorts A & B: AEs (Secondary Endpoint)

(~29-month median follow-up)

AEs were predictable and consistent with the known safety profile of cilta-cel

Cohort A

- **Hematologic TEAEs[a] were most common**
  - 95.0% neutropenia, all grade 3/4
- **Second primary malignancies[b]:**
  - Grade 3 mucoepidermoid carcinoma, n=1
- **Deaths:** PD, n=3[c]; sepsis, n=1[b]; pneumonia, n=1[d,e]

Cohort B

- **Hematologic TEAEs[f] were most common**
  - 94.7% neutropenia, almost all grade 3/4
- **Second primary malignancies[b]:**
  - Grade 2 prostate cancer, n=1
  - Grade 4 choroid melanoma, n=1[g]
- **Deaths:** PD, n=3; 1 cardiac arrest, n=1[b,g]

Select TEAEs, n (%)	Cohort A (N=20)		Cohort B (N=19)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Any TEAE	20 (100.0)	19 (95.0)	19 (100.0)	18 (94.7)
Serious TEAE	10 (50.0)	–	7 (36.8)	–
Hematologic				
Neutropenia	19 (95.0)	19 (95.0)	18 (94.7)	17 (89.5)
Lymphopenia	16 (80.0)	16 (80.0)	9 (47.4)	9 (47.4)
Thrombocytopenia	16 (80.0)	8 (40.0)	11 (57.9)	5 (26.3)
Anemia	15 (75.0)	9 (45.0)	11 (57.9)	9 (47.4)
Leukopenia	12 (60.0)	12 (60.0)	6 (31.6)	6 (31.6)

[a]Between a median follow-up of 17.1–29.9 months, new grade 3/4 cases of leukopenia (n=1), lymphopenia (n=2), and thrombocytopenia (n=1). [b]Not treatment related. [c]1 new death on day 666 since last data cut-off. [d]Patient also had an AE of sepsis in addition to COVID-19 pneumonia. [e]Treatment related. [f]No change since previous data cut-off. [g]New event since last data cut-off. AE, adverse event; cilta-cel, ciltacabtagene autoleucel; PD, progressive disease; TEAE, treatment-emergent AE.

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CARTITUDE-2 Cohorts A & B: CRS and CAR-T Cell Neurotoxicity (Secondary Endpoint)

(~29-month median follow-up)

CRS and CAR-T cell neurotoxicity were low grade in severity

AEs, n (%)	Cohort A (N=20)				
	Any Grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n
CRS	19 (95.0)	2 (10.0)	7	3	19
CAR-T cell neurotoxicity	6 (30.0)	1 (5.0)	–	–	–
ICANS	3 (15.0)	0	8	3	3
Other	3[a] (15.0)	1 (5.0)	30	80	2
MNT	0	0	–	–	–

AEs, n (%)	Cohort B (N=19)				
	Any Grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n
CRS	16 (84.2)	1 (5.3)	8	4	16
CAR-T cell neurotoxicity	6 (31.6)	1 (5.3)	–	–	–
ICANS	1 (5.3)	0	11	4	1
Other[b]	5[c] (26.3)	1 (5.3)	22	128	3
MNT	1[d] (5.3)	1 (5.3)	38	–[e]	–[e]

- In both cohorts, most cases of CRS and CAR-T cell neurotoxicity resolved
  - **Cohort A:** 19/19 CRS cases, 3/3 ICANS cases, and 2/3 other neurotoxicity cases resolved
  - **Cohort B:** 16/16 CRS cases, 1/1 ICANS case, and 3/5 other neurotoxicity cases resolved

[a]1 case each of peripheral sensorimotor neuropathy (recovering/resolving), anosmia (resolved), and facial paralysis (resolved). [b]1 new other neurotoxicity of grade 2 sensory loss (which resolved) since the last data cut-off. [c]1 case each of MNT (not resolved), hypoesthesia (not resolved), sensory loss (resolved), facial paralysis (resolved), and personality change (resolved). [d]Patient had associated risk factors for MNTs—high baseline tumor burden (95% plasma cells in BM biopsy at LD [M-protein from 5.0 g/dL at screening to 6.1 g/dL at LD chemotherapy]), worsening tumor burden despite bridging therapy, grade 4 CRS, and high CAR-T cell expansion and persistence. [e]Not recovered/resolved as of this data cut-off, patient died due to cardiac arrest on day 749 post cilta-cel. AE, adverse event; BM, bone marrow; CAR, chimeric antigen receptor; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; LD, lymphodepletion; MNT, movement and neurocognitive treatment-emergent AE.

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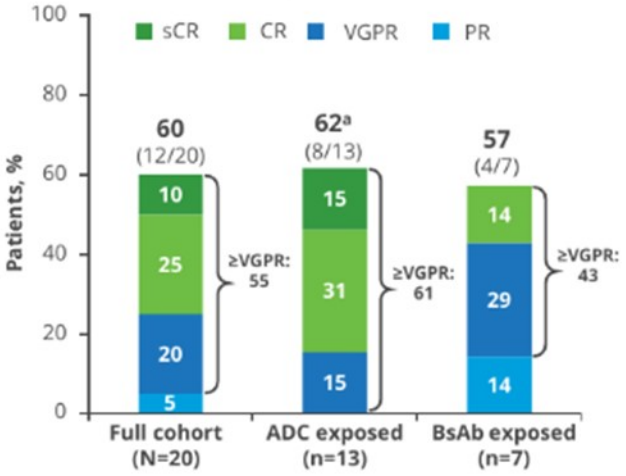
Cohort C of the trial evaluated the efficacy and safety of cilta-cel in 20 patients with prior exposure to a PI, IMiD, mAb, and non-cellular BCMA-targeting therapy including an ADC or BsAb. As of June 2022 (median follow-up was 18 months), ORR was 60% for the full cohort of ADC and BsAb exposed patients, which included 55% of patients achieving VGPR or better. Median duration of response was 12.3 months and median PFS was 9.1 months for the full cohort. Of the 10 patients with MRD-evaluable samples at 10^{-5} threshold, 7 (70%) were MRD negative. The hematologic TEAEs that were observed included neutropenia, thrombocytopenia, anemia, lymphopenia and leukopenia. CRS occurred in 12 (60%)

patients, and ICANS occurred in four patients. No cases of movement and neurocognitive treatment emergent AEs MNTs/ parkinsonism were observed.

Efficacy

- Of 10 patients with MRD-evaluable samples at 10^{-5} threshold, 7 (70%) were MRD negative[6]
  - 5 of 7 patients in the ADC-exposed group
  - 2 of 3 patients in the BsAb-exposed group
- Efficacy responses were similar in patients exposed to prior ADC vs prior BsAb[6](**Figure 2**; **Table**)
- Responses were centrally reviewed prospectively by a validated computerized algorithm and evaluated per IMWG criteria

FIGURE 2: Overall response rate



[a]Percentages may not sum appropriately due to rounding.
PR, partial response; sCR, stringent complete response.

TABLE: Median DOR, PFS, and OS

Estimate, months (95% CI)	Full cohort (N=20)	ADC exposed (n=13)	BsAb exposed (n=7)
DOR	12.3 (7.2–NE)	13.3 (7.2–NE)	8.2 (4.4–NE)
PFS	9.1 (1.5–13.2)	9.5 (1.0–15.2)	5.3 (0.6–NE)
OS	16.0 (8.3–NE)	21.0 (9.4–NE)	13.2 (0.6–NE)

NE, not estimable.

**Presented by Cohen et al. at the 20th International Myeloma Society (IMS) Annual Meeting and Exposition; September 27–30, 2023; Athens, Greece*

Safety

- Safety profile was manageable
  - Cytokine release syndrome occurred in 12 (60%) of 20 patients; 6 in the ADC group and 6 in the BsAb group (all grade ≤2); resolved in all[6]
  - 4 patients had immune effector–cell associated neurotoxicity syndrome (2 in the ADC group [1 grade 2; 1 grade 3] and 2 in the BsAb group [1 grade 2; 1 grade 4]); resolved in 3 patients[6]
  - No cases of movement and neurocognitive treatment-emergent adverse events/parkinsonism occurred[6]
- 12 deaths occurred due to progressive disease (n=8), COVID-19 pneumonia (n=2), *Clostridioides difficile* colitis (n=1; treatment related), and subarachnoid hemorrhage (n=1)[6]

**Presented by Cohen et al. at the 20th International Myeloma Society (IMS) Annual Meeting and Exposition; September 27–30, 2023; Athens, Greece*

CARTITUDE-2 Cohort C: Safety
(18-Month Median Follow-up)

- CRS occurred in 12 (60%) of 20 patients (all grade 1/2)
  - Median time to CRS onset: 7.5 days (range, 2–10)
  - Median duration: 5.5 days (range, 3–10)
  - CRS resolved in all patients
  - Tocilizumab was administered to 9 (45%) patients
- 4 patients had ICANS (3 grade 3/4)
  - Median time to onset: 9 days (range, 4–13)
  - Median duration: 7 days (range, 4–20)
  - ICANS resolved in 3 patients; 1 patient died on day 17 from *Clostridiodes difficile* colitis
- No cases of movement and neurocognitive treatment-emergent AEs/parkinsonism were observed
- 12 deaths occurred due to PD (n=8), COVID-19 pneumonia (n=2), *C. difficile* colitis (n=1; treatment related), and subarachnoid hemorrhage (n=1)

AEs, n (%)	Prior ADC (n=13)		Prior BsAb (n=7)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Hematologic (≥20%)				
Neutropenia	12 (92)	12 (92)	6 (86)	6 (86)
Anemia	10 (77)	7 (54)	4 (57)	4 (57)
Thrombocytopenia	9 (69)	8 (62)	7 (100)	6 (86)
Leukopenia	7 (54)	7 (54)	4 (57)	4 (57)
Lymphopenia	6 (46)	6 (46)	2 (29)	2 (29)
Nonhematologic				
CRS	6 (46)	0	6 (86)	0
Neurotoxicity	2 (15)	2 (15)	2 (29)	1 (14)
ICANS	2 (15)	2 (15)	2 (29)	1 (14)
Other	0	0	0	0

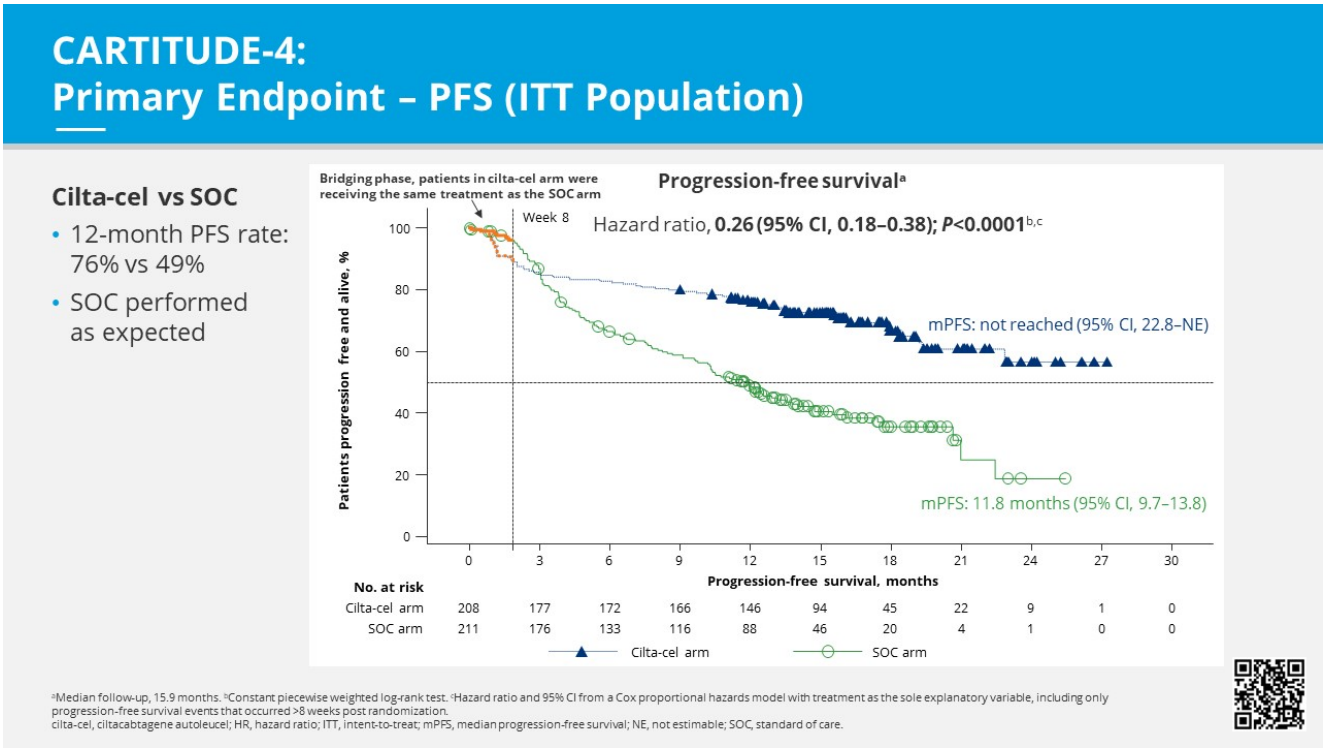
AE, adverse event; ADC, antibody-drug conjugate; BsAb, bispecific antibody; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; PD, progressive disease.

**Presented by Cohen et al at the 64th American Society of Hematology (ASH) Annual Meeting; December 10–13, 2022; New Orleans, LA, USA*

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 is progression free survival. On January 27, 2023 we announced CARTITUDE-4 met its primary endpoint of showing a statistically significant improvement in PFS compared to standard therapy at the study's first pre-specified interim analysis. The trial has been unblinded following the recommendation of an independent data monitoring committee.

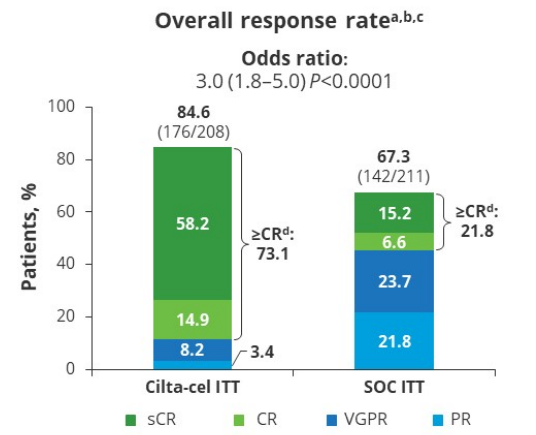
At a median follow-up of 15.9 months (data as of November 1, 2022), the median PFS was not reached in the cilta-cel arm (n= 208) and was 11.8 months in the standard care arm (n=211), with a HR of 0.26 (95% CI, 0.18-0.38) and P<0.0001. The 12-month PFS rates for the cilta-arm and standard care arm was 76% and 49%, respectively. In the cilta-cel arm, the ORR was 84.6% and 73.1% of patients had a CR or better. The median DOR was not reached with a 12-month DOR rate of 84.7%. MRD negativity was observed in 60.6% of patients in the cilta-cel arm. Among the 176 patients that received cilta-cel as study treatment, the ORR was 99.4% and 86.4% of patients had a CR or better. The 12-month PFS rate was 90% and 72% of patients were MRD negative and the 10^{-5} threshold. Patients in the standard care arm had a median DOR of 16.6 months with a 12-month DOR rate of 63.0%. MRD negativity was observed in 15.6% of patients in the standard care arm. Hematologic adverse events of any grade for both the cilta-cel and standard care arms included neutropenia (89.9% vs 85.1%), anemia (54.3% vs 26.0%), thrombocytopenia (54.3% vs. 31.3%), and lymphopenia (22.1% vs 13.9%). Deaths due to treatment-emergent adverse events were reported in 10 patients in the cilta-cel arm and 5 patients in the standard-care arm. Among the 176 patients that received cilta-cel as study treatment, any grade CRS was reported in 76.1% of patients (1.1% grade 3/4). Neurotoxicity of any grade was reported in 20.5% of patients (2.8% grade 3/4). Additional neurotoxicity events of any grade included ICANS in 8 (4.5%) patients, cranial nerve palsy in 16 (9.1 %) patients, peripheral neuropathy in 5 (2.8%) patients, and movement and neurocognitive treatment-emergent adverse events in 1 (0.6%) patients.



**Presented by Dhakal etal.at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023, Chicago, IL, USE & Virtual*

CARTITUDE-4: Secondary Endpoint (ITT) – Response

Cilta-cel had higher ORR vs SOC

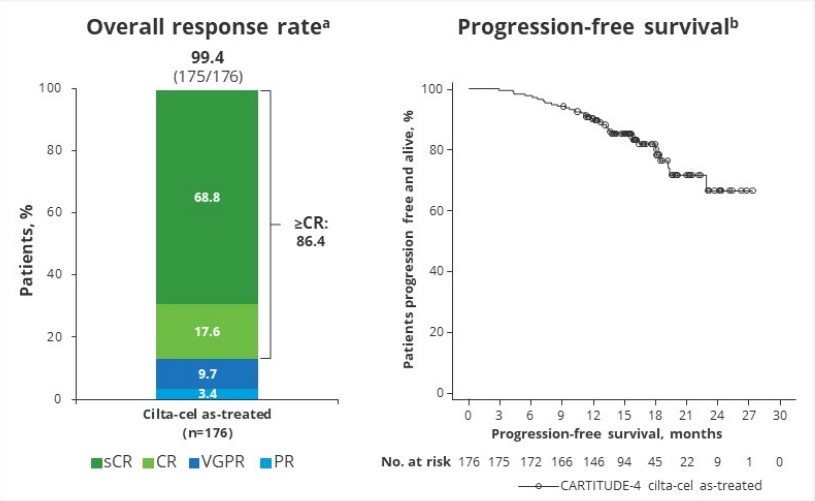


Outcome	Cilta-cel (N=208)	SOC (N=211)
12-month DOR rate, % (95% CI)	84.7 (78.1–89.4)	63.0 (54.2–70.6)
Duration of response, months median (95% CI)	NR	16.6 (12.9–NE)

[a]Assessed using a validated computerized algorithm; ORR is defined as the proportion of subjects who achieve a PR or better per IMWG criteria. [b]*P*-value from the Cochran Mantel-Haenszel Chi-Squared test. [c]In 176 patients who received cilta-cel as study treatment, ORR was 99%, ≥CR rate was 86%. [d]Odds ratio, 10.3; *P*<0.0001.
CR, complete response; DOR, duration of response; IMWG, International Myeloma Working Group; ITT, intent-to-treat; NE, not estimable; NR, not reached; ORR, overall response rate; PR, partial response; sCR, stringent complete response; SOC standard of care; VGPR, very good partial response.

Presented by Dhakal et al.at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023, Chicago, IL, USE & Virtual

CARTITUDE-4: Patients Treated With Cilta-cel as Study Treatment (As-Treated Population)



- For the as-treated population (n=176):
  - 99% ORR, with 86% ≥CR
  - 72% MRD negative at 10^{-5} (n=126/176)
  - 90% PFS rate (from apheresis) at 12 months

[a]Assessed using a validated computerized algorithm; ORR is defined as the proportion of subjects who achieve a PR or better per IMWG criteria. [b]Baseline begins at apheresis and excludes patients randomized to cilta-cel who had disease progression during bridging therapy or lymphodepletion, or died, and thus were not eligible to receive cilta-cel as study treatment.
cilta-cel, ciltacabtagene autoleucel; CR, complete response; IMWG, International Myeloma Working Group; ORR, overall response rate; PFS, progression-free survival; PR, partial response; sCR, stringent complete response; SOC standard of care; VGPR, very good partial response.

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CARTITUDE-4: TEAEs

Select TEAE ≥15%, n (%)	Safety population			
	Cilta-cel (n=208)		SOC (n=208)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any AE	208 (100)	201 (96.6)	208 (100)	196 (94.2)
Serious AE	92 (44.2)	67 (32.2)	81 (38.9)	70 (33.7)
Hematologic	197 (94.7)	196 (94.2)	185 (88.9)	179 (86.1)
Neutropenia	187 (89.9)	187 (89.9)	177 (85.1)	171 (82.2)
Anemia	113 (54.3)	74 (35.6)	54 (26.0)	30 (14.4)
Thrombocytopenia	113 (54.3)	86 (41.3)	65 (31.3)	39 (18.8)
Lymphopenia	46 (22.1)	43 (20.7)	29 (13.9)	25 (12.0)
Infections	129 (62.0)	56 (26.9)	148 (71.2)	51 (24.5)
Upper respiratory tract[a]	39 (18.8)	4 (1.9)	54 (26.0)	4 (1.9)
Lower respiratory tract[b]	19 (9.1)	9 (4.3)	36 (17.3)	8 (3.8)
COVID-19[c]	29 (13.9)	6 (2.9)	55 (26.4)	12 (5.8)

- **Hematologic TEAEs most common**
  - 85–90% **neutropenia**, almost all grade 3/4
  - Most high-grade cytopenias **resolved to grade ≤2 by day 30**
  - Grade 3/4 infections similar between arms
- **Second primary malignancies:**
  - Cilta-cel, 4.3% (n=9); most commonly cutaneous/noninvasive and hematologic
  - SOC, 6.7% (n=14); most commonly cutaneous/noninvasive[d]
- **Deaths due to TEAEs**
  - Cilta-cel, n=10[e] (7 due to COVID-19[f])
  - SOC, n=5[g] (1 due to COVID-19)

[a]Includes preferred terms upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, tonsillitis, pharyngitis, laryngitis, and pharyngotonsillitis. [b]Includes preferred terms lower respiratory tract infection, pneumonia, and bronchitis. [c]Treatment-emergent COVID-19 only; includes preferred terms COVID-19, COVID-19 pneumonia, and asymptomatic COVID-19. [d]With 1 case of peripheral T-cell lymphoma in the cilta-cel arm. [e]7 due to COVID-19, and 1 each due to neutropenic sepsis, pneumonia, and respiratory failure. [f]3 of 7 who died from COVID-19 were unvaccinated prior to cilta-cel. These COVID-19–related deaths contributed to the higher number of fatal events in the first year. [g]1 each due to COVID-19, progressive multifocal leukoencephalopathy, respiratory tract infection, septic shock, and pulmonary embolism.
AE, adverse event; cilta-cel, ciltacabtagene autoleucel; TEAE, treatment-emergent adverse event; SOC, standard of care.

Presented by Dhakal et al.at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023, Chicago, IL, USE & Virtual

CARTITUDE-4: CRS and CAR-T Cell-Related Neurotoxicity

AEs, n (%)	As-treated patients (n=176)				
	Any grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n
CRS	134 (76.1)	2 (1.1)	8	3	134
Neurotoxicity[a]	36 (20.5)	5 (2.8)			
ICANS	8 (4.5)	0[b]	10	2	8
Other[c]	30 (17.0)	4 (2.3)			
Cranial nerve palsy[d]	16 (9.1)	2 (1.1)	21	77	14
Peripheral neuropathy	5 (2.8)	1 (0.6)	63	201	3
MNT	1 (0.6)	0	85	–	0

In the cilta-cel as-treated population:

- 30 patients had non-ICANS neurotoxicities[c]
  - 16 cranial nerve palsies (14 recovered)
  - 5 peripheral neuropathies
  - 1 MNT (grade 1)
- **Lower incidence and severity of CRS, ICANS, MNTs, and some cytopenias[e] observed with CARTITUDE-4 vs CARTITUDE-1**
  - Cilta-cel may be better tolerated when used earlier in treatment
  - Effective bridging therapy enables better control of tumor burden prior to CAR-T infusion
  - MNTs were lower likely related to patient management strategies implemented to mitigate this risk

[a]There were no fatal neurotoxicities. [b]Grade 3 syncope reported as a symptom of grade 2 ICANS. [c]Other neurotoxicities include AEs reported as CAR-T cell neurotoxicity that are not ICANS or associated symptoms. [d]Cranial nerve palsies most commonly affected cranial nerve VII; supportive measures included corticosteroids (14 patients). No clear risk factors for cranial nerve palsies have been identified, and the mechanism is not understood. [e]Data for cytopenias not shown.
AE, adverse event; CAR-T, chimeric antigen receptor T cell; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; DPd, daratumumab, pomalidomide, and dexamethasone; ICANS, immune effector cell–associated neurotoxicity syndrome; MNT, movement and neurocognitive treatment-emergent adverse event.

Presented by Dhakal et al.at the2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023, Chicago, IL, USE & Virtual

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

We and Janssen are conducting a 650 patient, randomized, open-label, global, multicenter, Phase 3 trial in patients with newly diagnosed MM, which we refer to as CARTITUDE-5. Patients are randomized 1:1 to receive standard of care with VRd induction followed by lenalidomide (Revlimid), and dexamethasone maintenance or VRd induction followed by a single administration of cilta-cel (no maintenance). The primary endpoint of this trial is progression free survival. Our goal is to complete enrollment in CARTITUDE-5 by the end of the first half of 2024.

CARTITUDE-6 (Australia, Belgium, Czechia, Greece, Israel, Japan, Republic of Kora, Netherlands, Norway, Spain, Switzerland, Sweden, the United States and the United Kingdom)

Through a collaboration with the European Myeloma Network (the "EMN"), we and Janssen have initiated a 750 patient, randomized, open-label, global, multicenter, Phase 3 trial in patients with newly diagnosed MM, comparing treatment with cilta-cel to treatment with autologous stem cell transplant. This study is known as EMN028, and we refer to it as CARTITUDE-6. The dual primary end-points of the trial are PFS and sustained MRD-negative CR for at least 12 months, determined by next-generation sequencing (at least 10-5 threshold).

An IND for CARTITUDE-6 was submitted to and received by the FDA on November 14, 2022. Subsequently, the FDA requested additional safety data as a condition to permitting the study to continue under the U.S. IND, which primarily included requests for additional safety data to support the proposed dose and schedule and the proposed induction regimen. Based on such comments, it was decided to withdraw the IND. After reviewing additional safety information from the CARTITUDE-2 study, the FDA agreed that the additional data were sufficient to support the initiation of the CARTITUDE-6 study in the US. Thus, the IND for CARTIFUDE-6 was re-submitted by EMN and cleared by the FDA in November 2023.

Other Ongoing Phase 1 Clinical Trials in the United States

During November 2022, we announced that FDA had cleared our IND application to proceed with the clinical development of LB2102, an investigational, autologous CAR-T therapy for the treatment of adult patients with extensive stage small cell lung cancer ("SCLC"). LB2102 is designed to selectively target delta-like ligand 3 ("DLL-3"), a ligand that is highly restricted to various malignancies, including SCLC, large cell neuroendocrine carcinoma ("LCNEC"), certain other neuroendocrine tumors and some prostate cancers. DLL-3 has also been linked to tumor growth, migration and invasion. The Phase 1, first-in-human, open-label clinical study is designed to evaluate the safety and preliminary efficacy of LB2102 in subjects with extensive stage SCLC and patients with LCNEC, as well as to determine the recommended dose for Phase 2. In June 2023, the FDA granted orphan designation for LB2102 for treatment of SCLC. This study is currently enrolling in the United States.

During June 2022, we announced that FDA had cleared our IND application to evaluate LB1908 in a Phase 1 clinical trial in the United States. LB1908 is an investigational, autologous CAR-T therapy selectively targeting claudin 18.2 through a high-affinity VHH antibody for the treatment of adults with relapsed or refractory gastric, esophageal (including gastro-esophageal junction) or pancreatic cancers. Claudin18.2 is a tight junction protein commonly expressed in patients with these cancer subtypes. The Phase 1, first-in-human, open-label, multicenter clinical study seeks to characterize the safety and tolerability of LB1908, as well as determine the recommended dose for Phase 2 and evaluate preliminary efficacy. In November 2022, the FDA granted orphan designation for LB1908 for treatment of gastric cancer including gastroesophageal junction cancer.This study is currently enrolling in the United States.

Other Ongoing Investigator-Initiated and Preclinical Programs in China

In addition to cilta-cel, we have a broad portfolio of product candidates, both autologous and allogeneic, targeting various cancers that are in various stages of preclinical and clinical development, including some that are in investigator-initiated trials. We plan to use data from investigator-initiated clinical trials to prioritize which product candidates to advance into broader clinical testing.

Autologous CAR-T Product Candidate Clinical Development

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

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 solid tumors (including advanced gastric cancers and non-gastric cancers) in China. During June 2022, we announced that FDA had cleared our IND application to evaluate LB1908 in a Phase 1 clinical trial in the United States. In November 2022, FDA granted orphan designation for LB1908 for treatment of gastric cancer including gastroesophageal junction cancer. This study is currently enrolling in the United States. See "Item

4. Information on the Company—B. Business Overview—Our Programs—Other Ongoing Phase 1 Clinical Trials in the United States."

During November 2022, we announced that FDA had cleared our IND application to proceed with the clinical development of LB2102, an investigational, autologous CAR-T therapy for the treatment of adult patients with extensive stage small cell lung cancer (SCLC). In June 2023, FDA has granted orphan designation for LB2102 for treatment of SCLC. This study is currently enrolling in the United States. See "Item 4. Information on the Company—B. Business Overview—Our Programs—Other Ongoing Phase 1 Clinical Trials in the United States."

We are evaluating an autologous CAR-T therapy targeting CD19, CD20, and CD22 in a Phase 1 single-arm, open label investigator-initiated trial in patients with relapsed and refractory B-cell lymphoma in China. We are evaluating an autologous CAR-T therapy targeting CD19, CD20, and CD22 in a Phase 1 single-arm, open label investigator-initiated trial in patients with relapsed and refractory B-cell acute lymphocytic leukemia.

Allogeneic CAR-T and CAR-NK Product Candidate Clinical Development

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

We are evaluating an allogenic CAR-NK cell product candidate targeting BCMA in a Phase 1, single-arm, open-label investigator initiated trial in patients with relapsed or refractory multiple myeloma.

Collaboration and License Agreements

Collaboration and License Agreement with Janssen Biotech, Inc.

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

Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize cilta-cel. We and Janssen will collaborate to develop and commercialize cilta-cel for the treatment of MM worldwide pursuant to a global development plan and global commercialization plan.

Janssen will be responsible for conducting all clinical trials worldwide with participation by our team in the United States and Greater China for cilta-cel. We will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for Greater China, while Janssen will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for the rest of the world. We and Janssen will share development, production and commercialization costs and pre-tax profits or losses equally in all countries of the world except for Greater China, for which the cost-sharing and profit/loss split will be 70% for us and 30% for Janssen.

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

- $25 million, $30 million, and $30 million in January 2019, September 2019 and January 2020, respectively, upon the dosing of a specified numbers of patients in our CARTITUDE-1 clinical trial,
- a milestone payment of $25 million in September 2019 for the receipt of a response data readout from a specified number of patients in our CARTITUDE-1 clinical trial showing an ORR of at least 50%,
- a milestone payment of $75 million in January 2021 in connection with the completion of the pre-BLA meeting with the FDA, for the first marketing approval application in the United States for cilta-cel,
- a milestone payment of $15 million in July 2021 in connection with the acceptance of a submission of a Marketing Authorization to the EMA,
- milestone payments of $50 million during February 2022 in connection with the submission of an NDA to the PMDA in Japan and the enrollment of a specified numbers of patients in our CARTITUDE-5 clinical trial, and

- a milestone payment of $50 million during April 2022 in connection with the receipt of a commercialization approval for cilta-cel in the United States.

- a milestone payment of $15 million during August 2023 in connection with the acceptance of a submission of a Type II variation application to the EMA; and

- a milestone payment of $20 million during September 2023 in connection with the acceptance of a submission of a supplemental BLA to the FDA.

Additionally, we are eligible to receive further milestone payments up to $125 million for the achievement of specified manufacturing milestones, up to $210 million for the achievement of specified net trade sales milestones, and up to an additional $680 million for the achievement of specified future development and regulatory milestones.

Furthermore, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. The interest rate pursuant to the Janssen Agreement has transitioned in accordance with the LIBOR Act. Thus, outstanding advances accrue interest at 12 month CME term Secured Overnight Financing Rate ("SOFR") plus LIBOR/SOFR adjustment (12 month) plus a margin of 2.5% . Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the Janssen Agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the Janssen Agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest. As of December 31, 2023, the aggregate outstanding principal amount of such advances and interest were approximately $250.0 million and $31.3 million, respectively.

During the term of the Janssen Agreement neither we nor Janssen may develop or commercialize cilta-cel except as permitted under the Janssen Agreement. Additionally, for a period of up to 20 years after the effective date of the Janssen Agreement, neither we nor Janssen may develop or commercialize any CAR-T cell therapy targeting BCMA for the treatment of MM, either independently or in collaboration with a third party, except pursuant to the Janssen Agreement, subject to certain exceptions for mergers, acquisitions, in-licenses or similar transactions.

The Janssen Agreement will remain in force as long as cilta-cel is being sold. We or Janssen may terminate the Janssen Agreement on 90 days' notice for an uncured material breach by the other party. Janssen may also terminate the Janssen Agreement (i) in its entirety or on a geographic region-by-geographic region basis without cause on 180 days' notice to us or (ii) in its entirety upon the occurrence of an unforeseen material safety event on 60 days' notice to us. Upon any termination, we will have rights under Janssen's intellectual property to independently continue to develop and commercialize cilta-cel without compensation to Janssen.

In connection with the Janssen Agreement, we entered into the Interim Product Supply Agreement dated as of February 28, 2022 (the "IPSA") pursuant to which we will supply cilta-cel to Janssen for clinical and commercial use worldwide (excluding Greater China). Under the IPSA, Janssen pays us a transfer price for supplied product based on the total costs necessary to produce and supply such product. Ultimately, however, the cost for commercial supply and clinical supply of product are shared equally by us and Janssen as "Allowable Expenses" and "Development Costs," respectively, under the Janssen Agreement. The IPSA will remain in effect until June 30, 2024 or such alternate date determined by the joint manufacturing committee (the "JMC") that has been established under the Janssen Agreement. The IPSA will also terminate if the Janssen Agreement expires or is terminated. We expect to enter into a product supply agreement with Janssen that will replace the IPSA.

Novartis License

In November 2023, our wholly owned subsidiary, Legend Biotech Ireland Limited ("Legend Ireland" and together with the Company, the "Legend Entities")), entered into a License Agreement ("Novartis License Agreement") with Novartis Pharma AG ("Novartis"), pursuant to which the Legend Entities granted Novartis an exclusive worldwide license under certain intellectual property rights controlled by the Legend Entities in order to develop, manufacture, commercialize and otherwise exploit certain CAR-T cell therapies targeting DLL3, including our existing autologous CAR-T cell therapy candidate which we refers to as "LB2102" (the "Licensed Products").

In accordance with the Novartis License Agreement, on January 3, 2024, Novartis made to the Company an upfront payment of $100 million after closing the transaction. In addition, we will be eligible to receive from Novartis up to an aggregate of $1.01 billion in milestone payments upon achievement of specified clinical, regulatory and commercial milestones. We will also be eligible to receive tiered royalties from the high single digits to the low teens based upon net sales of Licensed Products, subject to certain reductions and offsets. Royalty payments obligations of Novartis continue on a Licensed Product-by-Licensed Product and country-by-country basis, until the latest of: (i) a specified period of time after the first commercial sale of such Licensed Product in such country; (ii) the expiration of the last-to-expire qualifying valid claim of a licensed patent that covers such Licensed Product in such country; and (iii) the expiration of regulatory exclusivity for such Licensed Product in such country.

We will be responsible for conducting a Phase 1 clinical trial in the United States for LB2102 (the "Legend Phase 1 Trial") in accordance with a mutually agreed development plan and development budget. Novartis will reimburse us for our development costs and expenses in conducting the Legend Phase 1 Trial, subject to certain limitations and exceptions. Other than with respect to the Legend Phase 1 Trial, Novartis will be solely responsible, at its cost, for the development, manufacture, commercialization and other exploitation of the Licensed Products.

For specified periods of time and subject to certain exceptions, (i) neither we nor Novartis will be permitted to conduct outside of the Novartis License Agreement clinical trial or commercialization activities for certain competing CAR-T cell therapies that are directed to DLL3 and (ii) Legend will not be permitted to conduct outside of the Novartis License clinical trial activities for in vivo CAR-T cell therapies that are directed to DLL3.

Unless terminated early by a party pursuant to its terms, the Novartis License will continue in effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the applicable royalty term.

The Novartis License Agreement is subject to customary termination provisions, including termination of the Novartis License in its entirety by either party for the other party's uncured material breach or the other party's bankruptcy or other similar financial distress, termination of the Novartis License in its entirety by Novartis for a material safety event, and termination of the Novartis License Agreement in its entirety or on a country-by-country basis, by Novartis, with or without cause, upon specified prior notice to us. In the event of certain terminations of the Novartis License Agreement, we are entitled to certain reversionary rights with respect to the terminated Licensed Products.

The Novartis License Agreement contains customary representations, warranties, covenants, and terms governing the prosecution and enforcement of certain intellectual property

Raw Materials

We currently source certain biological materials – such as cells, chemicals, water, cytokines, vectors, nucleic acids, antibodies, medium, serum, buffers —that are necessary to produce our product candidates from specialized third parties. We acquire these raw and starting materials through service agreements and do not systematically have long-term supply contracts in place. However, we believe that competitive pricing is achieved because there are a number of potential long-term replacements to each of our suppliers. Generally, the prices of the principal biological raw and starting materials that we purchase are stable or fluctuate within a limited range. To the extent that we are exposed to price fluctuations, we generally do not expect, in the near term, to be able to pass on cost increases because of the early development stage of our product candidates.

Commercialization

We have established a sales, marketing and operational infrastructure to support the commercialization of CARVYKTI in the United States. According to our collaboration and license agreement with Janssen, we have the right to elect to perform up to 50% of the overall commercialization effort in the United States (excluding any activities that Janssen has the exclusive right to perform). Janssen will commercialize cilta-cel in all countries excluding the United States and Greater China in accordance with a mutually agreed upon commercialization plan. If we launch cilta-cel in Greater China, we will lead commercialization efforts there and Janssen will have the right to elect to perform up to 30% of the overall commercialization effort there, excluding activities that we have the exclusive right to perform. As we move our product candidates through development toward marketing approval, we will evaluate several commercial strategies for each product candidate. These strategies may include further expansion of our external sales organization, entering into joint marketing collaboration agreements with other drug development companies, or out-licensing products to other drug development companies.

Intellectual Property

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

We have sought patent protection in the United States and internationally for our clinical candidates and platform technologies. As of December 31, 2023, we own 87 issued patents and 546 pending patent applications around the world covering our development platforms, commercial product, clinical products, and preclinical products. 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 (“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 or other patent offices around the world including the Chinese patent office (CNIPA) as provisional or priority patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional or priority application filing date. While we intend to timely file non-provisional patent applications relating to our provisional or priority patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file non-provisional applications and Patent Cooperation Treaty (“PCT”), applications that claim the benefit of the priority date of earlier filed provisional or priority 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 one published PCT application filed in August 2016 and one published PCT application filed in August 2017 relating to the cilta-cel BCMA product candidate. A total of 110 national phase applications from both these PCTs were filed broadly to acquire patent coverage in a variety of jurisdictions, including in the United States, Greater China (mainland China and Hong Kong), Yemen, Saudi Arabia, Qatar, Oman, Bahrain, Egypt, United Arab Emirates, Europe, South Korea, Brazil, Canada, Chile, Colombia, Costa Rica, Eurasian, Israel, India, Japan, Mexico, Philippines, Ukraine, Vietnam, Malaysia, South Africa, Singapore, Australia and New Zealand. As of December 31, 2023, we have obtained 45 granted patents regarding to cilta-cel (including three U.S. patents, one European patent, three Chinese patents, four Australian patents, three Japanese patents, one South Korean patent, two Canadian patents and two South African patents). If issued, composition of matter claims issuing from these applications are projected to expire in 2036 and 2037.

Regarding cilta-cel BCMA-targeting CAR-T cell therapy for multiple myeloma, we own one PCT application filed in December 2021, one PCT application filed in May 2022, one PCT application filed in November 2022, one PCT application filed in May 2022, one PCT application filed in February 2023, one provisional patent application filed in the U.S. in April 2023, and one PCT application filed in November 2023. Janssen is our co-applicant for these applications. If issued, treatment method claims issuing from these applications are projected to expire in 2041, 2042, 2043 and 2044.

Regarding our Claudin 18.2 product candidate, we own one PCT application filed in 2020, which has entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan. If issued, composition of matter claims issuing from this application are projected to expire in 2040.

Regarding our CD19/CD20/CD22 product candidate, we own four PCT applications filed in July 2021, which have entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan. If issued, composition of matter claims issuing from this application are projected to expire in 2041.

Regarding our GPC-3 product candidate, we own one PCT patent application filed in February 2020, which has entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan. If issued, composition of matter claims issuing from these applications are projected to expire in 2040.

Regarding our DLL3 product candidate, we own one PCT patent application filed in July 2020, which has entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan. If issued, composition of matter claims issuing from these applications are projected to expire in 2040.

Regarding our NK cell BCMA product candidate, we own one PCT patent application filed in December 2020 and one PCT patent application filed in July 2022, both of which have entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan. If issued, composition of matter claims issuing from these applications are projected to expire in 2040 and 2042.

Regarding our gamma delta T-cell BCMA product candidate, we own one PCT patent application filed in December 2020, which has entered the national phase in key jurisdictions including the U.S., Europe, Greater China, and Japan, and one PCT patent application filed in August 2022. If issued, composition of matter claims issuing from these applications are projected to expire in 2040 and 2042.

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 our product candidates.

Our manufacturing facility in the United States that we operate with Janssen currently supplies CARVYKTI for the U.S and EU markets, and we anticipate using such facility to supply other countries if we obtain approvals in such countries. Citla-cel for our clinical trials is currently supplied by our U.S. facility, one of our Belgium facilities and our facility in China. We intend to further expand the commercial-scale manufacturing capacities at our U.S. facility and are in the process of establishing manufacturing capabilities in Belgium for commercial supply in the EU and U.S. markets, and possibly additional markets. Moreover, with Janssen, we have engaged and are continuing to engage and pursue the use of

third-party CMOs to supplement our manufacturing facilities for clinical and commercial supply, including the Novartis Clinical Supply Agreement.

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 capabilities 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 continue to engage CMOs 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

CARVYKTI competes and any future 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' Kymriah is approved for the treatment of children and young adults with acute B lymphocytic leukemia, or ALL, that is refractory or has relapsed at least twice and for adults with relapsed or refractory diffuse large B cell lymphoma ("DLBCL"). Kite's Yescarta is approved for the treatment of adult patients with relapsed or refractory large B-cell lymphoma as well as follicular lymphoma. Kite's Tecartus is indicated for adult patients with relapsed or refractory mantle cell lymphoma (MCL) or adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Bristol-Myers Squibb's anti-CD19 CAR-T therapy, Breyanzi (liso-cel), as well as anti-BCMA CAR-T therapy, Abecma (ide-cel), in collaboration with bluebird bio, are also marketed CAR-T products.

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 Therapeutics, Inc., Arcellx, Inc., Autolus Therapeutics plc, bluebird bio, Inc., Bristol-Myers Squibb, Co., Caribou Biosciences, Inc., CARsgen Therapeutics Holdings Limited,, Celyad Oncology, Gracell Biotechnologies, Innovent Biologics, IASO Biotechnology, Poseida Therapeutics Inc., Novartis AG and Sana Biotechnology, Inc.;
- academic medical centers pursuing independent development of BCMA CAR-T technologies; and
- additional companies developing BCMA-targeted therapies for the treatment of MM, including Amgen, Inc., Regeneron Pharmaceuticals, Inc., GSK plc, Bristol-Myers Squibb, Co., Johnson & Johnson (the parent company of Janssen, our collaboration partner for cilta-cel), AbbVie and Pfizer Inc.

In that regard, Janssen, our cilta-cel collaboration partner, received FDA approval in October 2022 for Tecvalyi (teclistamab-cqyv), an off-the-shelf, T-cell directed, bispecific antibody targeting both BCMA and CD3.

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

In addition, our commercial success depends on our ability and the ability of our collaborators to develop, manufacture, market and sell our product and any future 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 efficiently or effectively manufactured, 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, success in manufacturing and patient access.

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. 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 ("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 ("IRB") or Ethics Committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness of the proposed biologic product candidate for its intended indications;
- preparation of and submission to the FDA of a BLA when adequate data are obtained from pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP regulations; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

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

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

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

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. For investigational products developed for oncology indications, the Phase 1 trials are normally conducted in patients with serious or life-threatening diseases without other treatment alternatives.

- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. For certain indications in patients with serious or life-threatening diseases and with no available therapies, it may be possible to obtain BLA approval based on data from Phase 2 trials if a positive benefit risk profile is demonstrated.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA unless a waiver or exemption applies.

Once an original BLA has been submitted, FDA has 60 days to determine whether the application can be filed. If FDA determines that an application to be deficient, on its face, in a way that precludes a complete review, FDA may not accept the application for review and may issue a refuse-to-file letter to the sponsor. If FDA determines the application is fileable, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process can be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facilities in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will identify the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the commercial product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant

might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. The FDA also may condition approval on, among other things, changes to proposed labeling, the development of adequate controls and specifications or post-approval safety measures. The FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMs") program to ensure the benefits of the product outweigh its risks. A REMs is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the FDA review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, in which case the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative medicine advanced therapy ("RMAT") designation is intended to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is

defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like fast track and breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development and/or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product,

including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMs program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are consistent with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

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

Biosimilarity, which requires that the product be highly similar and there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product be biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered to a patient more than once, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of first licensure for the reference product. In addition, the FDA may not approve a biosimilar product until 12 years from the date of first licensure of the reference product. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the competing product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether and to what extent products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual for, or the purchase or recommendation of an item or service for which payment may be made, directly or indirectly, under any federal healthcare program; federal civil and criminal false claims laws, including the civil False Claims Act, which prohibits, among other things, presenting, or causing to be presented, false or fraudulent claims for payment or approval to the federal government, including federal healthcare programs, and its criminal equivalent; the Civil Monetary Penalties Law, which prohibits, among other things, individuals or entities from knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal health care program; the federal Health Insurance Portability and Accountability Act of 1996 ("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 ("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, certain other healthcare professionals, such as nurse practitioners and physicians assistants, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. As there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States, coverage and reimbursement policies for drug products can differ significantly from payor to payor. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time- consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for

substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third- party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. In addition, the Tax Act was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures will impact the ACA and our business.

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 until 2031, unless additional Congressional action is taken.

In addition, 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 presidential executive orders, 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. For example, at the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA includes a provision requiring the Secretary of HHS to negotiate prices with drug companies for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). The number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The law establishes an upper limit for the negotiated price for a given drug or biologic, and specifies factors the Secretary of HHS is required to consider when negotiating these upper pricing limits. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA also imposes rebates under Medicare Part B and Medicare Part D that penalize manufactures for price increases that outpace inflation. Additionally, in response to the Biden administration's October 2022 executive order, on February

14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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.

European Union (EU) Regulation

As in the U.S., the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing in the EU is subject to a complex set of laws, rules and regulations affecting our business.

EU Medicinal Product Development

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

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

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

On January 31, 2022, Regulation EU No 536/2014 (the Clinical Trial Regulation ("CTR"), which repealed and replaced the former Directive No 2001/20 (the Clinical Trials Directive ("CTD")) and related national implementing legislation of member states of the EU ("EU Member States"), entered into application in the EU. The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse event reporting procedures, improve the supervision of clinical trials and increase their transparency. Specifically, the CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal," the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The CTR foresees a transitional period for clinical trials. For clinical trials in relation to which application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis for three years after the CTR entered into application (until January 31, 2025). By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Clinical trial applications submitted on or after January 31, 2023 must comply with the CTR.

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

Disclosure of Clinical Trial Information in the EU

Many jurisdictions have mandatory clinical trial information obligations incumbent on sponsors. In the EU, transparency requirements relating to clinical trial information are established in the CTR. The CTR establishes a general principle of transparency, according to which information contained in clinical trial applications and all the related documentation uploaded and stored in the CTIS are made publicly accessible unless confidentiality is justified on grounds of protection of personal data or CCI, is necessary to protect confidential communications between EU Member States in relation to the preparation of an assessment report, or is necessary to ensure effective supervision of the conduct of a clinical trial in EU Member States. This confidentiality exception may be overruled if there is an overriding public interest in disclosure. The publication of data and documents in relation to the conduct of a clinical trial will take place in accordance with specific timelines. Related timelines are established by the EMA and are determined based on the documents and the categorization of the clinical trial.

In addition, Regulation No 1049/2001 on access to documents, or the Access to Documents Regulation, and the related EMA policy 0043 on access to documents provide a right for EU-based interested parties to submit a request to the EMA to access documents containing certain information held by the EMA. Only very limited information is exempted from such disclosure requests. These exceptions, which - as such - are to be interpreted narrowly in the EU, include the protection of CCI and protected personal data. However, CCI protection is not afforded in those cases where the authorities conclude that there is an overriding public interest in disclosure. Case law of the Court of Justice of the European Union (the "CJEU") has also confirmed the absence of a general presumption of confidentiality over documents containing clinical and preclinical data provided to the EMA in support of a marketing authorization application.

EU Marketing Authorization

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization. The same rules also apply in the EFTA Pillar of the EEA (Norway, Iceland and Liechtenstein). A company may submit a marketing authorization application on the basis of centralized procedure, the decentralized procedure, or the mutual recognition procedure. Companies may also submit national marketing authorizations, which are issued by the competent NCAs and only cover their respective national territory.

To obtain a marketing authorization for a product in the EU, which is valid throughout the EEA, an applicant must submit a marketing authorization application either in accordance with the centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU Member States, the decentralized procedure, the national procedure or the mutual recognition procedure. A marketing authorization may be granted only to applicants established in the EU.

The centralized procedure provides for grant of a single marketing authorization by the European Commission that is valid for all the EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is mandatory for certain types of products, including for (i) medicinal products derived from certain biotechnology processes, (ii) products designated as orphan medicinal products, (iii) medicinal products containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other autoimmune dysfunctions and viral diseases. The centralized procedure is also mandatory for Advanced Therapy Medicinal Products ("ATMPs"), which comprise gene therapy, somatic cell therapy and tissue engineered products. The centralized procedure is optional for products containing a new active substance that are indicated for the treatment of other diseases, or for products that are deemed to constitute a significant therapeutic, scientific or technical innovation or for which a centralized authorization process is in the interest of patients in the EU.

Under the Centralized Procedure, the EMA's Committee on Medicinal Products for Human Use ("CHMP") conducts an initial assessment of the product and renders opinions about the safety, efficacy and quality of medicinal products on behalf of the EMA. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. The CHMP is composed of

experts nominated by each Member State's NCA, with one of them appointed to act as Rapporteur and another appointed to act as Co-Rapporteur for the co-ordination of the assessment.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days, excluding clock stops when additional information or oral explanation is to be provided by the marketing authorization applicant in response to questions of the CHMP. The process usually takes longer as additional information is requested, which triggers clock-stops in the procedural timelines. At the end of the review period, the CHMP provides an opinion to the European Commission. If the opinion is favorable, the European Commission may then adopt a decision to grant the marketing authorization. In the event of a negative opinion, the company may request a re-examination of the application within 15 days of receipt of the negative opinion. The company then has 60 days to provide the CHMP with detailed grounds for requesting the re-examination. Within 60 days of providing this information, the CHMP must re-examine its opinion. The European Commission follows the recommendation of the CHMP in almost all cases.

Accelerated assessment may be granted by the CHMP in exceptional cases when the medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The referenced EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures – Human ("CMDh") for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

A marketing authorization has, in principle, an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance of the medicinal product by the EMA or by the competent authority of the EU Member State in which the original marketing authorization was granted. The risk-benefit balance is made on the basis of scientific criteria concerning its quality, safety and efficacy. To support the application, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the electronic Common Technical Document ("eCTD"), providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance to proceed with one further five-year renewal period for the marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized marketing authorization) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

ATMPs include gene therapy products, somatic cell therapy products, and tissue engineered products. The grant of marketing authorization in the EU for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation (EC) No. 1394/2007 on ATMPs, read in combination with Directive (EC) No. 2001/83 of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation (EC) No. 1394/2007 establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization. In case of ATMPs, the

CHMP must consult with the Committee for Advanced Therapies ("CAT"), on any scientific assessment necessary to draw up its scientific opinion. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Cell-based products must also comply with Directive (EC) No. 2004/23 of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (the "Tissues and Cells Directive"). This Directive describes the conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws. However, various interpretations of the Tissue and Cells Directive have occurred and are reflected in individual EU Member States national implementing legislation which have led to diverging approaches.

In the EU, a conditional marketing authorization may be granted be granted by the European Commission in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional marketing authorization for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance is positive; (ii) if the benefit of the immediate availability on the market of the product is deemed to outweigh the risk inherent in the fact that additional data are still required; (iii) it is likely that the applicant will be able to provide comprehensive data post-authorization; and (iv) the medicinal product fulfills an unmet medical need. The conditional marketing authorization is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will cease to be renewed. This procedure can also be combined with a rolling review of data during the development of a promising medicine, to further expedite its evaluation.

A marketing authorization may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional marketing authorization, a marketing authorization granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard marketing authorization. However, unlike the conditional marketing authorization, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the marketing authorization will be withdrawn if the risk-benefit ratio is no longer favorable.

EMA Prime Scheme

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs. These include the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme intended to enhance the EMA's support for the development of medicinal products that target an unmet medical need. Eligible products must target conditions for which there is an unmet medical need (there is not satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will offer a major therapeutic advantage over existing treatments) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to early and proactive dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated assessment of marketing authorization application once a dossier has been submitted.

Our product cilta-cel was granted access to the PRIME scheme, making the product eligible for accelerated assessment.

Post-approval Requirements in the EU

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. Moreover, if a company obtains original marketing authorization for a product via an accelerated approval pathway, the company will often be required to conduct a post-marketing confirmatory trial to verify and describe the clinical benefit in support of full marketing authorization. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of the marketing authorization for a product.

All new marketing authorization applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials, Post-Authorization Efficacy Studies ("PAES"), or Post-Authorization Safety Studies ("PASS").

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with healthcare professionals ("HCPs"), misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations developed in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

In the EU, interactions between pharmaceutical companies and HCPs, healthcare organizations ("HCOs") and patient organizations ("POs") are subject to strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These rules limit the circumstances in which pharmaceutical companies may provide advantages to HCPs, HCOs or POs to prevent inducements.

Data privacy and security

Finally, very stringent data privacy requirements apply in the EEA and the UK. In particular, Regulation (EU) 2016/679 (the General Data Protection Regulation (the "EU GDPR") and the UK's GDPR (the "UK GDPR") , impose stringent data protection obligations on controllers or processors of personal data, including compliance with principles which require that personal data to be collected for specified, explicit and legal purposes, and processed in a manner consistent with those purposes. Personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed. The EU and UK GDPR also provide that personal data must be held securely, and not transferred outside of the EEA or UK, as applicable, unless certain steps are taken to ensure an adequate level of protection. The EU and UK GDPR also requires companies processing personal data to implement adequate technical measures in order to ensure the most appropriate level of security which may vary depending on different factors such as the categories of processed personal data, the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons. In addition, the EU and UK GDPR require companies processing personal data to take certain

organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For instance, the EU and UK GDPR require companies to make detailed disclosures to data subjects, provides for conditions under which a valid consent for processing can be obtained, requires the appointment of a data protection officer where sensitive personal data (e.g., health data) is processed on a large scale, imposes mandatory data breach notification throughout the EEA or UK and imposes additional obligations when contracting with service providers or partners. In addition, to the extent a company processes, controls or otherwise uses "special category" of personal data (including patients' health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. Failure to comply with the requirements of the EU and UK GDPR and the related national data protection laws of the EEA countries may result in fines up to 20 million euros (17.5 million British Pounds under the UK GDPR), or 4% of a company's global annual revenues for the preceding financial year, whichever is higher.

Pricing and Reimbursement in the EU

Typically, governments closely regulate pricing and reimbursement of medicinal products and often have a significant discretion in determining whether a product will be reimbursed at all and, if it is, how much it will be paid. In the EU, pricing and reimbursement schemes vary widely from country to country. In certain EU countries medicinal products cannot be commercially launched until a reimbursement price has been agreed. Some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EU Member States have increased the amount of discounts that pharmaceutical companies are requirement to offer. These efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products onto national markets. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices.

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA"), which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On December 13, 2021, the Health Technology Regulation ("HTA Regulation"), was adopted. While the HTA Regulation entered into force in January 12, 2022, it will only begin to apply from January 12, 2025 onwards, with preparatory and implementation-related steps to take place in the interim. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products (as well as certain high-risk medical devices), and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The results of assessments conducted on the basis of the HTA may result in increased parity of reimbursement levels for medicinal products between EU Member States.

Negotiating prices with governmental authorities can delay commercialization of our products. Payers in many countries use a variety of cost-containment measures that can include referencing prices in other countries and using those reference prices to set their own price, mandatory price cuts and rebates. This international patchwork of price regulation can lead to different prices across countries and some cross-border trade in our products from markets with lower prices. Even after a price is negotiated, countries can, and often do, request or require adjustments to the price and other concessions over time.

Data Exclusivity And Market Exclusivity in the EU

In the EU, innovative medicinal products that have been granted marketing authorization (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity. The data exclusivity period prevents applicants for the authorization of generic or biosimilar products from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, an application for authorization of a generic or biosimilar product may be submitted, and the data of the reference product may be referenced. However, no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period can be extended to a maximum of eleven years if, during the first eight years of those

ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological products.

Orphan Medicinal Product Designation and Exclusivity in the EU

Pursuant to Article 3 of Regulation (European Commission) No 141/2000, as implemented by Regulation (EC) No. 847/2000, a medicinal product may be designated by the European Commission as orphan if its sponsor can establish that (1) is the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of a marketing authorization application. A marketing authorization for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought. Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of a marketing authorization application. A marketing authorization for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure.

Upon grant of a marketing authorization, medicinal products receiving orphan designation are entitled to ten years market exclusivity for the approved therapeutic indication. During which time the EMA cannot accept another marketing authorization application, or grant a marketing authorization, or accept an application to extend a marketing authorization for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan, or PIP. market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that, if the original medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the legal threshold. Additionally, a marketing authorization may be granted to a similar product for the same orphan indication at any time during the ten-year period if: (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the manufacturer of the original orphan medicinal product cannot supply the orphan medicinal product in sufficient quantities. A company may voluntarily remove a product from the register of orphan products.

EU Supplementary Protection Certificates

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

Additional Protection for Pediatric Indications in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorisation application s for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP requirement also applies when a marketing authorization holder intends to add a new indication, pharmaceutical form or route of administration for a medicinal product that has already been authorized. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication for the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC"), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. This pediatric reward is granted subject to specific conditions and, in particular, that: (i) the applicant demonstrates having complied with all the measures contained in the PIP; (ii) the SmPC, and if appropriate the package leaflet, reflects the results of studies conducted in compliance with such PIP; and (iii) the product is authorized in all EU Member States. The rewards for conducting studies in the pediatric population can be granted irrespective of the fact that the information generated in compliance with the agreed PIP fails to lead to the authorization of a pediatric indication.

PRC Regulation

In the 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 ("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. A set of regulations have been subsequently promulgated for further implementation of the DAL; the primary one governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation ("DRR"). The DRR was promulgated by the CFDA 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 ("CFDA"), in 2018 as part of a government reorganization.

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 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. The NMPA promulgated the newly revised Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory on January 19, 2023, which became effective on July 1, 2023. Pursuant to the newly revised Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory, 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. On January 19, 2023, the NMPA issued the newly revised "Good Laboratory Practice for Nonclinical Testing Management Measures", which came into effect on July 1, 2023. These measures further clarified the requirements for good laboratory practice in nonclinical testing, including laboratory organization and management, scientific researchers, equipment and facilities, quality control, and risk management.

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 product 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 and 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, among which 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- marketing studies. The agency has done this for drugs that meet unmet clinical needs for life-threatening illnesses and also for drugs that treat orphan indications. In 2018, the NMPA and the NHC established a conditional approval program for drugs designated by the CDE that have been approved in the U.S., EU and Japan within the last 10 years and that meet one of the three criteria: (1) orphan indications, (2) drugs that treat life threatening illnesses for which there are not effective treatment or preventive methods, and (3) drugs that treat life threatening illnesses and that have a clear clinical advantage over other approved therapies.

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

- Procedures for ground-breaking therapeutic drugs: during the drug clinical trials for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or for which there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approaches, the applicant may request for application of procedures for ground-breaking therapeutic drugs.
- Procedures for conditional approval: during the drug clinical trials for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach and for which the clinical trial of such drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for

drugs urgently needed for public health and for which the clinical trial of such drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed if its benefits outweigh the risks according to the evaluation.

- Procedures for prioritized reviews and approval: at the time of the drugs' marketing registration, drugs that have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for ground-breaking therapeutic drugs; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.
- Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency. Drugs included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

Clinical Trials and Marketing Approval

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The materials required for this application and the data requirements are determined by the registration category. The NMPA has taken a number of steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the Administrative Regulations of Quality of Drug Clinical Practice, or the PRC's GCP to ensure data integrity.

Trial Approval

All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions which shall be under the filing administration. For imported drugs, proof of approval outside the PRC is required prior to the trial, unless the drug has never been approved anywhere in the world. In addition to a standalone China trial to support development, imported drug applicants may establish a site in China that is part of an international multicenter trial ("IMCT"), at the outset of the global trial. Domestically manufactured drugs are not subject to approval requirements outside the PRC, and in contrast to prior practice, the NMPA has recently decided to permit those drugs to conduct development via an IMCT as well.

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

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

Drug Clinical Trial Registration

Pursuant to the DRR, clinical trials of drugs are subject to approval and a bioequivalence test shall be filed. Clinical trials of drugs are required to comply with the PRC's GCP and must be carried out by drug clinical trial organizations which have completed filings pursuant to relevant provisions and which comply with the relevant provisions. On September 6, 2013, the NMPA released the Announcement on Drug Clinical Trial Information Platform, providing that for all clinical trials approved by the NMPA and conducted in China, instead of the aforementioned registration filed with the NMPA, clinical trial registration shall be completed and trial information shall be published through the Drug Clinical Trial Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete registration of certain follow-up information before the first subject's enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Human Genetic Resources Approval

On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that non-PRC-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. The State Council of PRC issued the Regulations on the Administration of Human Genetic Resources ("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. Non-PRC entities, non-PRC 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 non-PRC-owned entities. Pursuant to the new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

Biosecurity Law

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

On May 26, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Regulation on the Administration of Human Genetic Resources, which became effective on July 1, 2023 (the "Implementing Rules"). The Implementing Rules closely scrutinize all HGRs-related activities from upstream collection of HGR materials to downstream exploitation and external provision of the HGR materials and data derived therefrom (the "HGR data"). The Implementing Rules are intended to provide operational details and clarify questions that have emerged in the past few years after the HGR Regulations became effective. Under the Implementing Rules, clinical studies conducted for purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of HGR materials, shall be filed with the Ministry of Science and Technology (as opposed to the advance approval) if the HGR materials are collected by sites, and processed by sites or an onshore third-party lab specified in the clinical trial protocol. The Implementing Rules enumerate situations where a security review is required for external provision or utilization in an open manner of HGR data, such as external provision or utilization in an open manner of HGR data about important genetic pedigrees, HGR data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals.

Trial Exemptions and Acceptance of Non-PRC Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical

Guidance Principles on Accepting Foreign Drug Clinical Trial Data (the "Guidance Principles"), as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of non-PRC clinical trials must meet the authenticity, completeness, accuracy and traceability requirements and such data must be obtained consistent with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"). Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

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

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 drug marketing authorization holder, and this drug 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 drugs in accordance with the provisions of the DAL. The drug 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 authorization 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. On December 29, 2022, the NMPA promulgated the Regulation on the Implementation of Primary Responsibilities for Drug Quality and Safety by Drug Marketing Authorization Holders, requiring drug marketing authorization holders to set up management departments with clear responsibilities, equip management personnel appropriate to the scale of drug production and operation, and establish a sound quality management system for the whole life cycle of drugs.

Manufacturing and Distribution

According to the newly amended DAL and the Implementing Measures of the DAL, all facilities that manufacture drugs in China must receive a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years. According to the Measures on the Supervision and Administration of the Manufacture of Drugs, promulgated on August 5, 2004 with the latest amendment being effective as of July 1, 2020, to the extent the marketing authorization holder does not manufacture the drug but through contract manufacturing organization, the marketing authorization holder shall apply for drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

Similarly, to conduct sales, importation, shipping and storage, or distribution activities, a company must obtain a Drug Distribution License with an appropriate "scope of distribution" from the local drug regulatory authority, subject to renewal every five years.

China has formed a "Two Invoice System" to control distribution of drugs. The "Two-Invoice System" generally requires that no more than two invoices may be issued throughout the distribution chain, with one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary (or between the wholly owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System will become a prerequisite for pharmaceutical companies to participate in procurement processes with public hospitals, which currently provide most of China's healthcare. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process.

Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Two-Invoice System was first implemented in 11 provinces that are involved in pilot comprehensive medical reforms, but the program has expanded to nearly all provinces, which have their own individual rules for the program.

Human Cell Therapy

On March 20, 2003, the NMPA published the Technical Guidelines for Research on Human Cell Therapy and Quality Control of Preparations, which set some principles for the research of human cell therapy.

Pursuant to the DRR promulgated by the NMPA on July 10, 2007 and effective from October 1, 2007, human cell therapy and its products belong to biological products and the application for biological products shall be submitted as the process of new drug application.

On March 2, 2009, the MOH published the Management Measures for Clinical Application of Medical Technology, which came into effect on May 1, 2009 and prescribed that cell immunotherapy belongs to the Category 3 medical technology of which the clinical application shall be subject to the additional provisions of the MOH. In May, 2009, the MOH published the First List of Category 3 Medical Technologies Allowed for Clinical Application, or the Category 3 Medical Technologies which prescribed cell immunotherapy technology as Category 3 medical technologies were allowed for clinical application, and was abolished by the Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application on June 29, 2015. The Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application also cancelled the approval of Category 3 medical technology clinical application.

On November 30, 2017, the CFDA promulgated the Notice of Guidelines for Acceptance and Examination of Drug Registration (Trial), the application of clinical trials of therapeutic biological products and the production and listing application of therapeutic biological products shall be subject to the provisions thereof. On December 18, 2017, the CFDA promulgated the Technical Guiding Principles for Research and Evaluation of Cell Therapy Products (Trial) to regulate and guide the research and evaluation of cell therapy products that are researched on, developed and registered as drugs.

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

Post-Marketing Surveillance

Pursuant to the newly amended DAL, the drug marketing authorization holder shall be responsible for the monitoring, reporting and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. Marketing authorization holders, pharmaceutical manufacturer, pharmaceutical distributors and medical institutions shall regularly inspect the quality, efficacy and adverse reactions of drugs manufactured, distributed and used by them. Cases of suspected adverse reactions shall be promptly reported to the drug administrative authorities and the competent health administrative authority. The drug marketing authorization holder shall forthwith stop selling, notify the relevant pharmaceutical distributors and medical institutions to stop sales and use, recall sold drugs, promptly announce recall information if the drugs have quality issues or other safety hazards.

Advertising and Promotion of Pharmaceutical Products

China has a strict regime for the advertising of approved drugs. No unapproved drugs may be advertised. The definition of an advertisement is very broad and it can be any media that directly or indirectly introduces the product to end users. There is no clear line between advertising and any other type of promotion.

Each advertisement for drugs requires an approval from a local drug regulatory authority, and the content of an approved advertisement may not be altered without filing a new application for approval. An enterprise seeking to advertise a prescription drug may do so only in medical journals jointly approved by NMPA and the NHC, and the advertisement for a prescription drug shall tag "this advertisement is for medical and pharmaceutical professionals reading only."

Drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug's approval documentation, off-label content, is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

Product Liability

The Product Quality Law of the PRC (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 (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

NMPA and China National Intellectual Property Administration (CNIPA) jointly issued the "Implementing Measures for Drug Patent Dispute Early Resolution Mechanism (Tentative)" in July 2021 which came into effect in the same day. The Drug Patent Dispute Early Resolution Mechanism is similar to the US patent linkage system established in Hatch-Waxman Act but with some differences. This mechanism allows the patentee or interested person of an innovative drug to sue the generic drug or biosimilar producers when they submit the ANDA or biosimilar BLA. If a suit is filed, an automatic 9 month stay of marketing approval is placed on the generic drug or biosimilar, while the stay is 30 months in the US patent linkage system.

Patent term extension

According to the Patent Law issued by the Standing Committee of the NPC on October 17, 2020, which became effective on June 1, 2021, the patent administration department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years. On December 21, 2023, the PRC State Council promulgated the amendment to Implementing Rules of Patent Law, which will become effective on January 20, 2024. The amendment details the provision by stipulating that the compensated extension shall be calculated based on the number of days between the filing of the patent application and the date on which the new drug is approved to be listed on the market in China, minus five years. During the patent term compensation period, the scope of protection of the patent is limited to the technical solutions related to the new drug and its approved indications.

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 ("MIIT"), on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Reimbursement and Pricing

China's national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council in 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program. The insurance premium is jointly contributed by the employers and employees. In 2007, the State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL. A pharmaceutical product listed in the NRDL must be clinically needed, safe, effective, reasonably priced, easy to use, and available in sufficient quantity.

Factors that affect the inclusion of a pharmaceutical product in the NRDL include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public. Since 2016, special consideration has been given to, among others, innovative drugs with high clinical value and drugs for serious diseases. In addition, the PRC Ministry of Human Resources and Social Security has also been negotiating with manufacturers of expensive drugs with high clinical demands and proven effectiveness for price cuts in exchange for inclusion into the NRDL. The latest version of the NRDL was released on December 13, 2023 and was implemented on January 1, 2024.

Government price controls

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

Centralized procurement and tenders

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

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

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

Other PRC National- and Provincial-Level Laws and Regulations

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

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

Privacy and Data Security Protections

These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future, including restrictions on transfer of healthcare data.

Scientific data

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

Personal information

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

Data security

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

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

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

The CAC published the Measures on Security Assessment of Cross-border Transfer of Data on July 7, 2022, which became into effect on September 1, 2022. The Measures on Security Assessment of Cross-border Transfer of Data provides that a data processor is required to apply for security assessment for cross-border data transfer in any of the following circumstances: (i) where a data processor provides critical data abroad; (ii) where a CIIO or a data processor which processes personal information of more than 1,000,000 individuals provides personal information abroad; (iii) where a data processor has provided personal information in the aggregate of 100,000 individuals or sensitive personal

information of 10,000 individuals abroad since January 1 of the previous year; or (iv) other circumstances prescribed by the CAC for which declaration for security assessment for cross-board transfer of data is required.

On February 24, 2023, the CAC officially released the final version of the Measures for Standard Contract for the Outbound Transfer of Personal Information (the "Measures"). These Measures, including a template standard contract, took effect on June 1, 2023. According to the Measures, personal information processors that choose to establish standard contracts for providing personal information to overseas parties should follow the relevant provisions for contract establishment. Specifically, personal information processors should fully communicate with overseas recipients, clarify their rights and obligations, and ensure that the export of personal information is legal, secure, and compliant. After signing the standard contract, personal information processors are required to file with the provincial internet information department within 10 working days of the standard contract's effectiveness. The filing materials should include the standard contract and the report on the impact of personal information protection. Furthermore, if personal information processors choose to establish standard contracts to provide personal information to overseas parties, during the effective period of the standard contract, if there are situations such as personal information exporting, changes in personal information protection policies and regulations in the country or region where the overseas recipient is located, personal information processors should re-evaluate the impact of personal information protection, supplement or re-sign standard contracts, and fulfill the corresponding filing procedures.

PRC Regulation of Foreign Investment

Investment activities in China by foreign investors are principally governed by the Guidance Catalogue of Industries for Foreign Investment (the “Catalogue”), which was promulgated and is amended from time to time by the MOFCOM and the NDRC. The Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021) issued by the MOFCOM and the NDRC on December 27, 2021 and took into effect from January 1, 2022. The Negative List is further divided into two sub-categories: restricted industries and prohibited industries. Establishment of wholly foreign-owned enterprises is generally allowed in industries outside of the Negative List. For the restricted industries within the Negative List, some are limited to equity or contractual joint ventures, while in some cases Chinese partners are required to hold the majority interests in such joint ventures. Foreign investors are not allowed to invest in industries in the prohibited category. Industries not listed in the Catalogue are generally open to foreign investment unless specifically restricted by other PRC regulations. The Encouraged Industry Catalogue for Foreign Investment (2022), or the 2022 Encouraged Industry Catalogue, which became effective on January 1, 2023, 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 (the “Foreign Investment Law”), which became effective on January 1, 2020 and replaced the three old rules on foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperation Joint Venture Law and the Wholly Foreign- Owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law establishes the basic framework for the access to, and the promotion, protection and administration of foreign investments in view of investment protection and fair competition. According to the Foreign Investment Law, “foreign investment” refers to investment activities directly or indirectly conducted by one or more natural persons, business entities, or other organizations of a foreign country (collectively referred to as “foreign investor”) within China, and “investment activities” include the following activities: (i) a foreign investor, individually or together with other investors, establishes a foreign-invested enterprise within China; (ii) a foreign investor acquires stock shares, equity shares, shares in assets, or other similar rights and interests of an enterprise within China; (iii) a foreign investor, individually or together with other investors, invests in a new construction project within China; and (iv) investments in other means as provided by the laws, administrative regulations or the State Council. The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the Negative List.

On December 26, 2019, the State Council promulgated the Implementation Rules to the Foreign Investment Law, which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated Measures for Information Reporting on Foreign Investment, which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

M&A Rules

According to the M&A Rules jointly issued by the MOFCOM, the State Assets Supervision and Administration Commission of the State Council, the SAT, the State Administration for Industry and Commerce (now known as the SAMR), the CSRC and the SAFE, on August 8, 2006 and amended by the MOFCOM on June 22, 2009, among other things, (i) the purchase of an equity interest or subscription to the increase in the registered capital of non-foreign-invested enterprises, (ii) the establishment of foreign-invested enterprises to purchase and operate the assets of non-foreign-invested enterprises, or (iii) the purchase of the assets of non-foreign-invested enterprises and the use of such assets to establish foreign-invested enterprises to operate such assets, in each case, by foreign investors shall be subject to the M&A Rules. Particularly, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

Regulations Relating to Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of a public company listed outside of the PRC, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such company listed outside of the PRC, 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 (the "IIT"). The PRC subsidiaries of a company listed outside of the PRC have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Foreign Exchange

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

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

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

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

SAFE Circular 37

In July 2014, SAFE promulgated SAFE Circular 37, which replaces the previous SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles ("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 subsidiaries 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.

Enforcement of Civil Liabilities

References to "foreign" in this section entitled "Enforcement of Civil Liabilities" refer to countries outside the PRC and the Cayman Islands, as the case may be, unless the context indicates otherwise.

Legend Biotech is incorporated as an exempted company in the Cayman Islands to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

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

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

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

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

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

Maples and Calder (Singapore) LLP, our legal counsel as to Cayman Islands law, and JunHe LLP, our legal counsel as to PRC law, have advised us, respectively, that there is uncertainty as to whether the courts of the Cayman Islands and PRC, respectively, would:

- recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States; or

- entertain original actions brought in each respective jurisdiction against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

There is uncertainty with regard to Cayman Islands law relating to whether a judgment obtained from the United States courts under civil liability provisions of the securities laws will be determined by the courts of the Cayman Islands as penal or punitive in nature. If such a determination is made, the courts of the Cayman Islands will not recognize or enforce the judgment against a Cayman Islands company. Because the courts of the Cayman Islands have yet to rule on whether such judgments are penal or punitive in nature, it is uncertain whether they would be enforceable in the Cayman Islands. Maples and Calder (Singapore) LLP have advised us that although there is no statutory enforcement in the Cayman Islands of judgments obtained in the federal or state courts of the United States, a judgment in personam obtained in such jurisdiction will be recognized and enforced in the courts of the Cayman Islands at common law, without any re-examination of the merits of the underlying dispute, by an action commenced on the foreign judgment debt in the Grand Court of the Cayman Islands, provided such judgment:

- is given by a competent foreign court with jurisdiction to give the judgment;
- imposes a specific positive obligation on the judgment debtor (such as an obligation to pay a liquidated sum or perform a specified obligation);
- is final and conclusive;
- is not in respect of taxes, a fine or a penalty; and
- was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

However, the Cayman Islands courts are unlikely to enforce a judgment obtained from the U.S. courts under civil liability provisions of the U.S. federal securities law if such judgment is determined by the courts of the Cayman Islands to give rise to obligations to make payments that are penal or punitive in nature. Because such a determination has not yet been made by a court of the Cayman Islands, it is uncertain whether such civil liability judgments from U.S. courts would be enforceable in the Cayman Islands. A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

JunHe LLP has further advised us that 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 form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in China 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 law or national sovereignty, security or social 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 or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign shareholders may originate actions based on PRC law against a company in China for disputes if they can establish sufficient nexus to China for a PRC court to have jurisdiction, and meet other procedural requirements, including, among others, the plaintiff must have a direct interest in the case, and there must be a concrete claim, a factual basis and a cause for the suit. However, it would be difficult for foreign shareholders to establish sufficient nexus to China by virtue only of holding our ADSs or ordinary shares.

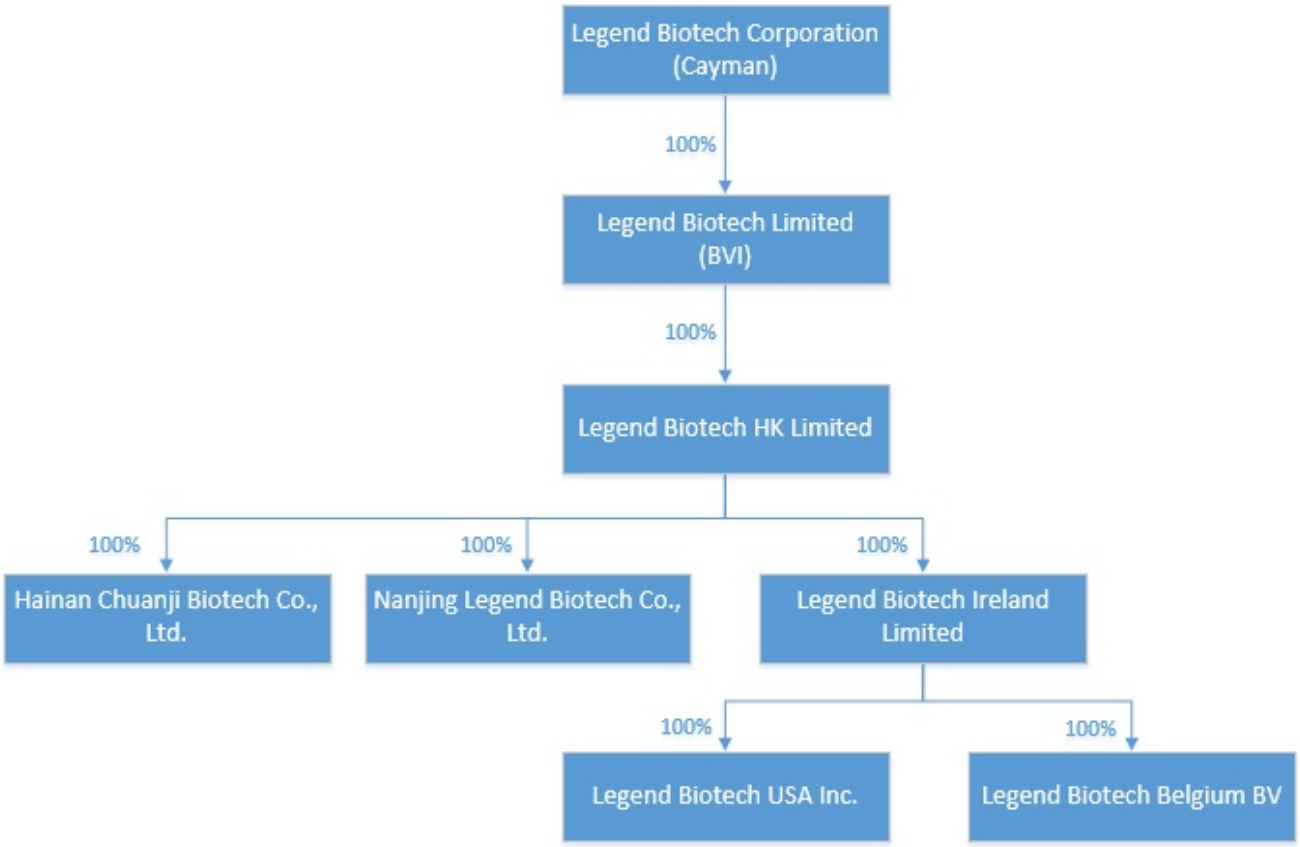
In addition, it will be difficult for U.S. shareholders to originate actions against us in China in accordance with PRC laws because we are incorporated under the laws of the Cayman Islands and it will be difficult for U.S. shareholders, by virtue only of holding our ADSs or ordinary shares, to establish a connection to China for a PRC court to have jurisdiction as required under the PRC Civil Procedures Law.

Facilities

Our principal executive offices are currently located at 2101 Cottontail Lane, Somerset, New Jersey 08873, where Legend Biotech USA, Inc. owns an approximately 85,371 square foot facility, including approximately 32,039 square feet of office space and 53,332 square feet of warehouse space. We have completed the renovation of a significant portion of the warehouse space into GMP manufacturing space for the development and potential commercialization of our pipeline. We believe our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

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:



D. Property, Plants and Equipment

Principal Executive Offices

Our principal executive offices are currently located at 2101 Cottontail Lane, Somerset, New Jersey 08873, where Legend Biotech USA, Inc. owns an approximately 85,371 square foot facility, including approximately 32,039 square feet of office space and 53,332 square feet of warehouse space. We have recently completed the renovation of a significant portion of the warehouse space into GMP manufacturing space. We believe our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

Additional U.S. Facilities

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

- We have a research facility located at 10 Knightsbridge Road, Piscataway, New Jersey 08854, where we lease approximately 22,000 square feet from a subsidiary of Genscript.
- We are party to a lease with Janssen under which we expect to lease an approximately 106,000 square foot GMP manufacturing facility from Janssen located in Raritan, New Jersey. That lease will become effective on a future date in connection with our assumption of control of such facility in accordance with the Janssen collaboration and license agreement. CARVYKTI is manufactured at this facility.

European Union

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

- Janssen currently leases two facilities in Ghent, Belgium that will be used primarily for GMP manufacturing. These facilities include approximately 180,900 and 30,000 square feet, respectively, one of which is under construction, and the other has started producing cilta-cel for clinical trials. We expect that these facilities will be subleased to us, effective as of a future date, in connection with our assumption of control of such facilities in accordance with the Janssen collaboration and license agreement. Once completed and all regulatory approvals have been obtained, we plan to use these facilities for the clinical and commercial manufacture of CARVYKTI.
- We have an administrative office facility located in Ghent, Belgium, where lease approximately 19,300 feet.
- We have a research and administrative facility located in Dublin, Ireland, where we lease approximately 8,300 square feet.

PRC

In Nanjing, we hold a land-use right for approximately 50,000 square meters situated at the North of Yuehua Road and West of Qiande Road, Jiangning Hi-Tech Development Zone, Nanjing, Jiangsu Province. We completed the construction of a GMP manufacturing facility on this land in July 2023, which has a footprint of approximately 3,800 square meters and a gross floor area of approximately 21,000 square meters. In addition, we lease the following facilities in the PRC for a variety of purposes, including for office space, warehousing, laboratory work, storage and GMP manufacturing:

Address	**Scheduled Lease Expiration**	**Leased Area**	**Use of Premises**
1st, 2nd, 3rd and 4th Floors, Building 6, Nanjing Life Science Town, 568 Longmian Avenue, Jiangning District, Nanjing	31-Dec-2026	3,592 square meters	Office and GMP manufacturing
3rd, 4th and 5th Floors, Building 3, Nanjing Life Science Town, 568 Longmian Avenue, Jiangning District, Nanjing	30-May-2026	2,038 square meters	Office and laboratory
4th Floor, Block A, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	23-Jul-2024	2,940.67 square meters	Office
4th Floor, Block E, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	31-Dec-2028	7,250 square meters	Laboratory
1st Floor, Building 5, 28 Yongxi Road, Jiangning District, Nanjing*	30-Jun-2025	1,000 square meters	Office and laboratory
1st Floor, Block B, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	25-Aug-2024	1,279.8 square meters	Warehouse
3rd Floor, Block B, Production and Research Comprehensive Building, 33 Jingyou Road, Jiangning District, Nanjing	14-Sept-2024	1,334.28 square meters	Laboratory and office
Room 209, 2nd Floor, 298 Xiangke Road, Zhangjiang High-Tech Park, Shanghai	30-June-2024	351.56 square meters	Office
17th Floor, Block B, Golden Land Center, 91 Jianguo Road, Chaoyang District, Bejing	14-May-2025	327.87 square meters	Office
Tennis Court, 33 Jinyou Road, Jiangning District, Tongfang Industrial Park, Nanjing	23-July-2024	375 square meters	Storage of waste materials

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not Applicable

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading “Cautionary Statement Regarding Forward-Looking Statements” in this

Annual Report. In evaluating our business, you should also carefully consider the information provided under "Item 3.D. Risk Factors" for a discussion of important factors that could cause our actual results to differ materially from those projected in the forward-looking statements.

Overview

We are primarily a global, clinical-stage biopharmaceutical company engaged in the discovery, development, manufacturing and commercialization of novel cell therapies for oncology and other indications. Our team of approximately 1,800 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 T cell ("CAR-T") 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 relapsed and refractory multiple myeloma ("RRMM") patients with a manageable safety profile.

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

Since inception, we have incurred significant operating losses. Our net losses were $518.3 million and $446.3 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had accumulated losses of $1.5 billion. We expect to incur operating losses over the next several years as we advance the preclinical and clinical development of our research programs and product candidates. Based on our cash and cash equivalents, deposits and investments of $1.3 billion, as of December 31, 2023, we expect that we will be able to fund our planned operations and capital expenditure requirements through the end of 2025. We expect to need additional capital to fund our operations in 2026 and beyond, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. 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 to invest in our manufacturing capabilities, including investments in our facilities in the United States, Europe and China;
- continue our ongoing and planned clinical development for our other product candidates;
- continue our ongoing and planned research and development activities;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory or marketing 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 or marketing 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 (the "Janssen 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 and milestone payments, and we continue to be eligible to receive additional milestone payments. For a description of the upfront and milestone payments Janssen has made to us under the Janssen collaboration and license agreement and potential future milestone payments Janssen may make to us under that agreement, see "Item 4. Information on the Company—B. Business Overview—Collaboration and License Agreement with Janssen Biotech, Inc."

Furthermore, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. The interest rate pursuant to the Janssen Agreement has transitioned in accordance with the LIBOR Act. Thus, outstanding advances accrue interest at 12 month CME term Secured Overnight Financing Rate ("SOFR") plus LIBOR/SOFR adjustment (12 month) plus a margin of 2.5% . Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the Janssen Agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the Janssen Agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest As of December 31, 2023, the aggregate outstanding principal amount of such advances and interest were approximately $250.0 million and $31.3 million, respectively.

Global Economic Conditions

Worldwide economic conditions remain uncertain and we continue to monitor the impact of macroeconomic conditions, including those related to the public health crises, the Russia-Ukraine war, the conflict between Israel and Hamas, the failure and instability of financial institutions and rising inflation rates.

Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the Russia-Ukraine war, the conflict between Israel and Hamas and steps taken by governments and central banks, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Our product manufacturing in both the U.S. and China has continued. Currently we have not experienced any material impact to our material supply chain or as a result of inflation and rising interest rates. Increased quantities of certain raw materials and consumables have been stocked as an appropriate safety measure. We believe we have established robust sourcing strategies for all necessary materials and do not expect any significant impact.

In addition, in China, although we experienced disruptions from COVID-19 during the year ended December 31, 2023, we do not believe they had a material impact to our business. There are still uncertainties of COVID-19's future impact on our business in China, 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 COVID-19 resurges or if other public health crises create similar disruptions, 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.

If these changes in economic conditions continue or if they increase in severity, it could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. Although we do not believe that these macroeconomic conditions have had a material impact on our financial position or results of operations to date, we may experience impacts in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with public health crises, the ongoing conflict between Russia and Ukraine and the conflict between Israel and Hamas, and employee availability and wage increases, which may result in additional stress on our working capital resources.

Components of Our Results of Operations

Revenue

Our revenue to date has primarily consisted of license revenue pursuant to the upfront payments and milestone payments received under the Janssen Agreement. In 2022, the collaboration with Janssen started to generate collaboration revenue from product sales of CARVYKTI. 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.

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 B-cell maturation antigen (“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, 2023 and 2022, our total research and development expenses were $265.0 million and $210.9 million, respectively, for our BCMA program and $117.2 million and $124.7 million, respectively, for all other non-BCMA programs.

From inception through December 31, 2023, we have incurred approximately $1.5 billion 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 expenses, including salaries, benefits and share- based compensation expense, for personnel in executive, finance, accounting, business development, IT, 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 share-based compensation, travel expenses, recruiting expenses, costs of sponsorships and consulting fees paid to external parties related to the marketing and development of cilta-cel.

Other Income and Gains

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

Revenue recognition

Upfront fees

The transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for our services and materials and milestone payments due upon the achievement of specified events.

Upfront payment is allocated to the single performance obligation in the Janssen Agreement. The upfront fees from Janssen of $350.0 million were included in the transaction price upon contract inception in 2017 and were recognized when the performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The $350.0 million upfront fees were fully received by us in 2018.

Upfront payment is allocated to a single performance obligation in the Novartis Licensing Agreement. The $100.0 million upfront fees from Novartis were included in the transaction price upon contract inception in 2023 and will be recognized when the performance obligation to deliver the intellectual property and complete the Phase 1 trial are finished over time. The $100.0 million upfront fees were fully received by us in early 2024.

Milestone payments

Milestone payments represent a form of variable consideration which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered highly probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is highly probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is highly probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price.

Certain milestone payments were allocated to the single performance obligation in the Janssen Agreement to deliver the license of intellectual property, including a technology transfer service. We recognized license revenue of $50.0 million for the milestones included in the initial transaction price in 2018, the year in which the performance obligation was satisfied and it was highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract would not occur. The $50.0 million milestone fees were fully received by us in 2019.

Additionally, we are eligible to receive further milestone payments under the Janssen Agreement of up to $125 million for the achievement of specified manufacturing milestones and an additional $610 million consisting of $400 million for the achievement of specified future development and regulatory milestones and $210 million for the achievement of specified net trade sales milestones. Subsequent development, manufacturing and regulatory milestones will be recognized in full in the period in which it is highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract will not occur, as they are associated with the performance obligation to deliver the license of intellectual property, including a technology transfer service, that was satisfied in 2018. We will recognize revenue for sales-based milestones when the milestone is achieved pursuant to the royalty recognition constraint. We have assessed that achievement of the remaining milestones is highly uncertain and the related milestone payments are not included in the transaction price.

For a description of the upfront and milestone payments Janssen has made to us under the Janssen Agreement and potential future milestone payments Janssen may make to us under the Agreement, see “Item 4. Information on the Company—B. Business Overview—Collaboration and License Agreement with Janssen Biotech, Inc.”

With respect to the Novartis Licensing agreement we have concluded that that all potential future development, regulatory and sales milestones are considered fully constrained at the inception of the License Agreement since the Company could not conclude it was highly probable since we are not able to reasonably estimate the probability of success.

Licenses of intellectual property

In assessing whether a license is distinct from the other promises, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the counterparty can benefit from a license for its intended purpose without the receipt of the remaining promise(s) by considering whether the value of the license is dependent on the unsatisfied promise(s), whether there are other vendors that could provide the remaining promise(s), and whether it is separately identifiable from the remaining promise(s). We evaluate the nature of a promise to grant a license in order to determine whether the promise is satisfied over time or at a point in time. We evaluated that the license is a single performance obligation in the Janssen Agreement, including a technology transfer service, which 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.

We have concluded that revenue associated with the Novartis Licensing Agreement will be recognized over time using the input method as the delivery of the license is not distinct from the Legend Phase 1 trial.

Collaboration cost of revenue

Collaboration cost of revenue relates to the sale of CARVYKTI and includes costs incurred by us as well as our pro-rata share of collaboration cost of revenue. Collaboration cost of revenue includes the cost of inventory sold, manufacturing costs, other costs attributable to production, and provisions to write down inventory, such as for excess and obsolete inventory or inventory that did not meet quality specifications.

Research and development costs

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

Expenditures incurred on projects to develop new product candidates 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, our intention to complete and our 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 candidate development expenditure which does not meet these criteria is expensed when incurred.

Share-based compensation

We operate a share option scheme and a restricted share unit ("RSU") 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 using a binomial model, and the fair value of each RSU is determined by reference to market price of our shares at the respective grant date. See note 26 and note 27 to our consolidated financial statements in this Annual Report 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 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.

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.

For awards that do not ultimately vest because performance and/or service conditions have not been met, no expense is recognized

A. Operating Results

Comparison of Fiscal Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the fiscal years ended December 31, 2023 and 2022:

	Fiscal Year Ended December 31,		
	2023	2022	Variance
		(in thousands)	
Consolidated Statement of Operations Data:			
Revenue			
License revenue	35,160	50,000	(14,840)
Collaboration revenue	249,804	66,677	183,127
Other revenue	179	328	(149)
Total revenue	285,143	117,005	168,138
Operating expenses:			
Collaboration cost of revenue	(144,214)	(65,363)	(78,851)
Research and development expenses	(382,218)	(335,648)	(46,570)
Administrative expenses	(106,769)	(80,631)	(26,138)
Selling and distribution expenses	(94,158)	(93,417)	(741)
Other income and gains	58,126	12,049	46,077
Other expenses	(28,484)	(9,823)	(18,661)
Fair value (loss)/gain of warrant liability	(85,750)	20,900	(106,650)
Finance costs	(21,794)	(10,796)	(10,998)
Loss before tax	(520,118)	(445,724)	(74,394)
Income tax benefit/(expense)	1,864	(625)	2,489
Loss for the year	(518,254)	(446,349)	(71,905)

Revenue

License Revenue

License revenue for the year ended December 31, 2023 was $35.2 million, compared to $50.0 million for the year ended December 31, 2022. This decrease of $14.8 million was primarily driven by nature of and timing of milestones achieved as outlined in the Global Development Plan under the Janssen Agreement for cilta-cel.

Collaboration Revenue

Collaboration revenue for the year ended December 31, 2023 was $249.8 million, compared to $66.7 million for the year ended December 31, 2022. This increase of $183.1 million was due to an increase in revenue generated from sales of CARVYKTI in connection with the Janssen Agreement.

Other Revenue

Other revenue for the year ended December 31, 2023 was $0.2 million, compared to $0.3 million for the year ended December 31, 2022. Other revenue mainly relates to the licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates.

Operating Expenses

Collaboration cost of revenue

Collaboration cost of revenue for the year ended December 31, 2023 were $144.2 million, compared to $65.4 million for the year ended December 31, 2022. This increase of $78.8 million was primarily due to our share of costs of sales of CARVYKTI as part of the Janssen Agreement and expenditures to support expansion in manufacturing capacity.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2023 were $382.2 million, compared to $335.6 million for the year ended December 31, 2022. This increase of $46.6 million was primarily due to research and development activities in cilta-cel, including higher patient enrollment for Phase 3 clinical trials for cilta-cel, and an increase in research and development activities for other pipeline items. Also, the increase in research and development expenses is due to personnel and start up costs to establish the manufacturing facility in Belgium for initial clinical production. The other pipeline expenses include continued investment in our solid tumor programs, which includes two Investigational New Drug ("IND") approvals that advanced into Phase 1 development.

Administrative Expenses

Administrative expenses for the year ended December 31, 2023 were $106.8 million, compared to $80.6 million for the year ended December 31, 2022. This increase of $26.2 million was due to our expansion of supporting administrative functions to facilitate business growth and investment in building global information technology infrastructure.

Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2023 were $94.2 million, compared to $93.4 million for the year ended December 31, 2022. This increase of $0.8 million was due to costs associated with commercial activities for cilta-cel.

Other Income and Gains

Other income and gains for the year ended December 31, 2023 was $58.1 million, compared to $12.0 million for the year ended December 31, 2022. This increase of $46.1 million was primarily driven by increases in interest income and gain on investments for the year ended December 31, 2023.

Other Expenses

Other expenses for the year ended December 31, 2023 was $28.5 million, compared to $9.8 million for the year ended December 31, 2022. The increase of $18.7 million was primarily due to unrealized foreign exchange loss.

Finance Costs

Finance costs for the year ended December 31, 2023 was $21.8 million, compared to $10.8 million for the year ended December 31, 2022. The increase of $11.0 million was primarily due to interest on advance funding, which is interest-bearing borrowings funded by Janssen under the Janssen Agreement and constituted by principal and applicable interests upon such principal.

Fair Value (Loss)/Gain of Warrant Liability

Fair value loss of warrant liability for the year ended December 31, 2023 was $85.8 million, compared to a fair value gain of $20.9 million for the year ended December 31, 2022. The $106.7 million increase was due to the fair value loss recorded on the full exercise of the warrant we issued to an institutional investor in May 2021, which warrant was fully exercised on May 11, 2023.

Income Tax (Expense)/Credit

Income tax credit for the year ended December 31, 2023 was $1.9 million compared to $0.6 million of income tax expense for the year ended December 31, 2022. The $2.5 million decrease in income tax expense was due to the reversal of previously accrued reserves for uncertain tax positions upon the expiration of the statute of limitations.

Comparison of Fiscal Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the fiscal years ended December 31, 2022 and 2021:

	Fiscal Year Ended December 31,		
	2022	2021	Variance
		(in thousands)	
Consolidated Statement of Operations Data:			
REVENUE			
License revenue	50,000	65,402	(15,402)
Collaboration revenue	66,677	—	66,677
Other revenue	328	3,424	(3,096)
Total revenue	117,005	68,826	48,179
Operating expenses:			
Collaboration cost of revenue	(65,363)	—	(65,363)
Research and development expenses	(335,648)	(313,346)	(22,302)
Administrative expenses	(80,631)	(46,961)	(33,670)
Selling and distribution expenses	(93,417)	(102,542)	9,125
Other income and gains	12,049	3,059	8,990
Other expenses	(9,823)	(9,132)	(691)
Fair value (loss)/gain of warrant liability	20,900	(6,200)	27,100
Finance costs	(10,796)	(900)	(9,896)
Loss for the year	(445,724)	(407,196)	(38,528)
Income tax benefit/(expense)	(625)	3,614	(4,239)
Loss for the year	(446,349)	(403,582)	(42,767)

Revenue

License Revenue

License revenue for the year ended December 31, 2022 was $50.0 million, compared to $65.4 million for the year ended December 31, 2021. This decrease of $15.4 million was primarily driven by nature of and timing of milestones achieved as outlined in the Global Development Plan under the Janssen Agreement for cilta-cel in the year ended December 31, 2022.

Collaboration Revenue

Collaboration revenue for the year ended December 31, 2022 was $66.7 million, compared to none for the year ended December 31, 2021. This increase of $66.7 million was due to the commercial launch of CARVYKTI in the U.S. in connection with the Janssen Agreement.

Other Revenue

Other revenue for the year ended December 31, 2022 was $0.3 million, compared to $3.4 million for the year ended December 31, 2021. This decrease of $3.1 million was due to lower license and royalty revenue generated in 2022 for the licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates during the year ended December 31, 2022.

Operating Expenses

Collaboration cost of revenue

Collaboration cost of revenue for the year ended December 31, 2022 was $65.4 million, compared to none for the year ended December 31, 2021. This increase of $65.4 million was primarily due to our share of costs of sales incurred in the U.S. in connection with the commercial launch of CARVYKTI as part of the Janssen Agreement.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 were $335.6 million, compared to $313.3 million for the year ended December 31, 2021. This increase of $22.3 million was primarily due to research and development activities in cilta-cel in earlier lines of therapy and increase in our pipeline expenditures as we filed two IND filings and began preparation for Phase 1 clinical development in the U.S. in the year ended December 31, 2022.

Administrative Expenses

Administrative expenses for the year ended December 31, 2022 were $80.6 million, compared to $47.0 million for the year ended December 31, 2021. This decrease of $33.6 million was due to our expansion of supporting administrative functions to facilitate business expansion. This increase is primarily driven by implementation of the final phase of separation of information technology infrastructure from GenScript Biotech Corporation ("GenScript" or "Genscript"), required enhancements for cybersecurity and privacy, along with the required IT infrastructure build to support the product candidate manufacturing facilities.

Selling and Distribution Expenses

Selling and distribution expenses for the year ended December 31, 2022 were $93.4 million, compared to $102.5 million for the year ended December 31, 2021. This decrease of $9.1 million was due to decreased costs associated with commercial activities for cilta-cel.

Other Income and Gains

Other income and gains for the year ended December 31, 2022 was $12.0 million, compared to $3.1 million for the year ended December 31, 2021. This increase of $8.9 million was primarily driven by increases in interest income, government grants and fair value gain from financial assets at fair value through profit and loss for the year ended December 31, 2022.

Other Expenses

Other expenses for the year ended December 31, 2022 was $9.8 million, compared to $9.1 million for the year ended December 31, 2021. The decrease of $0.7 million was primarily due to foreign exchange loss.

Finance Costs

Finance costs for the year ended December 31, 2022 was $10.8 million, compared to $0.9 million for the year ended December 31, 2021. The increase of $9.9 million was primarily due to of interest on advance funding, which is interest-bearing borrowings funded by Janssen under the Janssen Agreement and constituted by principal and applicable interests upon such principal. We elected to borrow an incremental $130.3 million as of December 31, 2022 in accordance with the terms of the Janssen agreement.

Fair Value Gain/(Loss) of Warrant Liability

Fair value gain of warrant liability for the year ended December 31, 2022 was $20.9 million caused by changes in fair value of a warrant that we issued to an institutional investor through a private placement transaction in May 2021 with an initial fair value of $81.7 million at the issuance date. Concurrently, ordinary shares were sold to the same institutional investor in a private placement transaction. The warrant was assessed as a financial liability with a fair value of $67.0 million as of December 31, 2022.

Income Tax (Expense)/ Credit

Income tax expense for the year ended December 31, 2022 was $0.6 million compared to $3.6 million of income tax credit for the year ended December 31, 2021.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with the International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. 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

Upfront fees

The transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for our services and materials and milestone payments due upon the achievement of specified events.

Upfront payment is allocated to the single performance obligation in the Janssen Agreement. The upfront fees from Janssen of $350.0 million were included in the transaction price upon contract inception in 2017 and were recognized when the performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The $350.0 million upfront fees were fully received by us in 2018.

Upfront payment is allocated to a single performance obligation in the Novartis Licensing Agreement. The $100.0 million upfront fees from Novartis were included in the transaction price upon contract inception in 2023 and will be recognized when the performance obligation to deliver the intellectual property and complete the Phase 1 trial are finished over time. The $100.0 million upfront fees were fully received by us in early 2024.

Milestone payments

Milestone payments represent a form of variable consideration which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered highly probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is highly probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is highly probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price.

Certain milestone payments were allocated to the single performance obligation in the Janssen Agreement to deliver the license of intellectual property, including a technology transfer service. We recognized license revenue of $50.0 million for the milestones included in the initial transaction price in 2018, the year in which the performance obligation was satisfied and it was highly probable a significant reversal of the cumulative revenue recognized for the IFRS 15 contract would not occur. The $50.0 million milestone fees were fully received by us in 2019.

Additionally, we are eligible to receive further milestone payments under the Janssen Agreement of up to $125 million for the achievement of specified manufacturing milestones and an additional $610 million consisting of $400 million for the achievement of specified future development and regulatory milestones and $210 million for the

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

For a description of the upfront and milestone payments Janssen has made to us under the Janssen Agreement and potential future milestone payments Janssen may make to us under the Agreement, see "Item 4. Information on the Company—B. Business Overview—Collaboration and License Agreement with Janssen Biotech, Inc."

With respect to the Novartis License Agreement, we have concluded that that all potential future development, regulatory and sales milestones are considered fully constrained at the inception of the License Agreement since the Company could not conclude it was highly probable since we are not able to reasonably estimate the probability of success.

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. With respect to arrangements containing a license to our intellectual property that is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from amounts allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue.

We evaluated that the license is a single performance obligation in the Janssen Agreement, including a technology transfer service, 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.

We evaluated that the license (inclusive of know-how) and the delivery of the Handover Package Documents which includes performing the Legend Phase 1 trial, is a single performance obligation in the Novartis Licensing Agreement, which represents a right to use our license over time after the license is granted and the Legend Phase 1 trial is ongoing.

Input Method

We use input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We have concluded that revenue associated with the Novartis Licensing Agreement will be recognized over time using the input method as the delivery of the license is not distinct from the Legend Phase 1 trial.

Research and development costs

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

Expenditures incurred on projects to develop new product candidates 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 candidate development expenditure which does not meet these criteria is expensed when incurred.

Share-Based Compensation

We operate a share option scheme and a RSU 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 using a binomial model, and the fair value of each RSU is determined by reference to market price of our shares at the respective grant date. See note 26 and note 27 to our consolidated financial statements in this Annual Report 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 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. 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,	
	2023	2022
Expected life of options (years)	10	10
Expected volatility	66.1 %	73.0% - 87.1%
Risk-free interest rate	3.40%-4.84%	0.52% - 3.11%
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 ordinary shares, exercise price of our stock options, expected volatility of our ordinary shares 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 International Financial Reporting Standards

See note 2.3 to our consolidated financial statements in this Annual Report for a description of recent accounting pronouncements applicable to our consolidated financial statements.

B. Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We expect to incur operating losses over the next several years as we advance the preclinical and clinical development of our research programs and product candidates. Based on our cash and cash equivalents, deposits and investments of $1.3 billion, as of December 31, 2023, we expect that we will be able to fund our planned operations and capital expenditure requirements through the end of 2025. We expect to need additional capital to fund our operations in 2026 and beyond, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

With the exception of our first product, CARVYKTI, which was approved by the FDA on February 28, 2022 for the treatment of adults with RRMM who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, we do not currently have any approved products and we have not generated any revenue from product sales for other products. From inception through December 31, 2023, we have funded our operations primarily with approximately:

- $3.9 million in capital contributions from Genscript;
- $160.5 million in gross proceeds from the sale of our Series A preference shares;
- $685.0 million in upfront and milestone payments from Janssen under our collaboration and license agreement;
- $450.1 million in net proceeds from our U.S. initial public offering and an additional $12.0 million from a concurrent private placement with Genscript;
- $300.0 million in net proceeds from our private placement to an investor and related warrant issuance in May 2021;
- $323.4 million in net proceeds from our public offering of ADSs that closed in December 2021
- $250.0 million in advances from Janssen under our the Janssen Agreement;
- $377.6 million in net proceeds from our public offering of ADSs that closed in July 2022;
- $234.4 million in net proceeds from private placements to certain investors in May and June 2023;
- $349.3 million in net proceeds from our public offering of ADS that closed in May 2023; and
- $199.7 million in net proceeds from the exercise in full of a warrant held by one of our investors.

As of December 31, 2023, we had approximately $1.28 billion of cash and cash equivalents, approximately $34.7 million of time deposits, and accumulated losses of $1.48 billion.

Certain of our subsidiaries, including those registered as wholly foreign-owned enterprises in the People's Republic of China (the "PRC"), 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 flows:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Net cash used in operating activities	(393,276)	(201,281)	(198,465)
Net cash provided by/(used in) investing activities	92,786	(77,092)	(194,983)
Net cash provided by financing activities	791,490	377,976	626,663
Net increase in cash and cash equivalents	491,000	99,603	233,215

Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $393.3 million, primarily as a result of net loss before tax of $520.1 million after adjusting for non-cash items, changes in operating assets and liabilities, and cash items. Non-cash items mainly include $54.5 million of finance income, $21.8 million of finance cost, $3.6 million for the provision for the inventory reserves, $10.7 million of depreciation expense of property, plant and equipment, $1.9 million of amortization expense of intangible assets, $7.8 million of depreciation of right-of-use assets, $85.8 million of fair value gain of warrant liability, $28.2 million of foreign exchange loss and $47.7 million of equity-settled share-based compensation expenses. Changes in operating assets and liabilities mainly include an increase in trade receivables of $99.0 million primarily resulted from a $100 million receivable in connection with the Novartis License Agreement which was received after December 31 2023, increase in prepayment, other receivable and other assets of $8.7 million, increase in collaboration inventories of $12.7 million, decrease in trade payables of $12.7 million, increase in other payables and accruals of $38.8 million, increase in contract liabilities (current) of $52.5 million and an increase in contract liabilities (non-current) of $47.5 million. Cash items primarily include Interest income received of $47.3 million, income tax received of $1.0 million, which is a refund of prior year's income tax return previously paid partially offset by interest on lease payments $1.4 million.

Net cash used in operating activities for the year ended December 31, 2022 was $201.3 million, primarily as a result of net loss before tax of $445.7 million after adjusting for non-cash items, changes in operating assets and liabilities, and cash items. Non-cash items mainly include $8.2 million of finance income, $10.8 million of finance cost, $10.2 million of depreciation expense of property, plant and equipment, $2.5 million of amortization expense of intangible assets, $5.7 million of depreciation of right-of-use assets, $20.9 million of fair value gain of warrant liability, $9.2 million of foreign exchange loss and $34.3 million of equity-settled share-based compensation expenses. Changes in operating assets and liabilities mainly include a decrease in trade receivables of $50.3 million primarily resulted from receipt of two milestone payments, increase in prepayment, other receivable and other assets of $50.6 million, decrease in other non-current assets of $3.7 million, increase in collaboration inventories of $8.6 million, increase in deferred government grant of $6.2 million, increase in trade payables of $25.9 million, increase in other payables and accruals of $165.9 million and an increase of $0.2 million in other non-current liabilities. Cash items primarily include finance income received of $5.6 million and income tax received of $3.7 million, which is a refund of prior year's income tax return previously paid.

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

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2023 was $92.8 million, consisting primarily of Cash received from withdrawal of financial assets measured at fair value through profit or loss of $185.0 million, a decrease in time deposits of $19.6 million and cash receipt of investment income of $8.8 million partially offset

by prepayment to collaborator for collaboration assets of $98.8 million, purchases of property, plant and equipment of $20.1 million and purchase of intangible assets of $2.6 million.

Net cash used in investing activities for the year ended December 31, 2022 was $77.1 million, consisting primarily of purchases of property, plant and equipment of $20.9 million, purchase of intangible assets of $1.3 million, prepayment to collaborator for collaboration assets of $14.8 million, net purchase of financial assets at fair value through profit and loss of $185.0 million, partially offset by a decrease in time deposits of $113.6 million, redemption of financial asset measured at amortized cost of $30.0 million and cash receipt of investment income of $1.3 million.

Net cash used in investing activities for the year ended December 31, 2021 was $195.0 million, consisting primarily of purchases of property, plant and equipment of $42.2 million, purchase of intangible assets of $3.2 million, prepayment to collaborator for collaboration assets of $1.7 million, purchase of financial assets measured at amortized cost of $29.8 million and purchases of time deposits of $298.1 million, partially offset by a decrease in time deposits of $180.0 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $791.5 million, consisting primarily of net proceeds from issuance of ordinary shares for follow-on public offering of $349.3 million in July, proceeds from issuance of ordinary shares for institutional investors, net of issuance cost of $234.4 million, proceeds from exercise of warrant by warrant holder, net of issuance cost of $199.7 million and proceeds from exercise of share option of $11.8 million, partially offset by principal portion of lease payments of $3.8 million.

Net cash provided by financing activities for the year ended December 31, 2022 was $378.0 million, consisting primarily of net proceeds from issuance of ordinary shares for follow-on public offering of $377.6 million in July, proceeds from exercise of share option of $2.9 million, partially offset by principal portion of lease payments of $2.6 million.

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

Capital Expenditure

Our capital expenditures for the years ended December 31, 2023, 2022 and 2021 amounted to $104.0 million, $70.3 million and $44.5 million, respectively. These expenditures primarily consisted of property, plant, equipment and collaboration assets.

As of December 31, 2023 and 2022, we had commitments for capital expenditures of approximately $11.3 million and $22.7 million, respectively, primarily for contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. We anticipate our capital expenditure in 2024 to be financed from our cash and cash equivalents on hand. Primarily, these capital expenditures will be made both in the United States and China, where our principal research and development facilities are currently located.

Funding Requirements

The following table sets forth our contractual obligations and commitments as of December 31, 2023:

	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	Total
			(in thousands)		
Lease obligations	$ 5,060	$ 9,367	$ 8,098	$ 43,988	$ 66,513
Capital commitment	8,640	2,630	—	—	11,270
Total	$ 13,700	$ 11,997	$ 8,098	$ 43,988	$ 77,783

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

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, following FDA's approval of CARVYKTI, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. For example, in addition to investing in our own facilities, we expect to supplement our manufacturing capabilities and infrastructure by entering into agreements with one or more CMOs. 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 macroeconomic conditions, including global conflicts and inflation, and resulting economic uncertainty could adversely affect our liquidity and capital resources in the future, and cash requirements may fluctuate based on the timing and extent of many factors such as those discussed below, we currently expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

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

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

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

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

Under the Janssen Agreement, until such time as our collaboration experiences its first profitable year, we are entitled to receive advances from Janssen if the collaboration's estimated working capital for any year falls below $50 million. In such event, Janssen provides advances to us in an amount equal to the excess of $50 million over the collaboration's working capital for the year. The total amount of such advances in any calendar year may not exceed $125 million and the total amount of such advances outstanding at any time may not exceed $250 million. The interest rate pursuant to the Janssen Agreement has transitioned in accordance with the LIBOR Act. Thus, outstanding advances accrue interest at 12 month CME term Secured Overnight Financing Rate ("SOFR") plus LIBOR/SOFR adjustment (12 month) plus a margin of 2.5% . Janssen has the right to recoup such advances and interest from our share of the collaboration's pre-tax profits and, subject to some limitations, from milestone payments due to us under the Janssen Agreement. We are not otherwise obligated to repay the advances or interest, except in connection with our change in control or a termination of the Janssen Agreement by Janssen due to our material breach of the agreement. We may at any time in our discretion voluntarily pre-pay any portion of the then outstanding advances or associated interest. As of December 31, 2023, the aggregate outstanding principal amount of such advances and interest were approximately $250.0 million and $31.3 million, respectively.

C. Research and Development, Patents and Licenses, etc

Full details of our research and development activities and expenditures and patents and licenses 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 above.

D. Trend Information

Other than as described elsewhere in this Annual Report, including under Item 5.A—Operating Results" and "Item 5.B. —Liquidity and Capital Resources," we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

E. Critical Accounting Estimates

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

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth certain information relating to our current directors and executive officers as of March 1, 2024:

Name	Age	Position
Executive Officers		
Ying Huang, Ph.D.	51	Chief Executive Officer and Director
Lori Macomber, CPA	53	Chief Financial Officer
Non-Employee Directors		
Fangliang Zhang, Ph.D.	59	Chairman of the Board of Directors
Ye (Sally) Wang, M.S.	55	Director
Li Zhu Ph.D.	74	Director
Darren Xiaohui Ji, M.D., Ph.D.	62	Independent Director
Corazon D. Sanders Ph.D.	67	Independent Director
Yau Wai Man Philip, CPA	48	Independent Director
Patrick Casey, Ph.D.	68	Independent Director
Li Mao, MD	67	Independent Director
Tomas Heyman	68	Independent Director

Executive Officers

Ying Huang, Ph.D., has served as our chief executive officer since September 2020 and previously served as our chief financial officer from July 2019 until May 2022. Dr. Huang has also been a director of Quanta Therapeutics, Inc., a privately-held company, since February 2022. Prior to joining us, Dr. Huang was a Managing Director and Head of Biotech Equity Research at BofA Securities, Inc. from August 2014 to July 2019, where he led a team of analysts covering more than 30 biotechnology companies including Amgen, Gilead, Celgene, Biogen and others that encompass a wide range of therapeutic areas. Dr. Huang has been a biotechnology analyst since 2007 and previously worked at Wells Fargo (formerly Wachovia), Credit Suisse, Gleacher and Barclays before joining BofA Securities, Inc. Prior to his Wall Street career, Dr. Huang was a Principal Scientist at Schering-Plough (now Merck & Co.) in the Department of Chemical Research focusing on small molecule drug discovery in the therapeutic areas of cardiovascular and central nervous system. He is also the co-author of multiple patents and peer-reviewed publications. Dr. Huang holds a Ph.D. in Bio-organic Chemistry from Columbia University. Dr. Huang also studied at Columbia Business School and in the Special Class for the Gifted Young at the University of Science and Technology of China. In December 2021, Dr. Huang was appointed to our board of directors as a Class I director.

Lori Macomber, CPA, has served as our chief financial officer since May 2022, in which capacity Ms. Macomber serves as our principal financial officer and principal accounting officer. Ms. Macomber previously served as our vice president, finance from March 2021 to May 2022 and as our vice president of supply chain finance and controller from September 2019 to March 2021. 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

Fangliang Zhang, Ph.D., has served as our director and chairman of our board of directors since August 2022. Dr. Zhang has been an executive director of GenScript since December 2022 and, prior that, was a non-executive director of GenScript from May 2022 to December 2022. Prior to that time, he was chairman and an executive director of GenScript from 2015 to 2020. He also serves as the general manager of several companies within the Genscript group. He co-founded the GenScript group in 2002 and has been the director of various group companies prior to GenScript becoming

the holding company of the group companies pursuant to the corporate reorganization for GenScript's initial public offering in 2015. In 2015, Dr. Zhang founded the Company as a subsidiary of GenScript, expanding GenScript's business goal to research, manufacture and commercialize a broad range of immunotherapy treatments. Dr. Zhang served as Chairman of our board of directors from 2015 to November 2020 and served as our Chief Executive Officer from August 2020 to September 2020. In 2018, Dr. Zhang was awarded Person of the Year at the China Healthcare Summit in recognition of his contribution to and significant impact on the healthcare field. Before founding GenScript, Dr. Zhang worked as a Principal Scientist at Schering-Plough from 1995 to 2002 where he received its Presidential Award. Dr. Zhang holds a Ph.D. in biochemistry from Duke University, a Master's degree from Nanjing University and a Bachelor's degree from Chengdu Institute of Geology.

Ye (Sally) Wang, M.S., has served as our director since May 2015 and from November 2020 to August 2022 was the chairwoman of our board of directors. Ms. Wang served as the Chief Operating Officer of Genscript from April 2014 to November 2017, has served on Genscript's board of directors since 2009 and has served as Genscript's President since December 2017, responsible for Genscript's strategies and overall operational management. She co-founded the Genscript group in 2002 and has taken various managerial positions in Genscript Corporation before Genscript became the holding company of the Genscript group of companies. Prior to joining Genscript, she worked as an Environmental Monitoring Engineer at Shenzhen Futian Environment Protection Surveillance Station. Ms. Wang 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 has served as a director of Genscript since November 2020. Dr. Zhu holds a B.S. in biology from the East China Normal University and a Ph.D. in molecular biology and immunology from Stanford University.

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

Corazon (Corsee) Sanders, Ph.D., has served as our director since May 2020. Dr. Sanders has been a member of the board of directors of Molecular Templates, Inc. since December 2019, of AltruBio Inc. (f/k/a AbGenomics Holdings Inc.) since March 2020, of Beigene, Ltd since August 2020, and of Ultragenyx Pharmaceuticals, Inc. since June 2021. Dr. Sanders previously served as a Strategic Advisor to the Office of the Celgene Chief Medical Officer from March 2018 to November 2019. Prior to that, Dr. Sanders was a Member of the Juno Therapeutics Executive Committee as Executive Vice President of Development Operations, with responsibilities for strategic operations, quantitative sciences, biosample and clinical operations from January 2017 to March 2018. Dr. Sanders was a Member of the Genentech/Roche Late Stage Portfolio Committee from 2009 to 2017, and Global Head of the Genentech/Roche Late Stage Clinical Operations from 2012 to 2017. Dr. Sanders also served on the Board of Trustees of the Fred Hutchinson Cancer Research Center and has been the co-chair of the board of Advisors of the newly created Fred Hutchinson Research Center since 2022. Dr. Sanders holds a B.S. and M.S. in statistics, graduating Magna Cum Laude from the University of the Philippines, and an M.A. and Ph.D. in statistics from the Wharton Doctoral Program at the University of Pennsylvania.

Yau Wai Man Philip, CPA, has served as our director since May 2020. Mr. Yau has been the chief financial officer of C. & J. Clarks International Limited since October 2021. Prior to that, he was the non-executive vice chairman of

AMTD Group, at which he led strategy development, corporate finance and investment functions from 2016 to December 2019. From 2011 to March 2016, he worked at Ernst & Young China Practice as a partner, risk advisory China South market leader, serving clients in Greater China, where he advised on finance, management, and business issues. From 2006 to 2011, he worked at Protiviti Shanghai Co., Ltd. as a managing director and Shenzhen office leader, where he was primarily responsible for overall management of the company. From 1997 to 2006, he worked at PricewaterhouseCoopers and Arthur Andersen & Co., his most recent position being senior manager in the risk consulting practice. Mr. Yau served as a director of China General Education Group Limited, an education services company, from June 2021 until April 2022. 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.

Li Mao, M.D., has served as our director since August 2022. Dr. Mao currently serves as Chief Medical Officer for SciClone Pharmaceuticals, Inc., a position he has held since June 2022. Prior to that, Dr. Mao served as Chief Medical Officer of Sino Biopharmaceutical Co., Ltd. from May 2021 to June 2022, Chief Executive Officer of Livzon Bio from March 2021 to April 2021 and Chief Executive Officer of Xcovery Holdings, Inc. from November 2018 to March 2021. Dr. Mao also served as Senior Vice President and Chief Medical Officer of Betta Pharmaceuticals Co., Ltd. from March 2018 to March 2021 and Vice President at Johnson & Johnson from June 2016 to February 2018. In addition, he served as a Professor at the MD Anderson Cancer Center from 2004 to March 2009 and a Professor at the University of Maryland, Baltimore from March 2009 to June 2016. Dr. Mao also served as a member of the board of directors of Betta Pharmaceuticals Co., Ltd, which is publicly listed on the Shenzhen Stock Exchange, from April 2018 to March 2021. Dr. Mao holds a Medical Doctor's degree from Nanjing Medical University. Dr. Mao also completed a postdoctoral fellowship in cancer genetics at The John Hopkins University School of Medicine.

Tomas J. Heyman, has served as our director since August 2022. Mr. Heyman previously served as the President of Johnson & Johnson's Corporate Venture Capital Group, the venture capital arm of Johnson & Johnson, a Global Healthcare Company from 2015 to September 2019 and as the Global Head of Business Development for Johnson & Johnson's Pharmaceutical Group from 1992 to 2015. In addition, Mr. Heyman previously served as Chief Executive Officer of Janssen Pharmaceutica N.V., a pharmaceutical company, from 2008 to 2016. Mr. Heyman has served as a director of OptiNose, Inc., a specialty pharmaceutical company, since December 2020, a director of Akero Therapeutics, Inc., a biotechnology company, since June 2020, a director of Invivyd Inc. (formerly known as Adagio Therapeutics Inc.), a biopharmaceutical company, since June 2021, and Xilio Therapeutics, Inc., a biotechnology company, since September 2022. Mr. Heyman graduated as Master of Law from the K.U. Leuven in Belgium. He continued with post-graduate studies in International Law in Geneva, Switzerland, and post-graduate studies in business management at the University of Antwerp in Belgium.

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, 2023, we paid an aggregate of $2.7 million in cash and benefits to our executive officers, which also includes $0.5 million that we paid to our our non-employee 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 ordinary shares, which are Dr. Ji, Dr. Sanders, Mr. Yau, Dr. Casey, Mr. Heyman and Dr. Mao 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. The Chair of the Audit Committee and the Chair of the Compensation Committee receive an additional $25,000 and $20,000, respectively, each year. 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.

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 Chair of the Audit Committee and the Chair of the Compensation Committee each receives an additional restricted share unit award for a number of ordinary shares equal to $70,000 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.

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.

Employment Agreements and Indemnification Agreements

We have employment agreements with each of our executive officers and each of our executive officers has executed a form of our standard intellectual property rights assignment, non-competition and confidentiality agreement, with modifications thereto addressed in their respective employment agreements. 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.

Amended and Restated Employment Agreement with Dr. Ying Huang, Our Chief Executive Officer

Under the terms of the amended and restated employment agreement, Dr. Huang’s annual base salary is $700,000 and Dr. Huang is eligible for a discretionary annual cash bonus with a target of 75% (the “CEO Annual Bonus”) of Dr. Huang’s then-current base salary (the “CEO Target Amount”). In March 2024, our board of directors approved an increase to Dr. Huang’s annual base salary to $750,750, to be effective as of March 31, 2024. Dr. Huang’s eligibility for the CEO Annual Bonus will be based upon the board of director’s assessment of the attainment of individual and corporate performance goals as determined by the board of directors in its sole discretion.

Pursuant to the terms of the employment agreement, Dr. Huang’s employment is at will and may be terminated at any time by us. If Dr. Huang’s employment is terminated by us without Cause (as defined in the employment agreement) or by Dr. Huang for Good Reason (as defined in the employment agreement) in either case not in connection with a Change in Control (as defined in the employment agreement), then Dr. Huang would be eligible to receive the following severance benefits, less applicable tax withholding (the “CEO Non-CIC Severance Benefits”):

- payment of Dr. Huang’s then-current base salary in accordance with normal payroll procedures for 18 months;
- payment of Dr. Huang’s annual bonus earned for the year prior to the year in which his termination occurs if unpaid as of the date such termination is effective (the “CEO Date of Termination”), calculated based on the attainment of applicable corporate performance metrics and, with respect to individual metrics, the average of Dr. Huang’s individual performance ratings over the two years prior to such performance year shall apply (the “CEO Prior Year Bonus”);

- pro-rated portion of Dr. Huang's CEO Target Amount for the year in which the Date of Termination occurs, without regard to whether service or performance metrics or ratings have been established or achieved (whether corporate or individual) (the "CEO Pro Rata Bonus");

- payment or reimbursement of continued health coverage for Dr. Huang and his dependents under COBRA for up to 18 months (the "CEO COBRA Payments");

- with respect to equity awards granted to Dr. Huang, that portion of any equity awards held by Dr. Huang that would have vested during the 18-month period following Dr. Huang's Date of Termination shall be accelerated, such that such then-unvested equity awards immediately vest and become fully exercisable or non-forfeitable without regard to any performance-based requirements, but only so long as any applicable corporate performance goals are achieved;

- the post-termination exercise period attributable to any stock options will extend up to 18 months from Dr. Huang's Date of Termination; and

- outplacement services with a nationally recognized provider or executive coaching services for a period of 12 months for up to $40,000 in annual fees (the "CEO Coaching Services").

Under the employment agreement, if Dr. Huang's employment is terminated by us without Cause or if Dr. Huang resigns for Good Reason, in either case within 3 months before or 18 months following the effective date of a Change in Control, then Dr. Huang would be entitled to the following severance benefits, less applicable tax withholding (the "CEO CIC Severance Benefits," together with the Non-CIC Severance Benefits, the "CEO Severance Benefits"):

- payment of his then-current base salary in accordance with normal payroll procedures for 24 months;

- payment of the CFO Prior Year Bonus if unpaid as of the Date of Termination;

- the CEO Pro Rata Bonus;

- Payment of two times the CEO Target Amount for the year in which the Date of Termination occurs;

- the CEO COBRA Payments;

- all equity awards held by Dr. Huang shall be accelerated, such that such then-unvested equity awards immediately vest and become fully exercisable or non-forfeitable as of the Date of Termination without regard to any performance-based requirements;

- if the options are assumed or converted, the post-termination exercise period attributable to any stock option shall be extended up to 18 months from the Date of Termination; and

- the CEO Coaching Services.

Payment of the CEO Severance Benefits is subject to Dr. Huang signing and delivering to us a separation agreement containing a general release of claims in favor of us. Under the employment agreement, if Dr. Huang's employment is terminated for Cause or Dr. Huang resigns without Good Reason, Dr. Huang will not receive any CEO Severance Benefits.

Amended and Restated Employment Agreement with Ms. Lori Macomber, Our Chief Financial Officer

Under the terms of the amended and restated employment agreement with Ms. Macomber's annual base salary is $400,000 and Ms. Macomber is eligible for a discretionary annual cash bonus with a target of 35% (the "CFO Annual Bonus") of her then-current base salary (the "CFO Target Amount"). In March 2023, our board of directors approved an increase to Ms. Macomber's CFO Target Amount to 45% of her then-current base salary. In March 2024, our board of directors approved an increase to Ms. Macomber's annual base salary to $412,000, to be effective as of March 31, 2024. Ms. Macomber's eligibility for the CFO Annual Bonus of up to 45% of her base salary will be based upon her performance, business conditions at Legend Biotech, and the terms of any applicable bonus plan and, to the extent required by the Compensation Committee of the board of directors, the achievement of performance targets as established by the board of directors or the Compensation Committee, based on the recommendations of our Chief Executive Officer.

Pursuant to the terms of the employment agreement, Ms. Macomber's employment is at will and may be terminated at any time by us. If Ms. Macomber's employment is terminated without Cause (as defined in the employment agreement) or by Ms. Macomber for Good Reason (as defined in the employment agreement) in either case not in connection with a Change in Control (as defined in the employment agreement), then Ms. Macomber would be eligible to receive the following severance benefits, less applicable taxes withholdings (the "CFO Non-CIC Severance Benefits"):

- payment of Ms. Macomber's then-current base salary in accordance with normal payroll procedures for 12 months;
- payment of Ms. Macomber's annual bonus earned for the year prior to the year in which her termination occurs if unpaid as of the Date of Termination, calculated based on the attainment of applicable corporate performance metrics and, with respect to individual metrics, the average of Ms. Macomber's individual performance ratings over the two years prior to such performance year (the "CFO Prior Year Bonus");
- a pro-rated portion of Ms. Macomber's Target Amount for the year in which the Date of Termination occurs, without regard to whether service or performance metrics or ratings have been established or achieved (whether corporate or individual) (the "CFO Pro Rata Bonus");
- payment or reimbursement of continued health coverage for Ms. Macomber and her dependents under COBRA for up to 12 months;
- with respect to equity awards granted to Ms. Macomber, that portion of any equity awards held by Ms. Macomber that would have vested during the 12-month period following Ms. Macomber's Date of Termination shall be accelerated, such that such then-unvested equity awards immediately vest and become fully exercisable or non-forfeitable without regard to any performance-based requirements, but only so long as any applicable corporate performance goals are achieved;
- the post-termination exercise period attributable to any stock options will extend to 12 months from Ms. Macomber's Date of Termination; and
- outplacement services with a nationally recognized provider or executive coaching services for a period of 12 months (the "CFO Coaching Services").

Under the Employment Agreement, if Ms. Macomber's employment is terminated by Legend Biotech without Cause or if Ms. Macomber resigns for Good Reason, in either case within 3 months before or 18 months following the effective date of a Change in Control, then Ms. Macomber would be entitled to the following severance benefits, less applicable tax withholding (the "CFO CIC Severance Benefits," together with the Non-CIC Severance Benefits, the "CFO Severance Benefits"):

- payment of her then-current base salary in accordance with normal payroll procedures for 18 months;
- the CFO Prior Year Bonus if unpaid as of the Date of Termination;
- the CFO Pro Rata Bonus;
- Payment of 1.5 times the CFO Target Amount for the year in which the Date of Termination occurs;
- payment or reimbursement of continued health coverage for Ms. Macomber and her dependents under COBRA for up to 18 months;
- all equity awards held by Ms. Macomber shall be accelerated, such that such then-unvested equity awards immediately vest and become fully exercisable or non-forfeitable as of the Date of Termination without regard to any performance-based requirements;
- if the options are assumed or converted, the post-termination exercise period attributable to any stock option shall be extended to 18 months from the Date of Termination; and
- the CFO Coaching Services.

Payment of the CFO Severance Benefits is subject to Ms. Macomber signing and delivering to us a separation agreement containing a general release of claims in favor of us. Under the employment agreement, if Ms. Macomber's employment is terminated for Cause or Ms. Macomber resigns without Good Reason, Ms. Macomber will not receive any CFO Severance Benefits.

Indemnification Agreements

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 Third Amended and Restated Memorandum and Articles of Association provides 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 each of our directors and executive officers that provide such persons with additional indemnification beyond that provided in our Third Amended and Restated Memorandum and Articles of Association. 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, 2023, options covering 6,366,538 ordinary shares with a weighted-average exercise price of $9.33 per share were outstanding, and 3,394,334 ordinary shares remained available for the future option grants.

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

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

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

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

Restricted Share Unit Incentive Plan 2020 Restricted Shares Plan

On 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, 2023, restricted share units covering 4,948,956 ordinary shares were outstanding, and 3,286,355 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 ten 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 raise or borrow money, to mortgage or charge its undertaking, property assets (present or future) and uncalled capital or any part thereof, and to issue debentures, debenture stock, bonds or other securities whether outright or as collateral 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 Nasdaq 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, Patrick Casey, Li Mao and Tom Heyman, representing six of our ten 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.

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq rules, we comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing 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;
- exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- exemption for the Nasdaq listing rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B. of Form 20-F;
- exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- exemption from the requirements that director nominees are selected, or recommended for selection by our board of directors, either by (1) independent directors constituting a majority of our board of directors' independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

We currently rely on foreign private issuer exemptions to Nasdaq Rules 5605(d) and 5605(e), as currently only two of the three members of each of our compensation committee and nominating and corporate governance committee are independent directors. Additionally, we may in the future rely on additional foreign private issuer exemptions, including exemptions allowing for less than a majority of our board of directors to consist of independent directors, and so fewer board members would be exercising independent judgment and the level of board oversight on the management of our company may decrease as a result.

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 skills they actually possess and the care and diligence 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

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 election and qualification of successor directors at the third annual meeting following election, or until the director's earlier removal, resignation or death. Our directors are divided among the three classes as follows:

- Class I, which consists of Ye Wang, Darren Xiaohui Ji, Ying Huang, and Tomas Heyman, and their term expires at our annual meeting of shareholders in 2024;
- Class II, which consists of Patrick Casey, Yau Wai Man Philip, and Fangliang Zhang and their term expires at our annual meeting of shareholders in 2025; and
- Class III, which consists of Li Zhu, Corazon D. Sanders, and Li Mao and their term expires at our annual meeting of shareholders in 2026.

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, (iv) without special leave of absence from the board of directors, is absent from meetings of the board for three (3) consecutive meetings and the board of directors resolves that his or her office be vacated; (v) is removed from office pursuant to any other provision of the Third Amended and Restated Memorandum and Articles of Association; or (vi) 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 and Management 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 Nasdaq listing rules 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, including those in environmental, social and governance and cybersecurity;
- 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 Nasdaq listing rules.

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 of directors;
- 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 of directors on all matters of corporate governance and on any remedial action to be taken.

Board Diversity

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

Board Diversity Matrix				
Total Number of Directors	10			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	8	0	0
Part II: Number of Directors Who Identify in Any of the Categories Below:				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	2	6	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	0	2	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+	0			
Persons with Disabilities	0			

The information regarding the diversity of our board of directors as of March 31, 2023 is available in our Annual Report on Form 20-F for the year ended December 31, 2022.

D. Employees

As of December 31, 2023, we had approximately 1,800 employees, 161 of whom hold Ph.D. and/or M.D. degrees. Of these approximately 1,800 employees, 305 are engaged in research and development activities and the remainder are engaged in business development, finance, information systems, facilities, human resources, administrative support or other business functions. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. The average number of temporary employees during the most recent financial year was approximately 200.

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,		
	2023	**2022**	**2021**
Function:			
General and administrative	179	175	121
Research and development	305	305	371
Sales and marketing	62	57	60
Others	1,280	850	519
Total	1,826	1,387	1,071
Geography:			
United States	1,016	739	475
Asia-Pacific	544	563	582
Europe	266	85	14
Total	1,826	1,387	1,071

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.”

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

None.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

We had 363,822,069 ordinary shares outstanding as of December 31, 2023. Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2023:

- 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, 2023, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Number of ordinary shares beneficially owned	Percentage of Shares Beneficially Owned
5% or Greater Shareholders:		
Genscript Biotech Corporation [1]	174,497,556	47.99 %
AquaPoint L.P[2]	30,300,000	9.2 %
Entities affiliated with FMR LLC[3]	25,595,988	7.0 %
Entities affiliated with BlackRock, Inc.[4]	21,064,752	5.8 %
T. Rowe Price Associates, Inc. [5]	21,616,432	5.9 %
Executive Officers and Directors:		
Ying Huang, Ph.D.[6]	191,516	*
Lori Macomber, M.S.[7]	11,258	*
Fangliang Zhang, Ph.D.[8]	1,067,386	*
Ye (Sally) Wang, M.S. [9][2]	16	*
Darren Xiaohui Ji, M.D., Ph.D. [10]	18,427	*
Corazon D. Sanders, Ph.D [11]	28,885	*
Yau Wai Man Philip, CPA [12]	3,756	*
Li Zhu, Ph.D	—	*
Patrick Casey, Ph.D [13]	25,334	*
Li Mao, MD	6,934	*
Tomas Heyman	4,070	*
All Current Executive Officers and Directors as a Group (11 persons)	1,357,582	*

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

1. This information is based solely on a Schedule 13G/A filed with the SEC on February 14, 2024 by GenScript Biotech Corporation reporting its beneficial ownership as of December 31, 2023. The Schedule 13G/A reports that these holdings consist of (i) 169,680,000 ordinary shares held by GenScript before our initial public offering completed in June 2020, (ii) 1,043,478 ordinary shares issued to GenScript in a private placement transaction that closed concurrently with our initial public offering, which was reduced by 725,922 ordinary shares that were distributed by GenScript to its shareholders in connection with our initial public offering to effect an assured entitlement distribution pursuant to the rules of the Hong Kong Stock Exchange and (iii) 2,250,000 American Depositary Shares that were purchased in connection with our follow-on offering

completed in December 2021. The address for Genscript is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.

2. This information is based solely on a Schedule 13G/A filed with the SEC on February 14, 2023 by AquaPoint L.P. reporting its beneficial ownership as of December 31, 2022. The Schedule 13G/A reports that these holdings consist of 30,300,000 ordinary shares held by AquaPoint L.P. (in official liquidation) ("AquaPoint"). Pursuant to an order and judgment of the Financial Services Division of the Grand Court of the Cayman Islands (the "Court"), case number FSD 157 of 2021 (DDJ) *In the Matter of AquaPoint L.P.* (the "AquaPoint Judgment"), AquaPoint was ordered to be wound up and joint official liquidators were appointed by the Court over AquaPoint. The winding up of AquaPoint was subsequently upheld on appeal. Accordingly, pending the completion of the liquidation, all voting and dispositive power with respect to the 30,300,000 ordinary shares for which AquaPoint is the registered owner is held by the joint official liquidators pursuant to the AquaPoint Judgment. The address for AquaPoint is c/o The R&H Trust Co. Ltd., P.O. Box 897, Windward 1, Regatta Office Park, West Bay Road, Grand Cayman, KY1-1103, Cayman Islands.

3. This information is based solely on a Schedule 13G/A filed with the SEC on February 9, 2024 by FMR LLC and Abigail P. Johnson, reporting the beneficial ownership of FMR LLC and certain of its subsidiaries and affiliates including FIAM LLC, IA, Fidelity Institutional Asset Management Trust Company BK, Fidelity Management & Research (Japan) Limited IA, Fidelity Management & Research Company LLC * IA, Fidelity management Trust Company BK and Strategic Advisors LLC IA (together, the "FMR Reporters") as of December 29, 2023. The Schedule 13G reports that the FMR LLC has the sole voting and dispositive power with respect to the 25,582,794 ordinary shares. The address for the FMR Reporters is 245 Summer Street, Boston, Massachusetts 02210. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC.

4. This information is based solely on a Schedule 13G filed with the SEC on January 29, 2024 by BlackRock, Inc. reporting that BlackRock, Inc. has sold voting power over 9,892,358 ADS (the equivalent of 19,784,716 ordinary shares) and sole dispositive power over 10,532,376 ADS (the equivalent of 21,064,752 ordinary shares). The principal business office of BlackRock, Inc. is 50 Hudson Yards, New York, New York 10001.

5. This information is based solely on a Schedule 13G filed with the SEC on February 14, 2024 by T. Rowe Price Associates, Inc. reporting that T. Rowe Price Associates, Inc. has sole voting power over 5,179,343 ADS (the equivalent of 10,358,686 ordinary shares) and sole dispositive power over 10,808,216 ADS (the equivalent of 21,616,432 ordinary shares). The principal business office of T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, MD 21202.

6. Consists of 64,246 ADSs (the equivalent of 128,492 ordinary shares) directly held by Dr. Huang. Also includes options to acquire 31,512 ADSs (the equivalent of 63,024 ordinary shares) exercisable as of March 1, 2023, over which Dr. Huang has dispositive power but not voting power.

7. Consists of 5,629 ADSs (the equivalent of 11,258 ordinary shares) directly held by Ms. Macomber. Consists of 1,067,386 ordinary shares as of January 31, 2023 over which Dr. Zhang has voting power pursuant to an irrevocable proxy, which became effective upon the exercise of the stock options pursuant to which such ordinary shares were issued and terminates with respect to any such ordinary shares sold by their registered owner in a public market sale. 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 ordinary shares held by Genscript Biotech Corporation. Excludes 30,300,000 ordinary shares for which AquaPoint is the registered owner (the "AquaPoint Shares"). Pending the completion of AquaPoint's liquidation, all voting and dispositive power with respect to the AquaPoint Shares is held by the joint official liquidators pursuant to the AquaPoint Judgment. Upon completion of the liquidation, Dr. Zhang will not beneficially own the AquaPoint Shares. See note 2.

8. Through a family trust, Ms. Wang and her family hold 32.98% 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 AquaPoint Shares. Pending the completion of AquaPoint L.P.'s liquidation, all voting and dispositive power with respect to the AquaPoint Shares is held by the joint official liquidators pursuant to the AquaPoint Judgment. See note 2.

9. Consists of 9,213.5 ADSs (the equivalent of 18,427 ordinary shares) directly held by Dr. Ji.

10. Consists of 14,442.5 ADSs (the equivalent of 19,376 ordinary shares) directly held by Dr. Sanders.

11. Consists of 1,878 ADSs (the equivalent of 3,756 ordinary shares) directly held by Mr. Yau.

12. Consists of 12,667 ADSs (the equivalent of 25,334 ordinary shares) directly held by Dr. Casey.

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

As of December 31, 2023, we estimate that 159,779,270 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held in the United States by three holders of record, which represents in the aggregate 43.8% of our outstanding ordinary shares as of December 31, 2023. 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 or been a participant in since January 1, 2023, 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 Largest Shareholder Genscript

Genscript is our largest shareholder, owning approximately 48% of our outstanding ordinary shares as of December 31, 2023. 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.

Master Products, Services and Related Agreements

Master Products and Services Agreement

On October 1, 2022, Legend Biotech USA Inc. entered into a Master Products and Services Agreement with Genscript USA Inc., a subsidiary of Genscript (the "Master Products and Services Agreement"). All materials and services that we (including any of our subsidiaries) purchase from Genscript (and any of its affiliates, other than Legend Biotech and our subsidiaries) in the ordinary course of business (including any such services or materials that were otherwise purchased pursuant to other agreements between Legend Biotech and Genscript), are within the scope of, and subject to the Master Products and Services Agreement. Such services and materials include (i) services relating to gene synthesis, plasmid preparation, oligo synthesis, peptides, protein expression, reagent antibodies, GMP plasmid and viral vectors, biology discovery and development and other customized services and (ii) materials related to protein detection and cell isolation and activation. The parties may contract for additional products and services under separate statements of work under the Master Products and Services Agreement. During 2023, we incurred expenses of approximately $2.7 million under this agreement. The Master Products and Services Agreement had an initial term of one year, was automatically extended for an additional year, and will automatically extend for one additional year unless earlier terminated by either party. Under the agreement, aggregate purchases by Legend Biotech are capped at $7.3 million per calendar year.

Probio Exclusive License Agreement

We entered into the Exclusive License Agreement dated as of August 18, 2021 with Nanjing Probio Biotech Co., Ltd ("Probio"), a related party controlled by Genscript, pursuant to which we granted to Probio and its affiliates an exclusive license under specified patents and related know-how in exchange for Probio's payment to us of $1.5 million and its agreement to provide, within two years of the date of the agreement, $1.5 million in the form of CDMO services to us. Under this agreement, Probio is responsible for paying us a 10.0% royalty on any revenue generated by Probio as a result of Probio's sublicense of such specified patents and related know-how to third parties. During 2023, we recognized revenue of approximately $167,000 for royalties pursuant to this agreement.

Government Affairs Service Agreement

In January 2020, Legend Nanjing and entered into a Government Affairs Services Framework Agreement with Genscript Nanjing pursuant to which Genscript performed services relating to the establishment and maintenance of relationships with government agencies and institutions, government grant application, and assistance, advice, and support services with respect to centrally operated government affairs. The agreement has a scheduled expiration date of December 2025. During 2023, we incurred expenses of approximately $209,000 under this agreement.

Pay-on-behalf-of Services Agreement

In January 2020, Legend Nanjing entered into a Pay-on-behalf-of Agreement with Genscript Nanjing, pursuant to which Legend reimburses Genscript for payments Genscript makes on Legend's behalf to certain vendors who provide services to both Legend Biotech and Genscript. These services include domestic shipping, engineering maintenance, software licenses, electricity and waste expense, IT services, postal service, HR training, security, cafeteria services and other related services. The agreement has a scheduled expiration date of December 2025. During 2023, we incurred expenses of approximately $1.21 million under this agreement.

Facilities

Piscataway - Legend Biotech USA Inc., as tenant, was party to a lease agreement with Genscript USA Holdings, Inc. ("Genscript USA"), effective January 1, 2022, for an approximately 22,000 square foot facility in Piscataway, New Jersey. This lease agreement expired on December 31, 2023. Legend continues to occupy the leased premises in Piscataway on a month-to-month basis under the same terms of the recently expired lease agreement, and is currently negotiating a new lease with Genscript USA. Under the expired lease agreement, we agreed to pay $36,919 per month for rent during 2023. In addition, we agreed to pay Genscript USA $19,309 per month during 2023 for common area maintenance expenses, including allocations for (i) real estate taxes against the building and surrounding area, (ii) casualty and liability insurance, (iii) cleaning, landscaping, snow removal and similar expenses. There is an annual reconciliation of these payments against actual common area maintenance expenses, with any additional payment required by Legend Biotech capped at 20% of these scheduled payments. During 2023, we incurred expenses of approximately $832,000 under this lease agreement, which includes payments for rent, common area maintenance expenses, and utilities.

Animal Facility Lease and Services Agreements - We are party to an animal facility lease agreement with Genscript Nanjing, under which we lease a 1,000 square meter animal facility in Nanjing, China, at a cost of approximately RMB 51,000 per month ($7,234 per month, based on the conversion rate of RMB 7.05 to $1.00, which was the exchange rate on December 31, 2023) (value-added tax included). The lease expires in June 2025. In addition, we entered into an Animal Technical Service Agreement with Genscript Nanjing during April 2021, which we renewed in January 2022, pursuant to which Genscript Nanjing provides facility operation, animal procurement, quarantine, animal feeding and care, and animal testing compliance services to us. During 2023, we incurred expenses of approximately $994,000 under this Animal Technical Service Agreement, which has a scheduled expiration date of December 31, 2024.

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

ROFR and Co-Sale Agreement

In March 2020 and April 2020, we issued and sold an aggregate of 20,591,629 Series A Preference Shares to new investors at a price of $7.792 per share, resulting in aggregate gross proceeds of $160.5 million. In connection with the sale of the Series A Preference Shares, we entered into a Right of First Refusal and Co-Sale Agreement on March 30, 2020 with

Genscript, AquaPoint L.P. and the new investors. Under the 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 and Restricted Stock Unit Grants to Directors and Executive Officers

We have granted share options and restricted stock units to certain of our directors and executive officers. For more information regarding the share options and restricted stock units 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 have entered 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, 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. Our audit committee charter provides that the audit committee shall review and approve or disapprove any related party transactions. 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.

Dividend Policy

Our board of directors has discretion on whether to distribute dividends, subject to the Third 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 Third Amended and Restated Memorandum and Articles of Association, the Companies Act (As Revised) of the Cayman

Islands, which we refer to as the Companies Act (As Revised) 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 (As Revised), insofar as they relate to the material terms of our ordinary shares, please refer to Exhibit 2.4 filed with this Annual Report.

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,” "Item 6. Directors, Senior Management and Employees," “Item 7.B. Related Party Transactions” 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.

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, 2023. 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, 2023, 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 (" 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, taxes withheld on any distributions on ADSs may be eligible for credit against a U.S. Holder's federal income tax liability. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit in their particular circumstances and the possibility of claiming an itemized deduction (in lieu of the foreign tax credit) for any foreign taxes paid or withheld.

Distributions on ADSs that are treated as dividends generally will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation" are eligible for taxation to non-corporate U.S. Holders at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain requirements are met. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on shares that are readily tradable on an established securities market in the United States. Our ADSs will generally be considered to be readily tradable on an established securities market in the United States for so long as they are listed on The Nasdaq Global Select Market. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

Sale, Exchange or Other Disposition of ADSs

Subject to the discussion above under "Item 10.E. Additional Information—Taxation—Passive Foreign Investment Company Consequences," a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of ADSs in an amount equal to the difference, if any, between the amount realized (*i.e.*, the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ADSs. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ADSs were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses

is subject to limitations. Any gain or loss recognized from the sale or other disposition of ADSs will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. If you are a U.S. Holder that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your ownership and disposition of ADSs.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Item 10.E. Additional Information—Taxation—Passive Foreign Investment Company Consequences," each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than $100,000 for ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting. In addition to these requirements, U.S. holders may be required to annually file FinCEN Report 114 (Report of Foreign Bank and Financial Accounts) with the U.S. Department of Treasury. U.S. holders are thus encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of the ADSs.

Dividends on and proceeds from the sale or other disposition of ADSs may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate United States taxpayer identification number or otherwise establish a basis for exemption (usually on IRS Form W-9), or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSS IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

PRC Taxation

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

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

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident enterprise holders of our ordinary shares or ADSs may be treated as income derived from sources within China and therefore, subject to a 10% withholding tax (or 20% in the case of non-resident individual holders) unless an applicable income tax treaty provides otherwise. In addition, capital gains realized by non-resident enterprise shareholders (including our ADS holders) upon the disposition of our ordinary shares or ADSs may be treated as income derived from sources within PRC and therefore, subject to 10% income tax (or 20% in the case of non-resident individual shareholders or ADS holders) unless an applicable income tax treaty provides otherwise. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. See Item 3.D. "Risk Factors—Risks Related to Doing Business in China—If we are classified as a "resident enterprise" of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected."

F. Dividends and Paying Agents

Not Applicable.

G. Statement by Experts

Not Applicable.

H. Documents on Display

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

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

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

With respect to references made in this Annual Report to any contract or other document of Legend Biotech, such references are not necessarily complete and you should refer to the exhibits incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary Information

Not Applicable.

J. Annual Report to Security Holders

We intend to submit any annual report provided to security holders in electronic format as an exhibit to a report on Form 6-K.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash is held in readily available operating accounts and short to medium term deposits and securities. These securities are principal secured and not adversely impacted by interest rate fluctuations. As a result, a change in market interest rates would not have any significant impact on our cash balance.

The interest rate pursuant to our collaboration and license agreement with Janssen, has transitioned in accordance with the LIBOR Act. Thus, outstanding advances accrue interest at 12 month CME term SOFR plus LIBOR/SOFR adjustment (12 month) plus a margin of 2.5%. Accordingly, changes in SOFR could result in fluctuations in our cash flow. For example, based on the $250.0 million aggregate principal amount of advances outstanding from Janssen as of December 31, 2023, a 0.5% (fifty basis point) per annum increase in SOFR would result in an additional $1.3 million per year in interest payable by the Company.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2023 and 2022.

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. (" JPMorgan"), as depositary for our ADSs, registers and delivers the ADSs. Each ADS represents an ownership interest in a designated number of shares which we deposit with the custodian, as agent of the depositary. Each ADS represents two ordinary shares. The ADS to share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

A deposit agreement among ourselves, the depositary, yourself as an ADR holder and all other ADR holders, and all beneficial owners of an interest in the ADSs evidenced by ADRs from time to time sets out the ADR holder rights as well as rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Payments from the Depositary to Us

Our depositary has agreed to share with us certain fees payable to the depositary by holders of ADSs. We anticipate that the fees shared with us by the depositary, after deduction of applicable U.S. taxes, will be approximately $0.4 million.

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a share dividend or share 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 share dividend or share split declared by us or an exchange of share regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of $0.05 or less per ADS held for any cash distribution made, or for any elective cash/share dividend offered, pursuant to the deposit agreement;
- an aggregate fee of $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;
- share 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. (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 a foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosure" page (or successor page) of www.adr.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, holders or

beneficial owners. The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.

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

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

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

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

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

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

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not Applicable.

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

A. Not Applicable.

B. Not Applicable.

C. Not Applicable.

D. Not Applicable.

E. Not Applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer 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, as required by Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our management has concluded that, as of December 31, 2023, 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 and Chief Financial Officer, to allow timely decisions regarding required disclosure.

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

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management, with the participation of the Chief Executive Officer and the Chief Financial Officer has assessed the effectiveness of internal control over financial reporting as of December 31, 2023. Management's assessment was based on the framework in "Internal Control – Integrated Framework (2013)" ("2013 framework"), issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Based on that assessment, management concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

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

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, independent registered public accounting firm, as stated in their report on the Company's internal control over financial reporting as of December 31, 2023, which is included herein. See paragraph (c) of the present Item 15, below.

C. Attestation Report of Independent Registered Public Accounting Firm

See report of Ernst & Young LLP, independent registered public accounting firm, included under “Item 18. Financial Statements” on page F-4.

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 Weaknesses

In connection with the audits of our consolidated financial statements as of and for the years ended December 31, 2022 and 2021, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting where we:

- lacked adequate review and monitoring of controls over complex agreements, specifically, the Janssen Agreement, and our disclosure controls and procedures were not effective, (the "2021 Material Weakness") and

- lacked adequate information technology general controls ("ITGCs") in the area of privileged and regular user access and change management over key information technology ("IT") systems that support our financial reporting processes and as a result, the related process-level IT dependent controls and application controls were also ineffective, (the "2022 Material Weakness")

In response to the 2021 Material Weakness, we implemented the following:

- additional responsive review and monitoring controls for complex agreements, including the Janssen Agreement, which includes additional review by the Chief Financial Officer and other senior finance staff over critical accounting judgements and estimates, reporting and disclosures

- expanded the capabilities of existing financial reporting personnel through specific continuous training and education in the application of IFRS standards, with a focus on complex agreements, including the Janssen Agreement

- hired additional financial reporting & technical accounting personnel as well as a Corporate Controller with relevant and appropriate IFRS accounting experience, including complex agreements. We also engaged additional external resources to aid and supplement our internal resources in executing this remediation plan.

In response to the 2022 Material Weakness, we implemented the following:

- we initially deployed in February 2023 a governance, risk and compliance tool ("GRC tool"), which automated previously manual processes within our ITGC environment. The GRC tool facilitates a more robust, timely, and precise execution of ITGCs, with a particular emphasis over privileged and regular user access and change management controls over key IT systems that support our financial reporting processes. This GRC tool was fully implemented and operating effectively as of fiscal year ended December 31, 2023.

- strengthened our IT governance, risk, and compliance oversight by adding additional personnel in in that function.

- developed and implemented additional training and awareness programs addressing ITGCs and policies, including educating control owners concerning the principles and requirements of each control, with a focus on user access

- strengthened the ITGC review processes, including user access reviews, by adding enhanced guidance on executing ITGCs and adding additional reviews

As of December 31, 2023, based on the 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, 2023, 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.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Philip Wai Man Yau, 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 as defined in Item 16A(b) of Form 20-F.

ITEM 16B. CODE OF ETHICS

We adopted a Code of Business Conduct and Ethics that is applicable to the directors, officers and employees of Legend Biotech and our subsidiaries and affiliates, in accordance with applicable federal securities laws and Nasdaq rules. Our Code of Business Conduct and Ethics is available on our website at *https://legendbiotech.com/compliance*. 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.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Ernst & Young LLP has served as our independent auditor since May 2022 and has audited our consolidated financial statements for the years ended December 31, 2022 and December 31, 2023. The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by Ernst & Young LLP for the periods indicated. We did not pay any other fees to Ernst & Young LLP during the periods indicated below.

	For the Years Ended December 31, US$'000	
	2023	2022
Audit Fees[1]	3,478	4,509
Audit-related Fees[2]	—	—
Total	3,478	4,509

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 LLP 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."

Audit Committee Pre-approved Policies and Procedures

Currently, all audit services and permissible non-audit services to be provided by our independent registered public accountant, Ernst & Young LLP, must be approved by our audit committee, other than those for de minimis services which are approved by the audit committee prior to the completion of the audit, in accordance with paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X. All of the services related to us provided by Ernst & Young LLP during the year ended December 31, 2023 were pre-approved by the audit committee.

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 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 listing rules. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing 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;
- exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- exemption for the Nasdaq listing rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B. of Form 20-F;
- exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- Exemption from the requirements that director nominees are selected, or recommended for selection by our board of directors, either by (1) independent directors constituting a majority of our board of directors' independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

We currently rely on foreign private issuer exemptions to Nasdaq Rules 5605(d) and 5605(e), as currently only two of the three members of each of our compensation committee and nominating and corporate governance committee are independent directors. Additionally, we may in the future rely on additional foreign private issuer exemptions, including exemptions allowing for less than a majority of our board of directors to consist of independent directors, and so fewer board members would be exercising independent judgment and the level of board oversight on the management of our company may decrease as a result. The foreign private issuer exemptions do not modify the independence requirements for the audit committee.

ITEM 16H. MINE SAFETY DISCLOSURE

Not Applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

ITEM 16J. INSIDER TRADING POLICIES

Not Applicable.

ITEM 16K. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and trade secrets, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information ("Information Systems and Data").

Our security management and legal departments work with the information security function within the Company and third-party service providers to help identify, assess and manage the Company's cybersecurity threats and risks. Our information security function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, manual and automated tools, internal or external audits, subscribing to and analyzing reports and intelligence feeds that identify cybersecurity threats and threat actors, conducting third party threat assessments, evaluating our and our industry's risk profile, conducting vulnerability assessments to identify vulnerabilities, conducting scans of the threat environment, dark web monitoring, scans for cyber insurance purposes, coordinating with law enforcement concerning threats, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response (including through an incident response plan), data encryption, network security controls, a vendor risk management program, access controls, system monitoring, penetration testing, an employee focused on cybersecurity, employee training, policies to address cyber issues (including a Cybersecurity Policy, an Acceptable Use Policy, and a Data Governance Policy, risk assessments, cyber insurance, and physical security mechanisms.

The information security function works with senior management to evaluate material risks from cybersecurity threats against our overall business objectives and prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms (including legal counsel), threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, pen testing firms, and dark web monitoring services.

We also use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, management consultants, transportation services, insurance and benefits providers, distributors, and supply chain resources. We manage cybersecurity risks associated with our use of these providers by reviewing their security assessments and questionnaires, analyzing vulnerability scans related to the vendor, conducting security assessment calls with the vendor's security personnel, imposing information contractual obligations on the vendor, and reviewing their written security program and applicable reports.

Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may also involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under "Item 3D – Risk Factors – Risks Related to Our Business Operations", including "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, expose us to regulatory investigations, give rise to significant liability, subject us to costly and protracted litigation, cause significant reputational harm and interfere with our ability to operate our business effectively," and "We are or may become subject to a variety of stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security, and our failure or failure of our third-party vendors, collaborators, contractors or consultants to comply with existing or future laws and regulations related to privacy

or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, disruptions of our business operations, reputational harm, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs, could limit their use or adoption, and could otherwise negatively affect our operating results and business".

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors of the Company has primary responsibility for overseeing the Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including (1) our Senior Director of Information Security, who has over 20 years of experience leading a variety of functions, including cybersecurity, security governance, risk and compliance, and security audit, holds degrees and certifications, including MBA, CISA, CFE, and CDPSE, and is our Security Officer; (2) our Assistant Director, Cybersecurity Cloud Architect, who is responsible for a variety of functions, including identity and access management and information assurance governance and who has over 20 years of experience in cybersecurity, hold certifications in ISSAP, CEHv11, CISSP, CCSP, CMMC; and (3) our Network Security Engineer, who runs our Security Operations Center (SOC) and has over 15 years of experience in network security and incident response.

Our information security function is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our CFO is responsible for approving budgets, our information security function, and prepares for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our response process to cybersecurity incidents is designed to escalate certain incidents to members of management depending on the circumstances, including our CEO and CFO. In the event of a cybersecurity incident, our CEO and CFO and others would work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the board of directors committee responsible for certain cybersecurity incidents.

The audit committee receives periodic reports from our information security function (including our Chairman of the Board of Directors and Head of IT) concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

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.

ITEM 19. EXHIBITS

Exhibit Index
(Incorporated by Reference)

	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*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act
2.5***	Subscription Agreement, dated as of May 13, 2021, by and between LGN Holdings Limited and the Registrant (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-3 (File No. 333-257625), filed with the SEC on July 2, 2021)
2.6***	Subscription Agreement, dated as of April 19, 2023, by and between Legend Biotech Corporation and RA Capital Healthcare Fund, L.P. (incorporated herein by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form F-3 (File No. 333-272222), filed with the SEC on May 26, 2023)
2.7***	Form of Securities Purchase Agreement, dated as of May 5, 2023, between Legend Biotech Corporation, T. Rowe Price Associates, Inc., and Purchasers (incorporated herein by reference to Exhibit 4.1 to the Registrant's Report on Form 6-K (File No. 001-39307), filed with the SEC on May 8, 2023
2.8***	Subscription Agreement, dated April 26, 2023, by and between Legend Biotech Corporation and LGN Holdings Limited (incorporated herein by reference to Exhibit 4.6 to the Registrant's registration Statement on Form F-3 (File No. 333-272222), filed with the SEC on May 26, 2023)
2.9***	Subscription Agreement, dated May 19, 2023, by and between Legend Biotech Corporation and LGN Holdings Limited (incorporated herein by reference to Exhibit 4.7 to the Registrant's registration Statement on Form F-3 (File No. 333-272222), filed with the SEC on May 26, 2023)

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+***	Amended and Restated Employment Agreement, by and among the Registrant, Legend Biotech USA Inc. and Ying Huang, effective August 3, 2022 (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 August 4, 2022
4.4+*	First Amendment to Amended and Restated Employment Agreement by and among the Registrant, Legend Biotech USA Inc. and Ying Huang, effective December 14, 2023
4.5+***	Amended and Restated Employment Agreement, by and among Registrant, Legend Biotech USA Inc and Lori Macomber, effective September 28, 2022 (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 October 3, 2022
4.6+*	First Amendment to Amended and Restated Employment Agreement, by and among the Registrant, Legend Biotech USA Inc., and Lori Macomber, effective December 14, 2023
4.7+***	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)
4.8***	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)
4.9+***	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)
4.10***^	Interim Product Supply Agreement, dated as of February 28, 2022, between Legend Biotech USA Inc. and Janssen Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.7 to the Registrant's Form 20-F (File No. 001-39307), filed with the SEC on March 31, 2022)
4.11*	Non-Employee Director Compensation Policy .
4.12***^	Amendment No. 1 to Interim Product Supply Agreement, dated as of July 7, 2022, between Legend Biotech USA Inc. and Janssen Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 99.1 to the Registrant's Report on Form 6-K (File No. 001-39307), filed with the SEC on July 13, 2022)
4.13***	Amendment No. 2 to Interim Product Supply Agreement, dated as of October 17, 2022, between Legend Biotech USA Inc. and Janssen Pharmaceuticals, Inc. (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 November 22, 2022)
4.14***	Amendment No. 3 to Interim Product Supply Agreement, dated as of November 16, 2022, between Legend Biotech USA Inc. and Janssen Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K (File No. 001-39307), filed with the SEC on November 22, 2022)

4.15***^	Amendment No. 1 to Collaboration and License Agreement, dated as of February 26, 2018 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc. (incorporated herein by referenced to Exhibit 4.12 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023.
4.16***	Amendment No. 3 to Collaboration and License Agreement, dated December 10, 2018 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc. (incorporated herein by referenced to Exhibit 4.13 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023)
4.17***^	Amendment No. 5 to Collaboration and License Agreement, dated November 30, 2020 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc. (incorporated herein by referenced to Exhibit 4.14 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023)
4.18***^	Amendment No. 6 to Collaboration and License Agreement, dated December 7, 2020 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited and Janssen Biotech, Inc. (incorporated herein by referenced to Exhibit 4.15 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023)
4.19***^	Amendment No. 7 to Collaboration and License Agreement, dated July 26, 2021 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited, Janssen Biotech, Inc. and Janssen Pharmaceutica NV (incorporated herein by referenced to Exhibit 4.16 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023).
4.20***^	Amendment No. 8 to Collaboration and License Agreement, dated November 11, 2021 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited, Janssen Biotech, Inc. and Janssen Pharmaceutica NV (incorporated herein by referenced to Exhibit 4.17 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023).
4.21***^	Amendment No. 9 to Collaboration and License Agreement, dated July 7, 2022 between and among Legend Biotech USA Inc., Legend Biotech Ireland Limited, Janssen Biotech, Inc., and Janssen Pharmaceutica NV (incorporated herein by referenced to Exhibit 4.18 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023)
4.22***^	Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product, dated April 12, 2023, between and among Janssen Research & Development, LLC, Legend Biotech USA Inc., and Novartis Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 99.1 to the Registrant's Report on Form 6-K (File No. 001.39307), filed with the SEC on April 14, 2023)
4.23*#	Amendment No. 1 to Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product, dated December 13, 2023, between and among Janssen Research & Development, LLC, Legend Biotech USA Inc., and Novartis Pharmaceuticals Corporation
4.24*^	License Agreement, dated November 10, 2023, between Legend Biotech Ireland Limited and Novartis Pharma AG
4.25+*	Incentive Compensation Recoupment Policy
4.26*^	Amendment No. 2 to Master Technology Transfer, Manufacturing and Clinical Supply Services Agreement for BCMA CAR-T Product, dated March 15, 2024, between and among Janssen Research & Development, LLC, Legend Biotech USA Inc., and Novartis Pharmaceuticals Corporation
8.1***	List of Principal Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 8.1 to the Registrant's Annual Report on Form 20-F (File No. 001-39307), filed with the SEC on March 30, 2023).
11.1*	Code of Business Conduct and Ethics of the Registrant

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 LLP, an independent registered public accounting firm.
15.2*	Consent of Ernst & Young Hua Ming LLP, an independent registered public accounting firm.
101*	The following materials from Legend Biotech Corp.'s Report on Form 20.F formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) the Consolidated Statements of Profit or Loss and Other Comprehensive Income, (ii) the Consolidated Statements of Financial Position, (iii) the Consolidated Statements of Changes in Equity, (iv) the Consolidated Statements of Cash Flows, (v) Notes to the Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed with this Annual Report on Form 20-F.
** Furnished with this Annual Report on Form 20-F.
***Previously filed.
+ Indicates management contract or compensatory plan
^ Certain portions of this exhibit have been redacted because they are both not material and is the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, an unredacted copy of this exhibit.
# Pursuant to Item 601(a)(5) of Regulation S-K promulgated by the Securities and Exchange Commission, certain exhibits and schedules to this agreement have been omitted. The Company hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, any or all of such omitted exhibits or schedules.

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 its behalf.

Legend Biotech Corporation

/s/ Ying Huang

Name: Ying Huang

Title: Chief Executive Officer

Date: March 19, 2024

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 statement of financial position of Legend Biotech Corporation (the Company) as of December 31, 2023 and 2022, the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 19, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Collaboration and license agreement with Janssen Biotech, Inc.

Description of the matter

As discussed in Note 2 to the consolidated financial statements, the Company entered into a collaboration and license agreement (“collaboration agreement”) with Janssen Biotech, Inc. ("Janssen"). Under the collaboration agreement, the Company granted Janssen a worldwide, co-exclusive (with the Company) license to develop and commercialize cilta-cel. The Company and Janssen share equally revenue, expenses and profits of CARVYKTI in all areas other than the People's Republic of China.

Auditing the Company’s accounting for the collaboration agreement was challenging because the agreement is complex, and the Company exercised significant judgment in applying the existing accounting standards to the collaboration agreement, including as they relate to collaboration revenue, collaboration cost of revenue, collaboration inventories, and leases of collaboration assets.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over management’s review of the authoritative guidance applicable to the collaboration agreement and related accounting treatment for collaboration revenue, collaboration cost of revenue, collaboration inventories, and leases of collaboration assets. Our audit procedures to test the Company’s application of the authoritative guidance to the collaboration agreement included, among others, reading the contractual agreement and amendments, testing the completeness of management’s identified significant terms and assessing the terms of the agreement and amendments for relevant accounting implications, including the identification of the customer. We also evaluated the appropriateness of management’s selection and application of the authoritative guidance and the determination and consistency of its accounting policies, and we compared amounts recorded for consistency with the Company’s accounting policies and underlying documentation.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2022.

Iselin, New Jersey
March 19, 2024

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Legend Biotech Corporation's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Legend Biotech Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the accompanying consolidated statement of financial position of the Company as of December 31, 2023, the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the year ended December 31, 2023, and the related notes and our report dated March 19, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Iselin, New Jersey
March 19, 2024

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 profit or loss and other comprehensive income, changes in equity and cash flows of Legend Biotech Corporation (the "Company") for the year ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of its operations and its cash flows for the year ended December 31, 2021, 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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young Hua Ming LLP

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

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

	Notes	2023	2022	2021
		US$'000, except per share data	US$'000, except per share data	US$'000, except per share data
REVENUE	5			
License revenue		35,160	50,000	65,402
Collaboration revenue		249,804	66,677	—
Other revenue		179	328	3,424
Total revenue		285,143	117,005	68,826
Collaboration cost of revenue		(144,214)	(65,363)	—
Other income and gains	5	58,126	12,049	3,059
Research and development expenses		(382,218)	(335,648)	(313,346)
Administrative expenses		(106,769)	(80,631)	(46,961)
Selling and distribution expenses		(94,158)	(93,417)	(102,542)
Other expenses		(28,484)	(9,823)	(9,132)
Fair value (loss)/gain of warrant liability		(85,750)	20,900	(6,200)
Finance costs	7	(21,794)	(10,796)	(900)
LOSS BEFORE TAX	6	(520,118)	(445,724)	(407,196)
Income tax benefit/(expense)	8	1,864	(625)	3,614
LOSS FOR THE YEAR		(518,254)	(446,349)	(403,582)
Attributable to:				
Ordinary equity holders of the parent		(518,254)	(446,349)	(403,582)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	9			
Basic		(1.47)	(1.40)	(1.43)
Diluted		(1.47)	(1.40)	(1.43)
OTHER COMPREHENSIVE INCOME				
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:				
Exchange differences:				
Exchange differences on translation of foreign operations		29,633	9,807	5,215
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		29,633	9,807	5,215
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX		29,633	9,807	5,215
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(488,621)	(436,542)	(398,367)
Attributable to:				
Ordinary equity holders of the parent		(488,621)	(436,542)	(398,367)

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
AS AT DECEMBER 31, 2023 AND 2022

	Notes	December 31, 2023	December 31, 2022
		US$'000	US$'000
NON-CURRENT ASSETS			
Property, plant and equipment	10	108,725	105,168
Advance payments for property, plant and equipment		451	914
Right-of-use assets	13	80,502	55,590
Time deposits	17	4,362	—
Intangible assets	11	4,061	3,409
Collaboration prepaid leases	13	151,216	65,276
Other non-current assets	12	1,493	1,487
Total non-current assets		350,810	231,844
CURRENT ASSETS			
Collaboration inventories	14	19,433	10,354
Trade receivables	15	100,041	90
Prepayments, other receivables and other assets	16	69,251	61,755
Financial assets at fair value through profit or loss	32	663	185,603
Pledged deposits	17	357	1,270
Time deposits	17	30,341	54,016
Cash and cash equivalents	17	1,277,713	786,031
Total current assets		1,497,799	1,099,119
Total assets		1,848,609	1,330,963
CURRENT LIABILITIES			
Trade payables	18	20,160	32,893
Other payables and accruals	19	132,802	184,109
Government grants	22	68	451
Lease liabilities	13	3,175	3,563
Tax payable		7,203	9,772
Warrant liability	21	—	67,000
Contract liabilities	5	53,010	—
Total current liabilities		216,418	297,788
NON-CURRENT LIABILITIES			
Collaboration interest-bearing advanced funding	23	281,328	260,932
Lease liabilities long term	13	44,169	20,039
Government grants	22	7,305	7,659
Contract liabilities	5	47,962	—
Other non-current liabilities		56	233
Total non-current liabilities		380,820	288,863
Total liabilities		597,238	586,651
EQUITY			
Share capital	24	36	33
Reserves	27	1,251,335	744,279
Total ordinary shareholders' equity		1,251,371	744,312
Total equity		1,251,371	744,312
Total liabilities and equity		1,848,609	1,330,963

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

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	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
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
As at January 1, 2021	**27**	**708,306**	**6,314**	**(351)**	**(116,525)**	**597,771**
Loss for the year	—	—	—	—	(403,582)	(403,582)
Other comprehensive loss:						
Exchange differences on translation of foreign operations	—	—	—	5,215	—	5,215
Total comprehensive loss for the year	**—**	**—**	**—**	**5,215**	**(403,582)**	**(398,367)**
Issuance of ordinary shares relating to private placement for an institutional investor	2	218,298	—	—	—	218,300
Issuance of ordinary shares for follow-on public offering, net of issuance costs	2	323,438	—	—	—	323,440
Exercise of share options	—	6,089	(1,447)	—	—	4,642
Reclassification of vested restricted share units	—	5,323	(5,323)	—	—	—
Equity-settled share-based compensation expense	—	—	20,158	—	—	20,158
As at December 31, 2021	**31**	**1,261,454** *	**19,702** *	**4,864** *	**(520,107)** *	**765,944**
Loss for the year	—	—	—	—	(446,349)	**(446,349)**
Other comprehensive loss:						
Exchange differences on translation of foreign operations	—	—	—	9,807	—	9,807
Total comprehensive loss for the year	**—**	**—**	**—**	**9,807**	**(446,349)**	**(436,542)**
Issuance of ordinary shares relating to private placement for an institutional investor	—	—	—	—	—	—
Issuance of ordinary shares for follow-on public offering, net of issuance costs	2	377,641	—	—	—	377,643
Exercise of share options	—	4,070	(1,141)	—	—	2,929
Reclassification of vested restricted share units	—	13,850	(13,850)	—	—	—
Equity-settled share-based compensation expense	—	—	34,338	—	—	34,338
As at December 31, 2022	**33**	**1,657,015** *	**39,049** *	**14,671** *	**(966,456)** *	**744,312**
Loss for the year	**—**	**—**	**—**	**—**	**(518,254)**	**(518,254)**
Other comprehensive loss:						—
Exchange differences on translation of foreign operations	—	—	—	29,633	—	29,633
Total comprehensive loss for the year	**—**	**—**	**—**	**29,633**	**(518,254)**	**(488,621)**
Issuance of ordinary shares relating to private placement for institutional investors, net of issuance costs	1	234,409	—	—	—	234,410
Issuance of ordinary shares relating to registered direct offering, net of issuance costs	1	349,277	—	—	—	349,278
Issuance of ordinary shares relating to the exercise of warrant	1	352,490	—	—	—	352,491
Exercise of share options	—	18,051	(6,230)	—	—	11,821
Reclassification of vested restricted share units	—	25,878	(25,878)	—	—	—
Equity-settled share-based compensation expense	—	—	47,680	—	—	47,680
As at December 31, 2023	**36**	**2,637,120** *	**54,621** *	**44,304** *	**(1,484,710)** *	**1,251,371**

* These reserve accounts comprise the consolidated reserves of US$1,251 million, US$744 million and US$766 million in the consolidated statements of financial position as at December 31, 2023, 2022 and 2021, respectively

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

	Notes	2023	2022	2021
		US$'000	US$'000	US$'000
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss before tax		(520,118)	(445,724)	(407,196)
Adjustments for:				
Finance income	5	(54,487)	(8,182)	(971)
Finance costs	7	21,794	10,796	900
Provision for inventory reserve*		3,627	5,288	—
Depreciation of property, plant and equipment	10	10,704	10,173	8,139
Loss on disposal of property, plant and equipment		226	481	974
Amortization of intangible assets	11	1,924	2,476	1,379
Depreciation of right-of-use assets	13	7,823	5,743	4,399
Fair value loss/(gain) of warrant liability	21	85,750	(20,900)	6,200
Fair value gains on financial assets measured at fair value change through profit or loss	5	(663)	(593)	—
Foreign currency exchange loss/(gain), net		28,224	9,159	4,867
Equity-settled share-based compensation expense		47,680	34,338	20,158
Deferred government grant		(628)	(307)	(295)
		(368,144)	(397,252)	(361,446)
(Increase)/decrease in trade receivables		(98,980)	50,320	24,590
(Increase)/decrease in prepayments, other receivables and other assets		(8,724)	(50,614)	(2,966)
Decrease/(increase) in other non-current assets		753	3,661	(1,175)
(Increase)/decrease in collaboration inventories*		(12,706)	(13,893)	51
Government grant received		23	6,180	80
(Decrease)/increase in trade payables		(12,702)	25,850	1,805
(Decrease)/increase in other payables and accruals		(38,809)	165,883	140,747
Increase/(decrease) in other non-current liabilities		(176)	(163)	(158)
Increase/(decrease) in contract liabilities (current)		52,500	—	—
Increase/(decrease) in contract liabilities (non-current)		47,500	—	—
Increase in pledged deposits, net		—	(15)	(1,060)
Cash used in operations		(439,465)	(210,043)	(199,532)
Income tax paid		(668)	—	—
Interest income received		47,275	5,580	652
Income tax received		976	3,709	557
Interest on lease payments		(1,394)	(527)	(142)
Net cash used in operating activities		(393,276)	(201,281)	(198,465)

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

*2022 increase/decrease in collaboration inventories has been reclassified to break out the provision for inventory reserve for comparative purposes in the 2023 presentation.

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

	Note	2023	2022	2021
		US$'000	US$'000	US$'000
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchase of property, plant and equipment		(20,084)	(20,927)	(42,197)
Purchase of intangible assets		(2,638)	(1,348)	(3,207)
Prepayment to collaborator for collaboration assets		(98,784)	(14,810)	(1,708)
Purchase of financial assets measured at fair value through profit or loss		—	(285,000)	(50,000)
Cash received from withdrawal of financial assets measured at fair value through profit or loss		185,000	99,990	50,081
Cash received from withdrawal of financial assets measured at amortized cost		—	30,000	—
Cash receipts of investment income		8,810	1,252	—
Proceeds from disposal of property, plant and equipment		—	—	4
Addition in time deposits		(4,863,149)	(369,971)	(298,107)
Decrease in time deposits		4,882,724	483,617	180,000
Decrease in pledged deposits		907	105	—
Purchase of financial assets measured at amortized cost		—	—	(29,849)
Net cash provided by/(used in) investing activities		92,786	(77,092)	(194,983)
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from issuance of ordinary shares for institutional investors, net of issuance cost		234,410	—	—
Proceeds from issuance of ordinary shares for follow on public offering, net of issuance costs		349,278	377,643	323,440
Proceeds from exercise of warrant by warrant holder, net of issuance cost		199,741	—	—
Proceeds from issuance of ordinary shares and warrant relating to private placement for an institutional investor		—	—	300,000
Proceeds from exercise of share options		11,816	2,929	4,642
Principal portion of lease payments		(3,755)	(2,596)	(1,419)
Net cash provided by financing activities		791,490	377,976	626,663

LEGEND BIOTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

	Note	2023	2022	2021
		US$'000	US$'000	US$'000
NET INCREASE IN CASH AND CASH EQUIVALENTS		491,000	99,603	233,215
Effect of foreign exchange rate changes, net		682	(2,510)	34
Cash and cash equivalents at beginning of year	17	786,031	688,938	455,689
CASH AND CASH EQUIVALENTS AT END OF YEAR	17	1,277,713	786,031	688,938
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances		1,312,773	841,317	858,607
Less: Pledged deposits		357	1,270	1,444
Time deposits		34,703	54,016	168,225
Cash and cash equivalents as stated in the statement of financial position	17	1,277,713	786,031	688,938
Cash and cash equivalents as stated in the statement of cash flows		1,277,713	786,031	688,938

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

LEGEND BIOTECH CORPORATION
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2023, 2022 AND 2021

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 Act (As Revised) 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.

Legend Biotech Corporation is an investment holding company. The Company's subsidiaries are principally engaged in the discovery, and development, manufacturing and commercialization of novel cell therapies for oncology and other indications.

In the opinion of the Company's Board of Directors, the ultimate holding company of Legend Biotech Corporation, a Cayman Islands corporation, is Genscript Corporation ("Genscript Corp"), which was incorporated in the United States of America.

Information about subsidiaries

Company	Place and date of incorporation	Issued ordinary shares/paid-up capital	Percentage of equity interest attributable to the Company		Principal activities
			Direct %	Indirect %	
Legend Biotech Limited ("Legend BVI")	The British Virgin Islands June 2, 2015	US$2,453,819,239	100	—	Investment holding
Legend Biotech HK Limited ("Legend HK")	Hong Kong June 3, 2015	US$2,453,819,239	—	100	Investment holding
Nanjing Legend Biotechnology Co., Ltd. ("Legend Nanjing")	PRC* November 17, 2014	US$ 212,500,000	—	100	Manufacture and sale of life sciences research products; performance and sale of research and development services
Legend Biotech USA Incorporated ("Legend USA")	Delaware, United States of America August 31, 2017	—	—	100	Manufacture and sale of life sciences products; performance of life sciences research and development
Legend Biotech Ireland Limited ("Legend Ireland")	Ireland November 13, 2017	US$2,217,445,234	—	100	Manufacture and sale of life sciences products; performance of life sciences research and development; treasury center for Legend Biotech
Legend Biotech Belgium B.V. ("Legend Belgium")	Belgium June 23, 2021	US$ 46,177,685	—	100	Manufacture and sale of life sciences products
Hainan Chuanji Biotechnology Co., Ltd. ("Hainan Chuanji")	PRC October 25, 2021	—	—	100	General & administrative

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

2.1 BASIS OF PREPARATION

The consolidated financial statements of Legend Biotech Corporation and its subsidiaries (collectively referred to as "the Company") have been prepared in accordance with International Financial Reporting Standards ("IFRSs") as issued by the International Accounting Standards Board 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 U.S. dollars ("$") and all values are rounded to the nearest thousand except when otherwise indicated.

Certain prior year amounts have been reclassified for comparative purposes. The reclassifications did not affect results of operations, total assets, total liabilities, or cash flows.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company for each of the three years ended December 31, 2023. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Company 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 Company the current ability to direct the relevant activities of the investee).

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 Company 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 Company. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between the Company are eliminated in full on consolidation.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

There were no new IFRS standards, amendments or interpretations that became effective in 2023 that had a material impact on the Company's consolidated financial statements.

2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

There are no new standards issued but not yet effective that are expected to have a significant impact on the Company's consolidated financial statements.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Company measures its financial assets at fair value through profit or loss and warrant liability at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company. 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 Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

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

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

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

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

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

Impairment of non-financial assets

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

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

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

Related parties

A party is considered to be related to the Company 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 Company;

  (ii) has significant influence over the Company; or

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

or

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

  (i) the entity and the Company are members of the same Company;

  (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 Company 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 Company or an entity related to the Company;

(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 Company of which it is a part, provides key management personnel services to the Company or to the parent of the Company.

Property, plant and equipment, and depreciation

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

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

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

Freehold land	Not depreciated
Building	39 to 50 years
Leasehold improvements	lesser of the lease term or the asset life
Machinery and equipment	5 to 15 years
Computer and office equipment	3 to 5 years
Transportation equipment	10 years

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

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss and other comprehensive income in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

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

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The useful lives of intangible assets are assessed to be either finite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

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

Software	3 years
Patents	up to 20 years

Research and development costs

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

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

Leases

The Company 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.

Company as a lessee

The Company applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Company recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets. The Company elected to allocate the consideration in the contract to the lease and non-lease components on the basis of the relative standalone price of each component.

(a) Right-of-use assets

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

Leasehold land	50 years
Building	up to 50 years
Machinery and equipment	5 to 15 years
Computer and office equipment	3 to 5 years

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

(b) Lease liabilities

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

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

(c) Short-term leases

The Company applies the short-term lease recognition exemption to its short-term leases, which are those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option.

Lease payments on short-term leases are recognized as an expense on a straight-line basis over the lease term.

Company as a lessor

When the Company 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 Company 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 term and is included in revenue in the statement of profit or loss and other comprehensive income 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 recognized over the lease term on the same basis as rental income.

Leases of collaboration assets

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

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

If the Company owns the asset, and on the basis of the terms and conditions of the collaboration agreement, there is a lease from the Company to the collaboration, the Company recognizes a finance lease for the asset it leases to the collaboration. In such cases, the Company's share of the asset that is jointly controlled by the collaboration is recorded in property, plant and equipment, and a lease receivable is recognized for the collaboration partner's share of the asset on the consolidated statements of financial position within prepayments, other receivables and other assets.

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

Investments and other financial assets

Initial recognition and measurement

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

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. With the exception of trade receivables that do not

contain a significant financing component or for which the Company has applied the practical expedient of not adjusting the effect of a significant financing component, the Company 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 Company has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for "Revenue recognition" below.

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

The Company's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows.

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

Subsequent measurement

Financial assets measured at amortized cost (debt instruments)

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

Financial assets measured at fair value through profit or loss

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

The Company's financial assets measured at fair value through profit or loss comprise of money market funds, which are classified as level 1 in the fair value hierarchy.

Derecognition of financial assets

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

- the rights to receive cash flows from the asset have expired; or
- the Company 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 Company has transferred substantially all the risks and rewards of the asset, or (b) the Company has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Company 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 Company continues to recognize the transferred asset to the extent of the Company's continuing involvement. In that case, the Company also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Company 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 Company could be required to repay.

Impairment of financial assets

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

General approach

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Company assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Company 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 Company considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Company may also consider a financial asset to be in default when internal or external information indicates that the Company is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Company. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

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

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

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

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

Simplified approach

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

Financial liabilities

Initial recognition and measurement

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

The Company's financial liabilities include trade payables, other payables, warrant liability, collaboration interest-bearing advanced funding, and lease liabilities.

Subsequent measurement

Financial liabilities measured at amortized cost (Loans and borrowings)

After initial recognition, collaboration interest-bearing advanced funding are subsequently measured at amortized cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in the statement of profit or loss and other comprehensive income when the liabilities are derecognized as well as through the effective interest rate amortization process.

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

Collaboration inventories

Collaboration inventories include finished goods manufactured, items in the process of being manufactured, and the materials to be used in the manufacturing process associated with goods that are to be sold to the Company's collaboration partner. Finished goods represent manufactured product that are pending quality release. Upon quality release, the product is delivered to the Company's collaboration partner to distribute to the customer.

Collaboration inventories are stated at the lower of cost and the collaboration inventory's net realizable value. Cost is determined on the first-in, first-out basis and, in the case of work in progress and finished goods, comprises direct materials, direct labor and an appropriate proportion of overheads. Net realizable value is based on the estimated selling prices the collaboration sells the product to customers less any estimated costs to be incurred to completion and disposal.

The Company records provisions for obsolete, slow moving or defective inventory. Collaboration inventory costs for product that is used for preclinical and clinical programs are charged to research and development expenses when the inventory is dedicated to preclinical or clinical use. The Company records within prepayments, other receivables and other assets the accounts receivable related to inventory purchased and delivered to the Company's collaboration partner as well as the amount the Company is entitled to be reimbursed from its collaboration partner for inventory costs incurred that are in process of production.

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 Company’s cash management.

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

Time deposits

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

Provisions

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

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

Income tax

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

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Company operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

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

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

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

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

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

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

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

Government grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss and other comprehensive income over the expected useful life of the relevant asset by equal annual installments.

Collaboration Arrangements

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

For collaboration arrangements that contain multiple elements, at contract inception the Company determines whether elements of the collaboration are reflective of a vendor-customer relationship and therefore are within the scope of IFRS 15. Elements of the collaboration arrangements that involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards of such activities are not arrangements with a customer and are outside the scope of IFRS 15. For a distinct bundle of goods or services within the arrangement that is not with a customer, the recognition and measurement of that unit of account shall be based on other authoritative accounting literature, or if there is no appropriate authoritative accounting literature, a reasonable, rational and consistently applied accounting policy election.

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

Janssen Agreement

In December 2017, the Company entered into a collaboration and license agreement (the “Janssen 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 share development, production and commercialization costs and pre-tax profits or losses equally in all countries of the world except for Greater China, for which the cost-sharing and profit/loss split will be 70% for us and 30% for Janssen

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

In connection with the Janssen Agreement, we entered into the Interim Product Supply Agreement dated as of February 28, 2022 (the “IPSA”) pursuant to which we will supply cilta-cel to Janssen for clinical and commercial use worldwide (excluding Greater China). Under the IPSA, Janssen pays us a transfer price for supplied product based on the total costs necessary to produce and supply such product. Ultimately, however, the cost for commercial supply and clinical supply of product are shared equally by us and Janssen as “Allowable Expenses” and “Development Costs,” respectively, under the Janssen Agreement. The IPSA will remain in effect until June 30, 2024 or such alternate date determined by the joint manufacturing committee (the “JMC”) that has been established under the Janssen Agreement. The IPSA will also terminate if the Janssen Agreement expires or is terminated. We expect to enter into a product supply agreement with Janssen that will replace the IPSA.

Revenue recognition

Revenue from contracts with customers

The Company recognizes revenue in accordance with IFRS 15, *Revenue from Contracts with Customers* (IFRS 15). Under IFRS 15, revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for agreements that we determine are within the scope of IFRS 15, the Company performs the following five-steps: (i) identify the contract, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Once a contract is determined to be within the scope of IFRS 15, at contract inception the Company assesses the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. A good or service that is promised to a customer is distinct if both of the following criteria are met: (a) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (b) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable or a combination of both. When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Company will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved. The contracts generally do not include a significant financing component.

The Company recognizes revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria: (i) the counterparty simultaneously receives and consumes the benefits provided by the Company's performance as the Company performs; or (ii) the Company's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.

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

Contracts may be amended to account for changes in contract specifications and requirements. Contract modifications exist when the amendment either creates new, or changes existing, enforceable rights and obligations. When contract modifications create new performance obligations and the increase in consideration approximates the standalone selling price for goods and services related to such new performance obligations as adjusted for specific facts and circumstances of the contract, the modification is considered to be a separate contract.

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

The Company accounts for a contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. In such case, the effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to

revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (the adjustment to revenue is made on a cumulative catch-up basis).

License and collaboration revenue

Licenses of Intellectual Property

For collaboration arrangements that include a grant of a license to the Company's intellectual property, the Company considers whether the license grant is distinct from the other performance obligations included in the arrangement. In assessing whether a license is distinct from the other promises, the Company 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 Company 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 Company evaluated that the license, including a technology transfer service, is a single performance obligation in the Janssen Agreement, which represents a right to use our license as it exists at the point in time that the license is granted. Revenue from licenses is recognized when the control of the right to use of the license is transferred to the customer. The Company evaluated that the license (inclusive of know-how) and the delivery of the Handover Package Documents which includes performing the Legend Phase 1 trial, is a single performance obligation in the Novartis Licensing Agreement, which represents a right to use our license over time after the license is granted and the Legend Phase 1 trial is ongoing. Revenue from licenses is recognized when the value of the right to use of the license is transferred to the customer which occurs over time during the Phase 1 trial.

Input Method

We use input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We have concluded that revenue associated with the Novartis Licensing Agreement will be recognized over time using the input method as the delivery of the license is not distinct from the Legend Phase 1 trial.

Milestone Payments

Milestone payments represent a form of variable consideration which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is highly probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price.

When the Company cannot conclude that it is highly probable that a significant revenue reversal of cumulative revenue under the contract will not occur, the Company constrains the related variable consideration resulting in its exclusion from the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price.

Royalty Payments

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

(a) the subsequent sale occurs; and

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

Janssen Agreement

The Company entered into a license and collaboration agreement with one customer (Janssen). The terms of the arrangement include: non-refundable upfront fees of $350.0 million and milestone payments for the achievement of specified manufacturing milestones, specified development milestones, specified regulatory milestones and specified net trade sales milestones of $125.0 million, $215.0 million, $800.0 million and $210.0 million, respectively. The Company has assessed that there is one distinct performance obligation, being the transfer of a license of intellectual property, including a technology transfer service. The Company considers this performance obligation is distinct from other collaborative activities as the license has stand-alone value without the Company being further involved in the research and development or other collaborative activities. Upon contract inception, the Company has estimated that the total transaction price is constrained to $400.0 million which included upfront fees of $350.0 million and milestone payments of $50.0 million. The transaction price was allocated to the single performance obligation in the contract.

Novartis Licensing Agreement

The Company entered into a license agreement with Novartis. The terms of the arrangement include: non-refundable upfront fees of $100.0 million and milestone payments for the achievement of specified development milestones and specified net trade sales milestones of up to $330.0 million and $680.0 million, respectively as well as tiered royalties. The Company has assessed that there are two distinct performance obligations. Performance Obligation 1 (PO1); A combined performance obligation that includes delivery of the license (inclusive of know-how) and the delivery of the Handover Package Documents which includes performing the Legend Phase 1 trial. Performance Obligation 2 (PO2); Supply of materials (supply of Lentivirus/other materials). Upon contract inception, the Company has estimated that the total transaction price is constrained to $125.3 million which included upfront fees of $100.0 million and variable consideration of $25.3 million. The transaction price was allocated to the two performance obligations (PO1) $120.7 million and (PO2) $4.6 million, respectively.

Upfront fees

Upfront payment is allocated to the single performance obligation in the Janssen Agreement. The upfront fees of $350.0 million were included in the transaction price upon contract inception in 2017 and were recognized when the single performance obligation to deliver the intellectual property, including a technology transfer service, was completed in 2018. The $350.0 million upfront fees were fully received by the Company in 2018.

Milestone payments

Certain milestone payments were allocated to the single performance obligation in the Janssen Agreement to deliver the license of intellectual property, including the technology transfer service. The initial two milestone payments of aggregate $50.0 million were included in the transaction price at contract inception in 2017 and were recognized when the single performance obligation was completed in 2018. 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 2021, an additional milestone with a payment of $75.0 million was achieved relating to the clinical development of cilta-cel. In 2021, three additional milestone payments amounting to $65.0 million were achieved relating to the submission of a Marketing Authorization to the EMA, enrollment of a specified number of patients in the CARTITUDE-5 clinical trial and filing of a Drug approval application for a product by the Ministry of Health, Labour and Welfare in Japan. In 2022, additional milestone payments of $50.0 million were achieved in connection with the submission of a NDA to the PMDA in Japan, the enrollment of a specified number of patients in the Company's CARTITUDE-5 clinical trial and in connection with the receipt of a commercialization approval for cilta-cel in the U.S. In 2023, two additional milestone payments amounting to $35 million were achieved relating to the

acceptance of a submission of a supplemental BLA to the FDA and the acceptance of a submission of a Type II variation application to the EMA.

As of December 31, 2023, pursuant to the Agreement, the remaining future contractual milestone payments for the Company aggregated to $1.02 billion for the achievement of various development, regulatory, manufacturing and net trade sales milestones. More specifically, the future contractual milestones consist of $125.0 million for the achievement of specified manufacturing milestones, $60.0 million for the achievement of specified development milestones, $620.0 million for the achievement of specified regulatory milestones and $210.0 million for the achievement of specified net trade sales milestones. The Company's development plans and research progresses might change from time to time, which would increase the uncertainties of achieving future contractual milestones. The Company does not believe $280.0 million of the remaining $1.02 billion contractual milestone payments would be eligible to be received based on a subsequent change in development plan with the collaborator. Furthermore, the Company assessed that achievement of all the remaining contractual milestones is highly uncertain and the related milestone payments are not included in the transaction price. The milestone is achieved when the triggering event described in the agreement occurs.

Profit sharing

The Company and Janssen share equally profits on sales of CARVYKTI in all areas other than the People's Republic of China, excluding the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan ("Greater China"), where the Company retains or bears 70% of pre-tax profits or losses. In all areas other than Greater China, as Janssen is the principal in the sale transaction with the customer, the Company recognizes a pro-rata share of collaboration net trade sales in the period Janssen completes the sale and delivers the product to the customer. The Company's share of collaboration net trade sales in all areas other than Greater China are recognized within collaboration revenue on the statement of profit or loss and other comprehensive income. Subsequent to regulatory approval, revenue from sales of product in Greater China will be recognized within Product sales on the statement of profit or loss and other comprehensive income as the Company will be the principal in the sale to the customer.

Collaborative activities

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

Product Sales

Revenue from the sale of goods is recognized at the point in time when control of the goods is transferred to the customer, generally on delivery of the goods. To date the Company has not generated any product sales. Our share of collaboration net trade sales in which Janssen is the principal in the sale transaction with the customer is recognized within collaboration revenue on the statement of profit or loss and other comprehensive income.

Collaboration cost of revenue

Collaboration cost of revenue relates to the sale of CARVYKTI and includes costs incurred by the Company as well as the Company's pro-rata share of collaboration cost of revenue. Collaboration cost of revenue includes the cost of inventory sold, manufacturing costs, other costs attributable to production, and provisions to write down inventory, such as for excess and obsolete inventory or inventory that did not meet quality specifications.

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.

Share-based payments

The Company operates a share option scheme and a restricted share unit scheme ("RSU Scheme") for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Company's operations. Employees and directors of the Company receive remuneration in the form of share-based payments, whereby employees and directors 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 using a binomial model, and the fair value of each RSU is determined by reference to market price of the Company's shares at the respective grant date, further details of which are given in notes 25 and 26 to the consolidated financial statements.

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

Service and 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 Company's best estimate of the number of equity instruments that will ultimately vest.

For awards that do not ultimately vest because performance and/or service conditions have not been met, no expense is recognized.

Other employee benefits

Pension scheme

The employees of the Company's subsidiaries which operates in Greater China and Hong Kong are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

Defined contribution plan

Employees in the U.S. are eligible to participate in the defined contribution plan we sponsor. The defined contribution plan allows employees to contribute a portion of their compensation on a pre-tax basis in accordance with specified guidelines. We match a percentage of employee contributions up to certain limits.

Foreign Currency Transactions

These consolidated financial statements are presented in U.S. dollars, which is the Company's functional currency. Each of the Company's subsidiaries determines its own functional currency and items included in the consolidated financial statements of each entity are measured using that functional currency.

Transactions that are denominated in a currency other than the functional currency of an entity are recorded at that functional currency by applying the spot exchange rates prevailing at the dates of the transactions. At the end of the reporting period, monetary assets and liabilities denominated in a currency other than the functional currency are revalued to the functional currency by applying the spot exchange rate prevailing at the end of the reporting period. Gains and losses arising from these foreign currency revaluations are recognized in net income as other income and gains or other expenses. Foreign-currency-denominated transactions that are classified as non-monetary are measured using the historical spot exchange rate.

Foreign Currency Translation

The functional currencies of certain subsidiaries established in the PRC and Europe are currencies other than the U.S. dollar. As at the end of the reporting period, the assets and liabilities of these entities are translated into U.S. dollars at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into U.S. dollars using the average foreign exchange rates during the period.

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

For the purpose of the consolidated statements of cash flows, the cash flows of the subsidiaries established in the PRC and Europe are translated into U.S. 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 U.S. dollars at the weighted average exchange rates for the year.

Use of Estimates

The preparation of the Company'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.

Global Economic Conditions

Worldwide economic conditions remain uncertain and we continue to monitor the impact of macroeconomic conditions, including those related to the public health crises, the Russia-Ukraine war, the conflict between Israel and Hamas, the failure and instability of financial institutions and rising inflation rates.

Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the Russia-Ukraine war, the conflict between Israel and Hamas and steps taken by governments and central banks, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. Our product manufacturing in both the U.S. and China has continued. Currently we have not experienced any material impact to our material supply chain or as a result of inflation and rising interest rates. Increased quantities of certain raw materials and consumables have been stocked as an appropriate safety measure. We believe we have established robust sourcing strategies for all necessary materials and do not expect any significant impact.

In addition, in China, although we experienced disruptions from COVID-19 during the year ended December 31, 2023, we do not believe they had a material impact to our business. There are still uncertainties of COVID-19's future impact on our business in China, 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 COVID-19 resurges or if other public health crises create similar disruptions, 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.

If these changes in economic conditions continue or if they increase in severity, it could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. Although we do not believe that these macroeconomic conditions have had a material impact on our financial position or results of operations to date, we may experience impacts in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with public health crises, the ongoing conflict between Russia and Ukraine and the conflict between Israel and Hamas, and employee availability and wage increases, which may result in additional stress on our working capital resources.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

Judgement

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

Revenue from contracts with customers

The Company has applied the following judgements that significantly affect the determination of the performance obligations and the method to estimate variable consideration of revenue from contracts with customers, specifically the historic accounting under the Janssen Agreement:

(i) Determining the performance obligations of the contract

A good or service that is promised to a customer is distinct if both of the following criteria are met: (a) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (b) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Company determined that the license is capable of being distinct under the Janssen Agreement. In assessing whether the license under the Janssen Agreement has standalone value to the customer, the Company considers factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace, which indicates that the customer can benefit from the license on its own. The Company determined that the license of intellectual property and technology transfer service form a single performance obligation. The license of intellectual property and technology transfer are highly interdependent and are not separately identifiable from each other. The technology transfer is essential for the customer's ability to obtain the use of and benefit from the license. The promise to transfer the license, including a technology transfer service, is distinct within the context of the contract. The license of intellectual property, including a technology transfer service, is separately identifiable in the contract and is meant to be transferred separate from other collaborative activities. The license, including a technology transfer service, is not an input that will be integrated with the service which represents a combined output. The preparation and attendance of the various steering committees and participation in the collaborative activities (e.g. joint development) is to assist in conducting clinical trials and obtaining regulatory approval of the technology, but does not modify the license and technology. In addition, the license, including the technology transfer service, is not highly interdependent or highly interrelated with the JSC and other collaborative activities, because the delivery of license and technology transfer service is not dependent on these activities to be provided in the future, and accordingly, it is not interdependent or interrelated with these activities.

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

The Company has allocated the entire transaction price to the license of intellectual property under the Janssen Agreement, as this is the sole performance obligation in the arrangement.

(ii) Determining the method to estimate variable consideration

Certain contracts include milestone payments that give rise to variable consideration. In estimating the variable consideration, the Company 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 Company 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 Company will be entitled.

Before including any amount of variable consideration in the transaction price, the Company considers whether the amount of variable consideration is constrained. The Company 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

The Company assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each reporting period. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows. There were no indicators of impairment for all periods presented.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses and deductible temporary differences can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. The outcome of their actual utilization may be different. Further details are contained in note 20 to the consolidated financial statements.

Warrant liability

The fair value of the warrant liability is determined by using the binominal model. The use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Management estimates expected volatility based on the historical volatility of the stock of comparable companies. The risk-free interest rate is based on treasury yield curve rates with a remaining term which approximates to the expected life of the warrant. Changes in these input variables would affect fair value of the warrant. Further details are contained in notes 21 and 32 to the consolidated financial statements. On May 11, 2023, the PIPE Investor exercised the Warrant in full, and as of year-end, there is no warrant liability balance.

Share-based compensation

The fair value of share options granted by the Company is estimated using the binomial model. The use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Management estimates expected volatility based on the historical volatility of the stock of comparable companies. Expiration date is the basis for determining the expected life of an option. The risk-free interest rate is based on treasury yield curve rates with a remaining term which approximates to the expected life assumed at the date of grant. Changes in these input variables would affect the amount of expense associated with 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. Further details are contained in note 25 and 26 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 Company 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 Board of 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 Company as a whole. Therefore, no further information on the operating segment is presented.

Geographic information

(a) Revenue

	2023	2022	2021
	US$'000	US$'000	US$'000
License and other revenue			
United States of America*	35,160	50,000	65,402
China	179	328	3,424
Total revenue and other revenue	35,339	50,328	68,826
Collaboration revenue			
United States of America*	234,734	66,602	—
Europe*	15,070	75	—
Total collaboration revenue	249,804	66,677	—
Total revenue	285,143	117,005	68,826

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

*Certain prior year amounts have been reclassified for comparative purposes

(b) Non-current assets

	December 31, 2023	December 31, 2022
	US$'000	US$'000
United States of America	151,225	114,426
China	56,007	54,510
Europe	139,216	62,908
Total	346,448	231,844

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

Information about major customer

Revenue of $35.2 million, $50.0 million and $65.4 million for the years ended December 31, 2023, 2022 and 2021, respectively, was derived from license revenue to a single customer and under the Janssen Agreement.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023	2022	2021
	US$'000	US$'000	US$'000
Revenue			
Licensing of intellectual property	35,160	50,000	65,402
Collaboration revenue	249,804	66,677	—
Other revenue	179	328	3,424
Total Revenue	285,143	117,005	68,826

Revenue from licensing of intellectual property is recognized at a point in time with respect to the Janssen collaboration. Revenue from licensing of intellectual property represents variable consideration relating to the milestone payments that were constrained in prior years but included in the transaction price when the achievement of the milestones was highly probable. Collaboration revenue includes our pro-rata share of collaboration net trade sales for which Janssen

Biotech, Inc. ("Janssen") is the principal in the sale to the customer under the collaboration and license agreement with Janssen (the "Janssen Agreement").

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

Novartis License Agreement

On November 10, 2023, Legend Biotech, through its wholly owned subsidiary, Legend Biotech Ireland Limited, entered into an exclusive, global license agreement with Novartis Pharma AG. The Company granted Novartis the rights to develop, manufacture and commercialize LB2102 and other potential chimeric antigen receptor T-cell (CAR-T) therapies selectively targeting Delta-like Ligand 3 (DLL3). The agreement was effective on December 28, 2023, with a $100 million receivable recorded, representing the Novartis upfront payment to be received shortly after December 31, 2023. Novartis has also agreed to pay up to $1.01 billion in milestone payments upon achievement of specified clinical, regulatory and commercial milestones, as well as tiered royalties on net sales. We determined that any milestone payments will be recognized when occur as they were determined to relate predominately to the license granted and therefore have been excluded from the transaction price. We determined that any sales-based royalties will be recognized when the related sales occur as they were determined to relate predominately to the license granted and therefore have been excluded from the transaction price. Under the Novartis License Agreement, Legend Biotech will conduct the Legend Phase 1 clinical trial for LB2102 in the U.S. Novartis will conduct all other development for the licensed products.

The following table shows the deferred revenue which is included in contract liabilities for the periods presented:

	2023	2022
	US$'000	US$'000
Contract liabilities (Current)	53,010	—
Contract liabilities (Non Current)	47,962	—
Total	100,972	—

Performance Obligations

The Novartis License Agreement represents a transaction with a customer and therefore is accounted for in accordance with IFRS 15. We identified the following performance obligations:

•Performance Obligation 1 (PO1)

A combined performance obligation that includes delivery of the license (inclusive of know-how) and the delivery of the Handover Package Documents which includes performing the Legend Phase 1 trial.

•Performance Obligation 2 (PO2)

Supply of materials (supply of Lentivirus/other materials).

We concluded that the license to intellectual property is not distinct from the completion of Phase 1 trial as the license has minimal utility prior to receipt of the completed Legend Phase 1 trial by Legend Biotech. The IP license granted at contract inception is unproven as it relates to products in the early development stage and, therefore the IP may be revised throughout the completion of the Phase 1 trial. In order for Novartis to get the full benefit of the IP, Novartis needs Legend Biotech to provide the IP, the know-how and the completion of the Legend Phase 1 clinical trial, which culminates with the delivery of the handover package. Without each of these deliverables, Novartis would have experienced significant delays in utilizing the IP and commencing the Novartis Phase 1 clinical trial.

Transaction Price

The following table summarizes the composition of the total transaction price for the following periods.

	December 31, 2023	December 31, 2022
	US$'000	US$'000
PO1: Licensing of intellectual property and performing Legend Phase 1 trial	120,710	—
PO2: Supply of materials	4,600	—
Total	125,310	—

PO1: In accordance with the Novartis License Agreement, Legend Biotech will receive a $100.0 million up-front payment from Novartis upon entering into the Novartis License Agreement. The Company determined this upfront payment represents fixed consideration to be included in the transaction price in accordance with IFRS 15 as the payment is non-refundable and represents consideration in exchange for Legend Biotech providing Novartis delivery of the license (inclusive of know-how).

PO1: Novartis must reimburse Legend Biotech for development costs incurred or paid by Legend Biotech prior to, on or after the Effective Date. There is up to $33 million in total aggregate reimbursable development costs through such occurrence. Given it is contractually agreed upon, the Company will include as variable consideration the expected amount it will be reimbursed by Novartis for the Legend Phase 1 clinical trial. The Company concluded that the development costs that are highly probable of being achieved should be included in the transaction price. We have included the estimate of cost reimbursement for the R&D in the transaction price for the first twelve months of expenses through the end of 2024; totaling $20.7 million. The remaining R&D Costs $12.3 million are constrained at inception of the contract as we concluded that they aren't highly probable that a significant reversal in the cumulative amount of revenue recognized would not occur.

PO2: Given supply is contractually agreed upon for the existing materials and clearly laid out for new materials it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur. As such the supply of materials cost included in the transaction price is $4.6 million.

The difference between the $125.3 million transaction price and the $100.0 million disclosed above is the variable consideration of $25.3 million.

The following table summarizes the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of December 31, 2023:

	December 31, 2023	December 31, 2022
	US$'000	US$'000
PO1: Licensing of intellectual property and completion of Legend Phase 1 trial	120,710	—
PO2: Supply of materials	4,600	—
Total	125,310	—
Remaining unsatisfied performance obligation	125,310	—

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as of December 31, 2023 are as follows:

	2023	2022	2021
	US$'000	US$'000	US$'000
Amounts expected to be recognized as revenue:			
Licensing of intellectual property and completion of Legend Phase 1 trial			
Within 1 year	63,360	—	—
1 - 2 years	37,920	—	—
2 - 3 Years	12,490	—	—
3 - 4 years	6,940	—	—
After 4 years	—	—	—
Total	120,710	—	—

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognized as revenue relate to Novartis Licensing Agreement, of which the performance obligations are to be satisfied over the completion of Legend Phase 1 trial for LB2102, which is estimated to be 4 years. As part of the Novartis transaction, the Company allocated the transaction price to performance obligations based on the estimated stand-alone selling prices of promised goods or services and specifically the residual approach for this performance obligation. The amounts disclosed above do not include variable consideration which is constrained. We re-evaluate the transaction price at the end of each reporting period.

Revenue

The following summarizes the revenue recognized for the periods presented:

There was no revenue recognized in the current reporting period that was included in the contract liabilities at the beginning of the reporting period and there was no revenue recognized from performance obligations satisfied in previous periods.

The Company will recognize revenue for the allocation of the transaction price for licensing of intellectual property and completion of Legend Phase 1 trial using the percentage of completion method using the input method (costs). The model used is based on budgeted R&D costs during our Phase 1 trial. There were no 2023 expenses incurred from the effective date through year end. As such, there was no revenue recognized in 2023 in this percentage of completion model.

The Company will recognize revenue for the allocation of the transaction price for supply of materials at a point in time. As of the end of 2023 no materials have been delivered, as such there will be no revenue recognized in 2023.

The following table summarizes the Total other income and gains:

	2023	2022	2021
	US$'000	US$'000	US$'000
Other income and gains			
Other income:			
Finance income	54,487	8,182	971
Government grants*	2,731	2,434	1,736
Other	245	88	35
Total income	57,463	10,704	2,742
Gains:			
Fair value gains on financial assets measured at fair value change through profit or loss	663	603	—
Other	—	742	317
Total gains	663	1,345	317
Total other income and gains	58,126	12,049	3,059

* The amount represents subsidies received from local government authorities to support the Company's business. There were no unfulfilled conditions and other contingencies attached to these government grants.

6. LOSS BEFORE TAX

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

	2023	2022	2021
	US$'000	US$'000	US$'000
Employee benefit expense (including directors' remuneration):			
Wages and salaries	204,128	147,385	105,751
Other employee benefits	7,729	5,057	2,257
Equity-settled share-based compensation expense	47,680	34,338	20,158

7. FINANCE COSTS

	2023	2022	2021
	US$'000	US$'000	US$'000
Interest on lease liabilities	1,394	527	142
Collaboration interest-bearing advanced funding	20,400	10,269	758
Total	21,794	10,796	900

8. INCOME TAX

The Company is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which the Company and its subsidiaries 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. The Company is subject to withholding tax on intercompany notes, which is insignificant.

British Virgin Islands

Under the current laws of the British Virgin Islands ("BVI"), the subsidiary that operates in BVI is not subject to tax on income or capital gains. Additionally, upon payments of dividends by the Company's subsidiary incorporated in the BVI to its shareholders, no withholding tax will be imposed.

Hong Kong

Under the current tax laws of Hong Kong, the subsidiary which operates in Hong Kong is subject to the two-tiered profits tax rates regime. The first HK$2,000,000 (2022 and 2021: HK$2,000,000) of assessable profits were taxed at 8.25% (2022 and 2021: 8.25%) and the remaining assessable profits were taxed at 16.5% (2022 and 2021: 16.5%). Under the Hong Kong tax law, the subsidiaries in Hong Kong are exempted from income tax on its foreign derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

United States of America

Under the current tax 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% (2022 and 2021: 21%) and state tax at a rate of 3.3% (2022 and 2021: 9%). Dividends payable by the Company'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 Corporate Income Tax ("CIT") at a rate of 12.5% (2022 and 2021: 12.5%) on its taxable trading income. Any non-trading income is subject to CIT at a rate of 25% (2022 and 2021: 25%). Dividend withholding tax is imposed on distributions made by Irish companies at a rate of 25% in 2023 (2022 and 2021: 25%) with many exemptions provided.

Greater China

Pursuant to the Corporate Income Tax Law of the People's Republic of China (the "PRC") and the respective regulations (the "CIT Law"), the subsidiaries which operate in Greater China are subject to CIT at a rate of 25% on the taxable income. Legend Nanjing is qualified as High and New Technology Enterprise, which is subject to income tax at a preferential tax rate of 15% during the year ended December 31, 2023. During the years ended December 31, 2022, and 2021, the applicable income tax rate was 25%. Dividends, interests, rent or royalties payable by the Company'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% CIT, namely withholding tax, unless the respective non PRC resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with the PRC that provides for a reduced withholding tax rate or an exemption from withholding tax.

Belgium

Under the current laws of Belgium, the subsidiary which operates in Belgium is subject to CIT at a rate of 25% on its taxable trading income. Dividend withholding tax is imposed on distributions made by Belgium companies at a rate of 30% with many exemptions provided.

Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the jurisdictions in which the Group operates.

	2023	2022	2021
	US$'000	US$'000	US$'000
Current – United States of America	511	224	211
Current – Elsewhere	(2,375)	401	416
Deferred (note 20)	—	—	(4,241)
Total tax charge/(credit) for the year	(1,864)	625	(3,614)

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

	2023		2022		2021	
	US$'000	%	US$'000	%	US$'000	%
Loss before tax	(520,118)		(445,724)		(407,196)	
At the statutory blended US federal and state income tax rate of 24.3% (2022 and 2021: 28.1%)	(126,638)	24.3	(125,293)	28.1	(114,463)	28.1
Preferential tax rate in other countries and regions	4,091	(0.8)	—	—	—	—
Effect of tax rate differences in other countries and regions	47,001	(9.0)	15,129	(3.4)	15,027	(3.7)
Research and development credit	(8,942)	1.7	(24,970)	5.6	(954)	0.2
State rate change	5,959	(1.1)	(107)	—	—	—
Effect of non-deductible expenses	2,111	(0.4)	1,829	(0.4)	2,298	(0.6)
Tax losses and deductible temporary differences not recognized*	83,054	(16.0)	137,912	(30.9)	106,623	(26.2)
Stock-based compensation income tax charge/(benefit)*	(7,911)	1.5	(4,050)	0.9	(13,674)	3.4
Others	(589)	0.2	175	—	1,529	(0.4)
Tax charge/(benefit) at the Company's effective rate	(1,864)	0.4	625	(0.1)	(3,614)	0.9

*Certain prior year amounts have been reclassified for comparative purposes.

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 352,165,418, 318,083,913 and 281,703,291 in issue during the years ended December 31, 2023, 2022 and 2021, 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, 2023, 2022 and 2021 in respect of a dilution as the impact of the outstanding share options, RSU and warrant liability had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	2023	2022	2021
	US$'000	US$'000	US$'000
Earnings			
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(518,254)	(446,349)	(403,582)

	Number of shares		
	2023	2022	2021
Shares			
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	352,165,418	318,083,913	281,703,291

10. PROPERTY, PLANT AND EQUIPMENT

	Freehold land	Buildings	Leasehold improvement	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$'000	US$'000
December 31, 2023								
At January 1, 2023								
Cost	2,889	45,075	21,974	42,576	3,638	41	14,184	130,377
Accumulated depreciation	—	(2,348)	(5,807)	(14,806)	(2,231)	(17)	—	(25,209)
Net carrying amount	2,889	42,727	16,167	27,770	1,407	24	14,184	105,168
At January 1, 2023, net of accumulated depreciation	2,889	42,727	16,167	27,770	1,407	24	14,184	105,168
Additions	—	238	156	48	6	—	14,616	15,064
Disposals	—	—	(87)	(77)	(1)	—	—	(165)
Depreciation provided during the year	—	(1,493)	(2,603)	(6,033)	(571)	(4)	—	(10,704)
Exchange realignment	—	(116)	(91)	(253)	(4)	(1)	(173)	(638)
Transfers	—	20,344	1,249	3,778	217	—	(25,588)	—
At December 31, 2023, net of accumulated depreciation	2,889	61,700	14,791	25,233	1,054	19	3,039	108,725
At December 31, 2023:								
Cost	2,889	65,540	23,117	45,480	3,622	40	3,039	143,727
Accumulated depreciation	—	(3,840)	(8,326)	(20,247)	(2,568)	(21)	—	(35,002)
Net carrying amount	2,889	61,700	14,791	25,233	1,054	19	3,039	108,725

	Freehold land	Buildings	Leasehold improvement	Machinery and equipment	Computer, fixtures and office equipment	Transportation equipment	Construction in progress	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2022								
At January 1, 2022								
Cost	2,889	16,011	20,908	35,251	2,977	45	41,367	119,448
Accumulated depreciation	—	(1,360)	(3,503)	(10,432)	(1,633)	(14)	—	(16,942)
Net carrying amount	2,889	14,651	17,405	24,819	1,344	31	41,367	102,506
At January 1, 2022, net of accumulated depreciation	2,889	14,651	17,405	24,819	1,344	31	41,367	102,506
Additions	—	1,732	522	583	34	—	14,346	17,217
Disposals	—	—	—	(122)	(14)	—	(406)	(542)
Depreciation provided during the year	—	(988)	(2,566)	(5,818)	(797)	(4)	—	(10,173)
Exchange realignment	—	—	(1,164)	(1,802)	(32)	(3)	(839)	(3,840)
Transfers	—	27,332	1,970	10,110	872	—	(40,284)	—
At December 31, 2022, net of accumulated depreciation	2,889	42,727	16,167	27,770	1,407	24	14,184	105,168
At December 31, 2022:								
Cost	2,889	45,075	21,974	42,576	3,638	41	14,184	130,377
Accumulated depreciation	—	(2,348)	(5,807)	(14,806)	(2,231)	(17)	—	(25,209)
Net carrying amount	2,889	42,727	16,167	27,770	1,407	24	14,184	105,168

11. INTANGIBLE ASSETS

	Software
	US$'000
December 31, 2023	
At January 1, 2023	
Cost	7,505
Accumulated amortization	(4,096)
Net carrying amount	3,409
At January 1, 2023, net of accumulated amortization	3,409
Additions	2,638
Disposals	(61)
Amortization provided during the year	(1,924)
Exchange realignment	(1)
At December 31, 2023, net of accumulated amortization	4,061
At December 31, 2023	
Cost	10,080
Accumulated amortization	(6,019)
Net carrying amount	4,061
December 31, 2022	
At January 1, 2022	
Cost	6,402
Accumulated amortization	(1,718)
Net carrying amount	4,684
At January 1, 2022, net of accumulated amortization	4,684
Additions	1,264
Disposals	(6)
Amortization provided during the year	(2,476)
Exchange realignment	(57)
At December 31, 2022, net of accumulated amortization	3,409
At December 31, 2022	
Cost	7,505
Accumulated amortization	(4,096)
Net carrying amount	3,409

12. OTHER NON-CURRENT ASSETS

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Prepaid expenses	1,208	1,092
Lease receivables	285	395
Total	1,493	1,487

13. LEASES

The Company as a lessee

The Company has leases for office, research laboratory and manufacturing facilities, equipment, vehicles and land. The terms of the leases vary, although most generally have lease terms between 3 and 29 years. Lump sum payments were made upfront to acquire the leasehold land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these leasehold land. Leases with terms of 12 months or less are expensed as incurred, Collaboration assets represent the Company's share of assets leased to the collaboration from Janssen, which purchased the assets on behalf of the collaboration, in connection with the Janssen Agreement. Collaboration assets under construction that will be leased to the collaboration from Janssen when placed into service are classified as collaboration prepaid leases on the consolidated financial statements.

(a) Right-of-use assets

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Leasehold land	4,192	4,357
Lease buildings	3,621	4,887
Collaboration assets	72,689	46,346
Total	80,502	55,590

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

	Non-Collaboration Assets Leased		Collaboration Assets Leased			
	Leasehold land	Buildings*	Buildings*	Machinery and equipment	Computer and office equipment	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
December 31, 2023						
Right-of-use assets at January 1, 2023	4,357	4,887	36,624	9,711	11	55,590
Additions	—	880	26,777	4,433	—	32,090
Accumulated depreciation	—	—	—	—	—	—
Exchange realignment	(72)	22	695	—	—	645
Depreciation of right-of-use assets	(93)	(2,168)	(3,556)	(2,002)	(4)	(7,823)
Right-of-use assets at December 31, 2023	4,192	3,621	60,540	12,142	7	80,502
December 31, 2022						
Right-of-use assets at January 1, 2022	4,862	2,324	19,907	11,174	16	38,283
Additions	—	4,677	18,486	298	—	23,461
Exchange realignment	(408)	(224)	221	—	—	(411)
Depreciation of right-of-use assets	(97)	(1,890)	(1,990)	(1,761)	(5)	(5,743)
Right-of-use assets at December 31, 2022	4,357	4,887	36,624	9,711	11	55,590

*Certain prior year amounts have been reclassified for comparative purposes

(b) Lease liabilities

Lease liabilities are as indicated below:

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

	2023	2022
	US$'000	US$'000
Carrying amount at January 1	23,602	2,504
Additions	26,692	23,703
Accretion of interest recognized during the year	1,394	527
Payments	(5,149)	(3,123)
Exchange realignment	805	(9)
Carrying amount at December 31	47,344	23,602
Analyzed into:		
Current portion	3,175	3,563
Non-current portion	44,169	20,039
Total	47,344	23,602

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

	2023	2022
	US$'000	US$'000
Interest on lease liabilities	1,394	527
Depreciation charge of right-of-use assets	7,823	5,743
Expense relating to short-term leases	2,338	1,132
Total amount recognized in profit or loss	11,555	7,402

The maturity analysis of lease liabilities is disclosed in note 33 to the financial statements. The total cash outflow for leases is disclosed in note 28 (c) to the financial statements.

The Company as a lessor

The Company leases assets it owns to the collaboration in accordance with the Janssen Agreement. These are finance leases for which the Company recognized an insignificant amount of finance income for the year ended December 31, 2023 and 2022.

At December 31, 2023 and 2022, the undiscounted minimum lease payments receivables by the Company in future periods under non-cancellable operating leases with its tenants are as follows:

	2023	2022
	US$'000	US$'000
Finance leases:		
Total	1,673	583

14. COLLABORATION INVENTORIES

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Raw materials	13,155	6,989
Work-in-process	2,990	690
Finished goods	3,288	2,675
Total collaboration inventories	19,433	10,354

The Company's reserve for inventory was $8.9 million as of December 31, 2023 and $5.3 million as of December 31, 2022. The Company's reserve for inventory as of December 31, 2023 was primarily related to expired material and certain batches or units of product that did not meet quality specifications that were charged to collaboration cost of sales.

15. TRADE RECEIVABLES

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Trade receivables	100,041	90

The Company's trading terms with its customers are mainly on credit. The credit period is 45 to 60 days. The Company seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by management. Trade receivables are non-interest-bearing. The Company had concentration of credit risk of $100 million trade receivables that were due from one single customer under a license agreement as of December 31, 2023.

As at December 31, 2023 and 2022, the expected credit loss is insignificant.

16. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Other Collaboration Receivables*	54,078	40,376
Interest receivable	47	1,517
Other receivables*	790	948
Lease receivables	1,388	188
VAT recoverable	717	1,396
Prepayments*	12,231	17,330
Total	69,251	61,755

*Certain prior year amounts have been reclassified for comparative purposes

The amounts due from the Company's related parties that are repayable on demand, which were included in the Company's other receivables, was $0.04 million and $0.3 million, for December 31, 2023 and 2022, respectively (note 30). As at December 31, 2023 and 2022, amounts prepaid to the Company's related parties were $0.2 million and $0.3 million, 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 Company estimated that the expected credit loss for the above receivables as at December 31, 2023 and 2022 is insignificant.

17. CASH AND CASH EQUIVALENTS, TIME DEPOSITS AND PLEDGED DEPOSITS

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Cash and bank balances	1,312,773	841,317
Less: Pledged deposits	(357)	(1,270)
Time deposits	(34,703)	(54,016)
Cash and cash equivalents	1,277,713	786,031
Denominated in USD	1,254,969	727,160
Denominated in RMB	12,675	21,472
Denominated in EUR	10,069	37,399
Cash and cash equivalents	1,277,713	786,031

The cash and cash equivalents of the Company denominated in Renminbi ("RMB") amounted to $12.7 million and $21.5 million in the consolidated statements of financial position as at December 31, 2023 and 2022, respectively. The RMB is not freely convertible into other currencies, however, under Greater China Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Company is permitted to exchange RMB for other currencies through banks authorized to conduct foreign exchange business.

The pledged deposit as at December 31, 2023 was pledged for credit card facilities. The pledged deposit as at December 31, 2022 was pledged for issuing bank acceptance notes to suppliers of the Company and credit card facilities.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default. The carrying amounts of the cash and cash equivalents approximate to their fair values.

18. TRADE PAYABLES

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Trade payables	20,160	32,893

The trade payables are non-interest-bearing and are normally settled on 30-day terms.

As at December 31, 2023 and 2022, amounts due to the Company's related parties, included in the Company's trade payables, were $0.6 million and $1.2 million, respectively (note 30).

19. OTHER PAYABLES AND ACCRUALS

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Accrued payroll	30,974	21,892
Accrued expense	71,462	127,390
Other payables	11,944	10,960
Payable for Collaboration Assets	16,338	22,852
Other tax payables	2,084	1,015
	132,802	184,109

Other payables are non-interest-bearing and repayable on demand.

As at December 31, 2023 and 2022, amounts due to the Company's related parties, included in the Company's other payables, were $0.9 million and $2.5 million, respectively (note 30).

20. DEFERRED TAX

The movements in the deferred tax liabilities and assets during the years ended December 31, 2023 and 2022, are as follows:

Deferred tax liabilities

	Collaboration revenue	License revenue - transitional adjustment	Difference allowance in excess of related depreciation[1]	Right of use assets	Total
	US$'000	US$'000	US$'000	US$'000	US$'000
At January 1, 2022	(14,125)	—	(8,636)	—	(22,761)
Deferred tax charged/(credited) to the statement of profit or loss during the year	14,125	—	885	(114)	14,896
Gross deferred tax liabilities at December 31, 2022	—	—	(7,751)	(114)	(7,865)
At January 1, 2023	—	—	(7,751)	(114)	(7,865)
Deferred tax charged/(credited) to the statement of profit or loss during the year	—	(3,144)	4,563	(6,374)	(4,955)
Gross deferred tax liabilities at December 31, 2023	—	(3,144)	(3,188)	(6,488)	(12,820)

Deferred tax assets

	Losses available for offsetting against future taxable profits	Difference in intangible assets amortization	Accrued expense	Lease liability	Cost recovery of R&D expense	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
At January 1, 2022	20,448	1,056	1,257	—	—	22,761
Deferred tax charged to the statement of profit or loss during the year	(20,448)	194	2,192	120	3,046	(14,896)
Gross deferred tax assets at December 31, 2022	—	1,250	3,449	120	3,046	7,865
At January 1, 2023	—	1,250	3,449	120	3,046	7,865
Deferred tax charged to the statement of profit or loss during the year	1,521	1,551	(1,500)	6,429	(3,046)	4,955
Gross deferred tax assets at December 31, 2023	1,521	2,801	1,949	6,549	—	12,820

1

The Company has tax losses arising in Hong Kong of $0.4 million in 2023 (2022: $1.9 million) that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

The Company has tax losses arising in Greater China of $90.9 million in 2022 that will expire in 10 years for offsetting against future taxable profits of the companies in which the losses arose.

The Company has tax losses arising in Ireland of $134.8 million in 2023 (2022 $118.6 million) that can be carried back for 1 year and carried forward indefinitely for offsetting against taxable profits of the company.

The Company has tax losses arising in the United States of America of $48.8 million in 2023 (2022: $179.8 million) that are available indefinitely for offsetting against up to 80% of future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognized in respect of these tax losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilized.

Deferred tax assets have not been recognized in respect of the following items as of the end of the reporting year:

	2023	2022
	US$'000	US$'000
Deductible temporary differences	440,801	210,953
Tax losses and credits	1,241,550	1,002,104
Total	1,682,351	1,213,057

Deferred income tax assets are recognized for tax losses carried-forward to the extent that realization of the related tax benefit through future taxable profits is probable. Deferred tax assets have not been recognized in respect of the above items as it is not considered probable that taxable profits will be available against which the above items can be utilized.

Pursuant to the PRC Corporate Income Tax Law, a 10% withholding tax is levied on dividends declared to foreign investors from the foreign investment enterprises established in Greater 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 Greater China and the jurisdiction of the foreign investors. For the Company, the applicable rate is 10%. The Company is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in Greater China in respect of earnings generated from January 1, 2008.

At December 31, 2023 and 2022, the subsidiaries in Greater China had no distributable retained earnings.

According to the US tax laws, dividends payable by the Company'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 Company, the applicable rate is 5%. The Company is therefore liable for withholding taxes on dividends distributed by those subsidiaries established in US.

At December 31, 2023 and 2022, the subsidiary in US had no distributable retained earnings.

21. WARRANT LIABILITY

On May 13, 2021, the Company entered into a subscription agreement with an institutional investor (the "PIPE Investor") relating to the offer and sale of 20,809,850 ordinary shares of the Company, par value $0.0001 per share (the "ordinary shares"), in a private placement at a purchase price of $14.41625 per ordinary share (the "PIPE Offering"). The total proceeds from the PIPE Offering were $300.0 million. Pursuant to the subscription agreement, the Company also issued the PIPE Investor, l concurrently with the PIPE offering a warrant (the "Warrant") exercisable for up to an aggregate of 10,000,000 ordinary shares (such transaction together with the PIPE Offering, the "Transactions"). The Transactions closed on May 21, 2021 (the "Closing Date"). The Warrant was exercisable, in whole or in part, at an exercise price of $20.0 per ordinary share. The Warrant was exercisable after the Closing Date and prior to the two-year anniversary of the Closing Date.

On May 11, 2023, the PIPE Investor exercised the Warrant in full for an aggregate exercise price of $200.0 million, and, as a result, the Company issued 10,000,000 ordinary shares to the PIPE Investor. The Warrant was accounted for as a

financial liability because the Warrant was net share settleable at the holder's option. In 2023, up to the exercise of the warrant, the Company recorded a fair value loss of $85.8 million.

The movement of the warrant liability is set out as below:

	2023	2022
	US$'000	US$'000
Balance, beginning of the period	67,000	87,900
Fair value loss/(gain) of the warrant liability	85,750	(20,900)
Exercise of the warrant liability	(152,750)	—
Balance, end of the period	—	67,000

22. GOVERNMENT GRANTS

	2023	2022
	US$'000	US$'000
Deferred government grants	7,373	8,110
Current	68	451
Non-current	7,305	7,659

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.

23. COLLABORATION INTEREST-BEARING ADVANCED FUNDING

	Effective interest rate	Maturity	December 31, 2023
	%		US$'000
Non-current			
Loans from a collaborator	8.07	No specific maturity date	281,328

Pursuant to the license and collaboration agreement entered into with a collaborator, the Company is entitled to receive funding advances from the collaborator when certain operational conditions are met. As a result, the Company took an initial funding advance with principal amounting to $17.3 million on June 18, 2021, a second funding advance with principal amounting to $53.1 million on September 17, 2021, a third funding advance with principal amounting to $49.3 million on December 17, 2021, a forth funding advance with principal amounting to $5.3 million on March 18, 2022, a fifth funding advance with principal amounting to $60.9 million on June 17, 2022, a sixth funding advance with principal amounting to $60.5 million on September 16, 2022, and a seventh funding advance with principal amounting to $3.6 million on December 16, 2022, by reducing the same amount of other payables due to the collaborator, respectively (collectively, the "Funding Advances").

These Funding Advances are accounted for as interest-bearing borrowings funded by the collaborator, constituted by a principal amounting to $250.0 million and applicable interests accrued amounting to $31.3 million upon such principal. The respective interest rate of each borrowing has transitioned from London Interbank Offered Rate (LIBOR) to Secured Overnight Financing Rate (SOFR) in accordance with the LIBOR ACT. Thus, outstanding advances accrue interest at 12 month CME term SOFR plus LIBOR/SOFR adjustment (12 month) plus a margin of 2.5% For each of the seven batches of funding advances, interest started to accrue from June 18, 2021, September 17, 2021, December 17, 2021, March 18, 2022, June 17, 2022, September 16, 2022, and December 16, 2022, respectively.

Pursuant to the terms of the license and collaboration agreement, the collaborator may recoup the aggregate amount of Funding Advances together with interest thereon from Company's share of pre-tax profits from the first profitable year of the collaboration program and, subject to some limitations, from milestone payments due to the Company under the Janssen Agreement. The Company's management estimated the loan will not be recouped by the collaborator within one year, nor does the Company expect to repay the funding advances within one year, and thus the loan was classified as a long-term liability.

24. SHARE CAPITAL AND SHARE PREMIUM

Shares

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Authorized:		
2,000,000,000 shares of $0.0001 each	200	200
Issued and fully paid:		
363,822,069 (2022: 330,134,480) ordinary shares of $0.0001 each	36	33

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, 2021 and January 1, 2022	308,456,852	31	1,261,454	1,261,485
Issuance of ordinary shares for follow-on public offering, net of issuance cost	18,722,000	2	377,641	377,643
Exercise of share options	2,040,580	—	4,070	4,070
Reclassification of vesting of restricted share units	915,048	—	13,850	13,850
At December 31, 2022 and January 1, 2023	330,134,480	33	1,657,015	1,657,048
Issuance of ordinary shares for private placements, net of issuance cost	8,834,742	1	234,409	234,410
Issuance of ordinary shares for registered direct offering, net of issuance cost	10,937,500	1	349,277	349,278
Issuance of ordinary shares for exercise of warrants	10,000,000	1	352,490	352,491
Exercise of share options	2,460,172	—	18,051	18,051
Reclassification of vesting of restricted share units	1,455,175	—	25,878	25,878
At December 31, 2023	363,822,069	36	2,637,120	2,637,156

On April 24, 2023, May 2, 2023 and May 19, 2023, the Company sold 7,656,968, 484,992 and 692,782 ordinary shares to institutional investors in private placement transactions, respectively, for net proceeds of $234.4 million, after deduction of related issuance costs of $0.4 million. On May 10, 2023, the Company sold 10,937,500 ordinary shares to certain investors in a registered direct offering at a price of $32.00 per share, for net proceeds of $349.3 million, after deduction of related issuance costs of $0.7 million. On May 11, 2023, the PIPE Investor exercised the Warrant in full for an aggregate exercise price of $200.0 million, and, as a result, the Company issued 10,000,000 ordinary shares to the PIPE Investor.

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 Company's operations. Eligible participants of the Scheme include the Company's directors, including independent non-executive directors, and employees of any member of the Company.

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:

	2023		2022		2021	
	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,	7.1370	9,180	2.8970	9,529	1.9353	14,241
Granted during the year	23.5300	355	19.4468	2,265	15.4774	595
Forfeited during the year	2.8336	(708)	4.2888	(573)	2.9987	(1,251)
Exercised during the year	5.0687	(2,460)	1.8032	(2,041)	1.3346	(4,056)
At December 31,	9.3287	6,367	7.1370	9,180	2.8970	9,529
Exercisable at December 31	4.5401	3,470	2.8705	3,281	1.4334	2,828

The weighted average share price at the date of exercise for share options exercised during 2023 was $31.8140 per share (2022: $22.5813, 2021: $18.4846).

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

December 31, 2023		
Number of options '000	Exercise price* US$ per share	Exercise period
1,747	0.5	2019/12/25 – 2027/12/25
801	1.0	2019/07/01 – 2028/08/29
84	1.0	2019/12/31 – 2028/12/30
723	1.5	2020/07/02 – 2029/07/01
152	11.5	2020/11/29 – 2029/11/28
54	11.5	2021/06/05 – 2030/06/04
255	16.3	2021/09/01 – 2030/08/31
210	14.1	2022/03/29 – 2031/03/28
160	19.0	2022/08/27 – 2031/08/26
409	18.4	2023/03/31 - 2032/03/30
740	18.2	2023/04/30 - 2032/04/29
80	18.4	2023/05/02 - 2032/05/01
40	18.4	2023/05/05 - 2032/05/04
80	18.4	2023/05/08 - 2032/05/07
200	18.4	2023/05/10 - 2032/05/09
10	19.7	2023/05/13 - 2032/05/12
207	27.5	2023/06/30 - 2032/06/29
60	23.3	2023/08/02 - 2032/08/01
355	23.5	2024/04/03 - 2033/04/02
6,367		

December 31, 2022

Number of options '000	Exercise price* US$ per share	Exercise period
2,875	0.5	2019/12/25 – 2027/12/25
1,248	1.0	2019/07/01 – 2028/08/29
271	1.0	2019/12/31 – 2028/12/30
1,393	1.5	2020/07/02 – 2029/07/01
201	11.5	2020/11/29 – 2029/11/28
90	11.5	2021/06/05 – 2030/06/04
322	16.3	2021/09/01 – 2030/08/31
410	14.1	2022/03/29 – 2031/03/28
165	19.0	2022/08/27 – 2031/08/26
740	18.4	2023/03/31 - 2032/03/30
750	18.2	2023/04/30 - 2032/04/29
80	18.4	2023/05/02 - 2032/05/01
40	18.4	2023/05/05 - 2032/05/04
80	18.4	2023/05/08 - 2032/05/07
200	18.4	2023/05/10 - 2032/05/09
15	19.7	2023/05/13 - 2032/05/12
240	27.5	2023/06/30 - 2032/06/29
60	23.3	2023/08/02 - 2032/08/01
9,180		

December 31, 2021

Number of options '000	Exercise price* US$ per share	Exercise period
4,054	0.5	2019/12/25 – 2027/12/25
1,849	1.0	2019/07/01 – 2028/08/29
382	1.0	2019/12/31 – 2028/12/30
1,822	1.5	2020/07/02 – 2029/07/01
332	11.5	2020/11/29 – 2029/11/28
90	11.5	2021/06/05 – 2030/06/04
385	16.3	2021/09/01 – 2030/08/31
20	13.6	2021/11/19 – 2030/11/18
430	14.1	2022/03/29 – 2031/03/28
165	19.0	2022/08/27 – 2031/08/26
9,529		

* The exercise price of the share options is subject to adjustment in the case of rights or bonus issues, or other similar changes in the Company's share capital. Pursuant to certain listing rules of the Hong Kong Stock Exchange to which members of the Genscript Group are subject to, the Company adjusted the exercise price of options granted during November 29, 2019 through December 9, 2019 to $11.50 per share. Concurrent with this adjustment, the Company agreed to pay each employee holding affected share options an amount in cash representing the difference between the adjusted exercise price over the original exercise price upon exercising the share options.

The fair value of the share options granted during the year ended December 31, 2023 was $4.8 million ($13.397 each) (2022: $27.2 million, $12.010 each; 2021: $5.7 million, $9.497 each). The Company recognized share option expense of $11.3 million (2022: $10.7 million, 2021: $2.4 million) during the year ended December 31, 2023.

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:

	2023	2022	2021
Dividend yield (%)	—	—	—
Expected volatility (%)	66.1 %	73.0% -87.1%	73.2% - 76.4%
Risk-free interest rate (%)	3.40% - 4.84%	0.52% - 3.11%	0.03%- 1.72%
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 $23.5300 used in the share option fair value valuation model during the year ended December 31, 2023.

As at December 31, 2023, the Company had 6,366,538 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 6,366,538 additional ordinary shares of the Company, an additional share capital of $637 and a share premium of $59.4 million (before issue expenses).

As at December 31, 2023, the Company had 6,366,538 share options outstanding under the share option scheme, which represented approximately 1.7% of the Company's shares in issue as at that date.

26. RESTRICTED SHARE UNITS

The Company operates a RSU scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Company’s operations. Eligible participants of the Scheme include the Company’s directors, including independent non-executive directors, and employees of any member of the Company. The RSU Scheme became effective on May 26, 2020 and, unless otherwise cancelled or amended, will remain in force. The RSU 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 RSUs outstanding for the year ended December 31, 2023, 2022 and 2021 was as follows:

	2023		2022		2021	
	Weighted average grant date fair value	Number of RSU	Weighted average grant date fair value	Number of RSU	Weighted average grant date fair value	Number of RSU
	US$ per unit	’000	US$ per unit	’000	US$ per unit	’000
Outstanding at January 1	18.3704	3,386	15.1808	2,601	15.3409	1,113
Granted during the year	29.6040	3,429	20.5695	2,200	15.0120	2,133
Vested during the year	17.7836	(1,455)	15.1354	(915)	15.2420	(349)
Forfeited during the year	21.5612	(411)	17.3746	(500)	14.4913	(296)
Outstanding at December 31	26.0613	4,949	18.3704	3,386	15.1808	2,601

The fair value of the awarded shares was calculated based on the market price of the Company’s shares at the respective grant date.

For the year ended December 31, 2023, the fair value of the RSUs granted during the period was $101.5 million ($29.604 each), of which the Company recognized RSU expense of $36.3 million.

For the year ended December 31, 2022, the fair value of the RSUs granted during the period was $45.3 million ($20.570 each), of which the Company recognized RSU expense of $23.6 million.

For the year ended December 31, 2021, the fair value of the RSUs granted during the period was $32.0 million ($15.012 each), of which the Company recognized RSU expense of $17.8 million.

As at December 31, 2023, the Company had 4,948,956 RSUs outstanding under the RSU Scheme, which represented approximately 1.4% of the Company's ordinary shares in issue as at that date.

27. RESERVES

The amounts of the Company's reserves and the movements therein for the current and prior years are presented in the consolidated statement of changes in equity of the consolidated financial statements.

The foreign currency translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of operations with a functional currency other than US$.

Under PRC laws and regulations, there are restrictions on the Company's PRC subsidiaries with respect to transferring certain of their net assets to the Company either in the form of dividends, loans, or advances. Amounts of net assets restricted include paid in capital and reserve funds of the Company's PRC subsidiaries, totaling $107.3 million and $81.8 million as at December 31, 2023 and 2022, respectively.

28. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

(a) Major non-cash transactions

For the year ended December 31, 2022 and 2021, the Company had non-cash additions to collaboration interest-bearing advanced funding of $130.3 million and $119.7 million which was received through the deduction of other payables to a collaborator. There were no such non-cash additions to the collaboration interest-bearing advanced funding in 2023.

For the year ended December 31, 2023, 2022 and 2021, the Company recorded a non-cash fair value loss of $85.8 million, non-cash fair value gain of $20.9 million, and non-cash fair value loss of $6.2 million of warrant liability, respectively.

For the years ended December 31, 2023, 2022 and 2021, the Company had non-cash additions to right-of-use assets of $26.7 million, $23.2 million and $0.7 million, and lease liabilities of $26.7 million, $23.7 million and $0.7 million, in respect of lease arrangements for buildings, respectively.

For the years ended December 31, 2023, 2022 and 2021, the Group had non-cash additions to collaboration prepaid leases included in the other payables and accruals for the assets leased from the collaboration partner of $16.30 million $26.5 million and $7.6 million, respectively, and had non-cash additions to property, plant and equipment included in other payables and accruals of $6.6 million, $5.1 million and $6.7 million, respectively.

(b) Changes in liabilities arising from financing activities

	Lease liabilities
	US$'000
At January 1, 2023	23,602
Additions of lease liabilities	26,692
Changes from financing cash flows	(3,755)
Disposal	—
Interest expense	1,394
Interest paid classified as operating cash flows	(1,394)
Foreign exchange movement	805
At December 31, 2023	47,344
At January 1, 2022	2,504
Additions of lease liabilities	23,703
Changes from financing cash flows	(2,596)
Disposal	—
Interest expense	527
Interest paid classified as operating cash flows	(527)
Foreign exchange movement	(9)
At December 31, 2022	23,602
At January 1, 2021	3,373
Additions of lease liabilities	678
Changes from financing cash flows	(1,419)
Disposal	(68)
Interest expense	142
Interest paid classified as operating cash flows	(142)
Foreign exchange movement	(60)
At December 31, 2021	2,504

(c) Total cash outflow for leases

The total cash outflow for leases included in the statement of cash flows is as follows:

	2023	2022	2021
	US$'000	US$'000	US$'000
Within operating activities	1,394	527	142
Within financing activities	3,755	2,596	1,419
Short-term leases	2,338	1,132	182
Total	7,487	4,255	1,743

29. COMMITMENTS AND CONTINGENCIES

(a) Capital commitments

The Company had the following capital commitments at the end of the year:

	2023	2022	2021
	US$'000	US$'000	US$'000
Construction in progress	11,270	22,706	25,897

(b) Loss contingencies

In September 2021, a former employee elected to enter into arbitration against Legend USA with the American Arbitration Association, claiming such former employee was discriminated against due to her gender and wrong fully terminated in retaliation for engaging in alleged protected activity. The former employee demanded Legend USA to pay damages of approximately $3.0 million for alleged lost pay, lost equity, damage to reputation, emotional distress and other related losses.

Management believes that the former employee's claims above are without merit and intends to defend vigorously. At the early stage of the process, management cannot predict the ultimate outcome of the above claims, whether in whole or in part, which may result in a loss, if any. Therefore, in the opinion of management and legal counsel, an estimate of the amount or arrange of reasonably possible losses cannot be made at this time. Accordingly, no provision for any liability has been made in the financial statements.

(c) Lease contingency

We are party to a lease with Janssen under which we expect to lease an approximately 106,000 square foot manufacturing facility from Janssen located in Raritan, New Jersey. That lease will become effective and recorded as a lease on a future date contingent on the U.S. Food and Drug Administration's approval of our Biologics License Application for cilta-cel, which we referred to as the Facility Transition Date. For this facility, which we collaboratively operate with Janssen, we continue to invest in manufacturing, quality, information technology and distribution capabilities to support the launch of CARVYKTI.

30. RELATED PARTY TRANSACTIONS

Company	Relationship
Genscript Biotech Corporation ("Genscript")	The Company's most significant shareholder
Nanjing GenScript Biotech Co., Ltd. (formerly named as Nanjing Jinsirui Biotechnology Co., Ltd.)	Controlled by Genscript or its parent, Genscript Corporation
Jiangsu GenScript Biotech Co., Ltd.	Controlled by Genscript or its parent, Genscript Corporation
Genscript USA Incorporated	Controlled by Genscript or its parent, Genscript Corporation
Genscript USA Holdings Inc	Controlled by Genscript or its parent, Genscript Corporation
Genscript Probio USA Inc	Controlled by Genscript or its parent, Genscript Corporation
Nanjing Probio Biotech Co., Ltd.	Controlled by Genscript or its parent, Genscript Corporation
Jiangsu GenScript Probio Biotech Co., Ltd.	Controlled by Genscript or its parent, Genscript Corporation
Genscript Netherlands	Controlled by Genscript or its parent, Genscript Corporation

(a) In addition to the transactions detailed elsewhere in the consolidated financial statements, the Company had the following transactions with related parties during the year:

(i) Licensing of patents to related parties:

	2023	2022	2021
	US$'000	US$'000	US$'000
Nanjing Probio Biotech Co., Ltd.	—	—	3,019

The sale was generated from an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates.

(ii) Sales of products and sales-based royalties from related parties:

	2023	2022	2021
	US$'000	US$'000	US$'000
Nanjing Probio Biotech Co., Ltd.	179	328	405

The sale was mainly generated from sales-based royalties related to the exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd and its affiliates.

(iii) Purchases from related parties:

	2023	2022	2021
	US$'000	US$'000	US$'000
Nanjing GenScript Biotech Co., Ltd.	4,078	6,174	9,615
Jiangsu GenScript Probio Biotech Co., Ltd	303	1,306	334
Genscript USA Incorporated	473	1,028	786
Genscript USA Holdings Inc	389	380	—
Nanjing Probio Biotech Co., Ltd.	35	237	21
Jiangsu GenScript Biotech Co., Ltd	1	51	146
GenScript Probio USA Inc.	—	8	—
Genscript Netherlands	—	5	6
Total	5,279	9,189	10,908

The transactions were made according to the price and terms agreed with related parties.

(iv) Shared services:

During the years ended December 31, 2023, 2022 and 2021, Nanjing GenScript Biotech Co., Ltd. provided certain accounting, legal, IT and administrative shared services to the Company for a consideration of $0.2 million, $1.6 million and $1.6 million, respectively.

(v) Compensation fee for termination of service agreement:

	2023	2022	2021
	US$'000	US$'000	US$'000
Jiangsu GenScript Biotech Co., Ltd.	—	—	2,666

In May 2021, pursuant to a settlement agreement between the Company and Jiangsu GenScript Biotech Co., Ltd., the Company incurred compensation charges for the termination of a service agreement related to the design and construction of a lab facility.

(vi) Financing from follow-on public offering, net of issuance cost

	2023	2022	2021
	US$'000	US$'000	US$'000
Genscript Biotech Corporation	—	—	84,600

Genscript purchased 4,500,000 ordinary shares, in the form of ADSs issued as part of the follow-on public offering on December 20, 2021, at the same price as these shares issued to the public.

(vii) Lease contract guarantee

In 2018, Legend Ireland entered into a property lease agreement with a third party in Dublin with lease period from 2018 to August 2028. Genscript provided a guarantee on Legend Ireland's payment obligations under the lease agreement for nil consideration.

(b) Outstanding balances with related parties:

The Company had the following significant balances with its related parties at the end of the year:

(i) Due from related parties

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Trade receivables		
Nanjing Probio Biotech Co., Ltd.	41	90

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Other receivables		
Nanjing GenScript Biotech Co., Ltd.	22	321
Genscript USA Incorporated	16	16
Jiangsu Genscript Biotech Co., Ltd	—	3
Total	38	340

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Prepayment		
Nanjing Probio Biotech Co., Ltd.	237	251
Jiangsu GenScript Probio Biotech Co., Ltd	—	21
Total	237	272

(ii) Due to related parties.

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Trade payables		
Nanjing GenScript Biotech Co., Ltd.	265	935
Genscript USA Incorporated	35	134
Jiangsu GenScript Biotech Co., Ltd	—	93
Jiangsu GenScript Probio Biotech Co., Ltd	272	—
Nanjing Probio Biotech Co., Ltd.	—	21
Total	572	1,183

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Other payables		
Nanjing GenScript Biotech Co., Ltd.	892	2,435
GenScript USA Incorporated.	—	58
Jiangsu Genscript Biotech Co., Ltd	—	7
Jiangsu Genscript Probio Biotech Co., Ltd	—	4
Nanjing Probio Biotech Co., Limited	—	3
Genscript Netherlands	—	1
Total	892	2,508

	December 31, 2023	December 31, 2022
	US$'000	US$'000
Lease liabilities		
Genscript USA Holdings Inc	—	427
Nanjing GenScript Biotech Co., Ltd.	136	205
Total	136	632

Except for lease liabilities with incremental borrowing rates between 5.14% and 7.94% repayable over 5 years, all other related party balances are unsecured and repayable on demand and interest free.

(iii) Compensation of key management personnel of the Company:

	2023	2022	2021
	US$'000	US$'000	US$'000
Equity-settled share-based compensation expense	8,037	3,582	2,907
Short-term employee benefits	2,691	2,170	1,942
Total	10,728	5,752	4,849

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, 2023

Financial assets

	Financial assets at amortized cost	Financial assets at value through profit or loss
	US$'000	US$'000
Trade receivables	100,041	—
Financial assets included in prepayments, other receivables and other assets (note 16)	56,303	—
Financial assets measured at fair value through profit and loss	—	663
Time deposits	34,703	—
Pledged deposits	357	—
Cash and cash equivalents	1,277,713	—
Total	1,469,117	663

Financial liabilities

	Financial liabilities at amortized cost	Financial liabilities at fair value
	US$'000	US$'000
Trade payables	20,160	—
Financial liabilities included in other payables and accruals (note 19)	11,944	—
Collaboration interest-bearing advanced funding	281,328	—
Lease liabilities	47,344	—
Total	360,776	—

As at December 31, 2022

Financial assets

	Financial assets at amortized cost	Financial assets at value through profit or loss
	US$'000	US$'000
Trade receivables	90	—
Financial assets included in prepayments, other receivables and other assets (note 16)	43,029	—
Financial assets measured at fair value through profit and loss	—	185,603
Time deposits	54,016	—
Pledged deposits	1,270	—
Cash and cash equivalents	786,031	—
Total	884,436	185,603

Financial liabilities

	Financial liabilities at amortized cost	Financial liabilities at fair value
	US$'000	US$'000
Trade payables	32,893	—
Warrant liability	—	67,000
Financial liabilities included in other payables and accruals (note 19)	10,960	—
Collaboration interest-bearing advanced funding	260,932	—
Lease liabilities	23,602	—
Total	328,387	67,000

32. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, pledged deposits, time deposits, financial assets included in prepayments, other receivables and other assets, trade receivables, trade 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 Company's finance department headed by the Corporate Controller is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the Corporate Controller. At December 31, 2023, the finance department analyzed the movements in the values of financial instruments and determined the major inputs applied in the valuation. The valuation was reviewed and approved by the finance manager. The valuation process and results are discussed with the directors once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The following table illustrates the fair value measurement hierarchy of the Company's financial instruments:

Asset measured at fair value:

As at December 31, 2023

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	US$'000	US$'000	US$'000	US$'000
Financial assets at fair value through profit or loss	663	—	—	663

Asset measured at fair value:

December 31, 2022

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	US$'000	US$'000	US$'000	US$'000
Financial assets at fair value through profit or loss	185,603	—	—	185,603

Financial assets measured at fair value consists of money market funds.

Liability measured at fair value:

December 31, 2022

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	US$'000	US$'000	US$'000	US$'000
Warrant liability	—	67,000	—	67,000

The following table lists the inputs to the binominal model used for the fair value valuation of warrant liability:

	December 31, 2022
Underlying stock price	$24.96
Volatility	62.3 %
Risk free rate	3.8%-4.7%
Dividend	0 %

During the year ended December 31, 2023 and 2022 there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

33. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Company's principal financial instruments comprise cash and cash equivalents, pledged deposits, time deposits, 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 Company's operations. The Company has various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The main risks arising from the Company's financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarized below.

Interest rate risk

As at December 31, 2023, the Company's exposure to the risk of changes in interest rates primarily relates to the Company's Funding Advances with a floating interest rate as disclosed in note 23 to the consolidated financial statements. As at December 31, 2023, management considered that any reasonable changes in the interest rate would not have significant impact on the interest expense from the Funding Advances. Accordingly, no sensitivity analysis for interest rate risk is presented.

Foreign currency risk

The Company has transactional currency exposures. Such exposures arise from sales or purchases by operating units in currencies other than the units' functional currencies. Approximately 5.0% in 2023, 2022 in 0.3% and 2021 in 54% of the Company's sales were denominated in currencies other than the functional currencies of the operating units making the sale.

As at December 31, 2023, 2022 and 2021, the Company had no outstanding foreign currency forward exchange contract. At present, the Company does not intend to seek to hedge its exposure to foreign exchange fluctuations. However, management constantly monitors the economic situation and the Company'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 Euro ("EUR") and RMB exchange rate against US$, with all other variables held constant, of the Company'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$'000
Year ended December 31, 2023		
If US$ strengthens against RMB	5	1,300
If US$ weakens against RMB	(5)	(1,300)
If US$ strengthens against EUR	5	(51,887)
If US$ weakens against EUR	(5)	51,887
Year ended December 31, 2022		
If US$ strengthens against RMB	5	1,314
If US$ weakens against RMB	(5)	(1,314)
If US$ strengthens against EUR	5	(1,441)
If US$ weakens against EUR	(5)	1,441
Year ended December 31, 2021		
If US$ strengthens against RMB	5	1,215
If US$ weakens against RMB	(5)	(1,215)
If US$ strengthens against EUR	5	(3,086)
If US$ weakens against EUR	(5)	3,086

Credit risk

The Company trades only with recognized and creditworthy third parties. It is the Company'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 Company's exposure to bad debts is not significant. For transactions that are not denominated in the functional currency of the relevant operating unit, the Company does not offer credit terms without the specific approval of the Head of Credit Control.

The credit risk of the Company's other financial assets, which comprise cash and cash equivalents, pledged deposits, 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 Company's exposure to credit risk arising from trade receivables and other receivables are disclosed in notes 15 and 16 to the consolidated financial statements, respectively.

Since the Company trades only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by debtor. The Company had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 15 to the consolidated financial statements.

Liquidity risk

The Company 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 Company's financial liabilities as at the end of the reporting period, based on contractual undiscounted payments, is as follows:

As at December 31, 2023

	Less than 1 years	Over 1 years	Total
	US$'000	US$'000	US$'000
Trade payables	20,160	—	20,160
Other payables	11,944	—	11,944
Collaboration interest-bearing advanced funding	—	281,328	281,328
Lease liabilities	4,703	60,088	64,791
Total	36,807	341,416	378,223

As at December 31, 2022

	Less than 1 years	Over 1 years	Total
	US$'000	US$'000	US$'000
Trade payables	32,893	—	32,893
Other payables	10,960	—	10,960
Warrant liability	67,000	—	67,000
Collaboration interest-bearing advanced funding	—	260,932	260,932
Lease liabilities	3,966	23,193	27,159
Total	114,819	284,125	398,944

Note: Pursuant to the terms of the license and collaboration agreement, the collaborator may recoup the aggregate amount of Funding Advances together with interest thereon from Company's share of pre-tax profits for the first profitable year of the collaboration program and, subject to some limitations, from milestone payments due to the Company under the Janssen Agreement. The Company's management estimated the loan will not be recouped by the collaborator within one year.

Capital management

The primary objectives of the Company's capital management are to safeguard the Company's ability to continue as a going concern and to maintain a strong credit rating and healthy capital ratios in order to support its business and maximize shareholders' value.

The Company 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 Company may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Company is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the reporting periods.

The Company 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, 2023	December 31, 2022
	US$'000	US$'000
Total liabilities	597,238	586,651
Total assets	1,848,609	1,330,963
Gearing ratio	32 %	44 %

34. SUBSEQUENT EVENT

No events have occurred subsequent to December 31, 2023 that could significantly affect these audited financial statements.

35. APPROVAL OF THE CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements were approved and authorized for issue by the Board of Directors on March 18, 2024.