UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40947

LianBio

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands **(State or other jurisdiction of incorporation or organization)**	**98-1594670** **(I.R.S. Employer Identification No.)**
103 Carnegie Center Drive, Suite 309 **Princeton, NJ** **(Address of principal executive offices)**	**08540** **(Zip Code)**

Registrant's telephone number, including area code: (609) 486-2308

Securities 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 1 ordinary share, $0.000017100448 par value per share	**LIAN**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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. ☐

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recent completed second fiscal quarter, the aggregate market value of the ordinary shares, including in the form of American Depositary Shares ("ADSs"), each representing one ordinary share, held by non-affiliates of the registrant was approximately $97.3 million, based upon the closing price of the registrant's ADSs on the Nasdaq Global Market of $2.16 as of such date. In determining the market value of the voting equity held by non-affiliates, ordinary shares of the registrant beneficially owned by each director and officer and each person who owns 10% or more of the registrant's outstanding ordinary shares have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 23, 2023, 107,161,871 ordinary shares of the registrant, par value $0.000017100448 per share, were outstanding, of which 41,306,477 ordinary shares were held in the form of ADSs. This total number of ordinary shares and total number of ordinary shares held in the form of ADSs excludes 2,057,148 ordinary shares that are held by the depositary on reserve to satisfy obligations of the registrant under the registrant's equity plans.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A for its 2023 Annual Meeting of Shareholders scheduled to be held on June 21, 2023. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about us and our industry that involve substantial risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, prospects, plans, objectives of management and expected growth, are forward-looking statements. These statements are based on our current beliefs, expectations and assumptions regarding our intentions, beliefs or current expectations concerning, among other things, the future of our business, future plans and strategies, our operational results and other future conditions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements can be identified by words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "seek," "target," "will," "would," "could," "should," "continue," "contemplate" and other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to successfully develop, gain regulatory approval for and launch commercial products in Greater China and other Asian markets;
- our ability to deliver innovative therapeutic solutions to patients and become a leading biopharmaceutical company in Greater China, including Mainland China, Hong Kong, Taiwan and Macau, and other Asian markets;
- our plans and ability to leverage data generated in our partners' global registrational trials and clinical development programs to obtain regulatory approval for and bring our current product candidates to market in our licensed territories, and our plans to maximize patient reach for each of our product candidates;
- our partners' announced plans and expectations with respect to the success, cost and timing of their product development activities, preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the timing of expected review from regulatory authorities and the period during which the results of the trials are expected to become available;
- our ability to expand our pipeline through the continued strategic in-licensing of innovative and complementary product candidates with the potential to become the new standard of care in Greater China and other Asian markets;
- our ability to successfully establish an international infrastructure, including by building a focused salesforce in China and leveraging the commercial infrastructure we create to benefit our other assets;
- our ability to establish and maintain relationships and collaborations with investors and our current and any future licensing partners that will contribute to our success in sourcing value and creating partnerships to enable us to build out a broad and clinically validated pipeline;
- our ability to design, initiate and complete any clinical trials to advance our current product candidates, including mavacamten, TP-03, NBTXR3, infigratinib, BBP-398, LYR-210, omilancor and NX-13, as well as any future product candidates, towards regulatory approval in China and our other licensed territories;
- our ability to conduct, and the timing of and costs related to, our product development activities, including any preclinical studies and related clinical trials in Greater China and other Asian markets of our current and any future product candidates, and our ability to obtain, and the timing of and costs related to, potential regulatory approval of such product candidates in Greater China and other Asian markets;
- our plans to pursue the development of certain product candidates for additional treatment indications;
- our ability to successfully utilize the data we may generate from any clinical trials we conduct in Greater China or other territories, including in conjunction with data from clinical trials conducted by our partners, to seek regulatory approval in Greater China and other Asian markets;

- our plans and ability to join our current and future partners' clinical and registrational trials and our plans and ability to initiate and complete our standalone clinical and registrational trials;
- our ability to design and implement the development strategies for our product candidates in each of our licensed territories and, where applicable, our ability to design and implement global development strategies for our product candidates in new indications in connection with our local development strategies;
- the potential for certain of our current and future product candidates to have more benign safety profiles or result in differentiated safety profiles than currently available therapeutic options;
- the size, composition and growth potential of the patient populations and markets we intend to target with our product candidates and our ability to develop and commercialize product candidates to address those patient populations and markets;
- our ability to successfully procure from our partners or other third parties, as applicable, sufficient supply of our product candidates for any preclinical studies, clinical trials or commercial use, if approved;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates and our general and administrative expenses;
- the rate and degree of market acceptance of our product candidates;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations and of any legal and regulatory developments in our licensed territories or internationally;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to license intellectual property relating to our product candidates and to comply with our existing license and collaboration agreements;
- our reliance on third parties to conduct product development, manufacturing and other services, and any agreements we have or into which we may enter with such parties in connection with the commercialization of our product candidates and any other approved product;
- our expectations regarding the time during which we will be an emerging growth company or smaller reporting company;
- the direct and indirect impact of the COVID-19 pandemic on our business, operations (including clinical trials) and the markets and communities in which we and our partners, collaborators and vendors operate;
- our estimates of our expenses, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed in "Part I—Item 1A—Risk Factors" of this Annual Report on Form 10-K.

Although we base these forward-looking statements on assumptions that we believe are reasonable when made, we caution investors that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this Annual Report on Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, those results or developments may not be indicative of results or developments in subsequent periods.

Given these risks and uncertainties, investors are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statement that we make in this Annual Report on Form 10-K speaks only as of the date of such statement, and we undertake no obligation to update any forward-looking statements or to publicly announce the results of any revisions to any of those statements to reflect future events or developments. 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. Investors should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

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 10-K, 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 potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Unless the context requires otherwise, references in this report to the "Company," "LianBio," "we," "us" and "our" refer to LianBio and its consolidated subsidiaries.

Risk factors summary

Our business is subject to a number of risks that are discussed more fully in "Part I—Item 1A—Risk Factors" of this Annual Report on Form 10-K. These risks include the following:

- Changes in the economic, political, legal and social conditions and policies of the Chinese government or in relations between China and the United States (or other countries) may materially and adversely affect our business, financial condition, results of operations, access to capital, and the market price of our American Depositary Shares ("ADSs"). Statements and regulatory actions undertaken by China's government, including the enactment of the Data Security Law of the People's Republic of China (the "Data Security Law"), as well as our obligations to comply with China's Cybersecurity Review Measures, regulations and guidelines relating to the multi-level protection scheme ("MLPS"), the Personal Information Protection Law of the People's Republic of China (the "PIPL") and any other future laws and regulations may require us to incur significant expenses and could materially affect our ability to conduct our business, accept foreign investments, list on a foreign exchange or stay listed on Nasdaq. For additional information regarding the risks associated with having the majority of our operations in China, see "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations."
- China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.
- Although the audit report included in this Annual Report on Form 10-K is prepared by U.S. auditors who are currently inspected by the Public Company Accounting Oversight Board (the "PCAOB"), there is no guarantee that future audit reports will be prepared by auditors that are completely inspected by the PCAOB and, as such, our investors may in the future be deprived of such inspections, which could result in limitations or restrictions to our ability to access the U.S. capital markets. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act (the "HFCA Act") or the Consolidated Appropriations Act, 2023 (the "CAA") if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely or the SEC identifies us as a Commission-Identified Issuer (as defined below), and as a result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities.
- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.
- The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs, and the Chinese government has indicated an intent to increase the government's oversight and control over offerings conducted overseas and foreign investment in China-based issuers, which could significantly limit or completely hinder our ability to offer ADSs to our investors, and could cause the value of our ADSs to significantly decline or become worthless. Due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business, results of operations and the market price of our ADSs.

- As of the date of this Annual Report on Form 10-K, we are not required to obtain prior approval or prior permission from the CSRC or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect for offerings of our equity securities to foreign investors. On February 17, 2023, the CSRC promulgated a new set of regulations consisting of the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the "Trial Measures") and five supporting guidelines which will come into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form. According to the Trial Measures, we may be required to submit filings to the CSRC in connection with future offerings of our equity securities to foreign investors. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. Any uncertainties and/or negative publicity regarding the aforementioned approval(s), filing or other procedure(s), the interpretation and implementation of existing laws and regulations, or any further laws, regulations or interpretations that may be released and enacted in the future could have a material adverse effect on our business and/or on the trading price of the ADSs.
- Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain.
- We have incurred significant losses since our incorporation, have not generated any revenue from product sales to date and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.
- Our business model is designed to continue to in-license additional product candidates for development. We will likely need substantial additional funding for our future in-licensing and product development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.
- We have a very limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are heavily dependent on the successful development and commercialization of our late-stage product candidates, including mavacamten, TP-03 and NBTXR3.
- All of our product candidates are still in clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially adversely affected.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.
- If we breach our licenses or other intellectual property-related agreements for our product candidates or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.
- We rely on Perceptive Advisors, LLC ("Perceptive"), our founder and a significant shareholder in our company, as a source for identifying partners from which we may in-license product candidates. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise in sourcing opportunities and our business could be substantially harmed. Perceptive and its affiliates exercise significant influence over our Company, which may limit the ability of our investors and other holders to influence corporate matters and could delay or prevent a change in corporate control. Additionally, Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our business in such a way that may not always coincide with minority ADS holders' interests.
- We rely on third parties to conduct some of our preclinical studies and clinical trials.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us, and our ability to successfully develop and commercialize any of our product candidates and technology may be adversely affected.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks investors should consider before making an investment in our securities, see "Part I—Item 1A—Risk Factors."

INDUSTRY AND MARKET DATA

Although we are responsible for all disclosure contained in this Annual Report on Form 10-K, in some cases we have relied on certain market and industry data obtained from third-party sources that we believe to be reliable. Our estimates of the addressable market for our various product candidates are derived from independent industry publications, government publications and third-party forecasts, as well as epidemiological data, including incidence and prevalence estimates of addressable populations from peer-reviewed scientific journal and medical research articles related to diagnosis and treatment of our various therapeutic indications. Certain population data used in this Annual Report on Form 10-K was calculated using information from the World Health Organization International Agency for Research on Cancer and the United Nations Population Prospectus 2019. While we are not aware of any misstatements regarding any market, industry or similar data presented herein, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Cautionary Note Regarding Forward-Looking Statements" and in "Part I—Item 1A—Risk Factors" in this Annual Report on Form 10-K.

TRADEMARKS AND SERVICE MARKS

We have applied for rights to trademarks, service marks and trade names for use in connection with the operation of our business, including, but not limited to, LianBio, 联拓 and 联拓生物. All other trademarks or service marks appearing in this Annual Report on Form 10-K that are not identified as marks owned or applied for by us are the property of their respective owners.

Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K may be listed without the ®, (TM) and (sm) symbols, but we will assert, to the fullest extent under applicable law, our applicable rights in these trademarks, service marks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

PART I

Item 1. Business

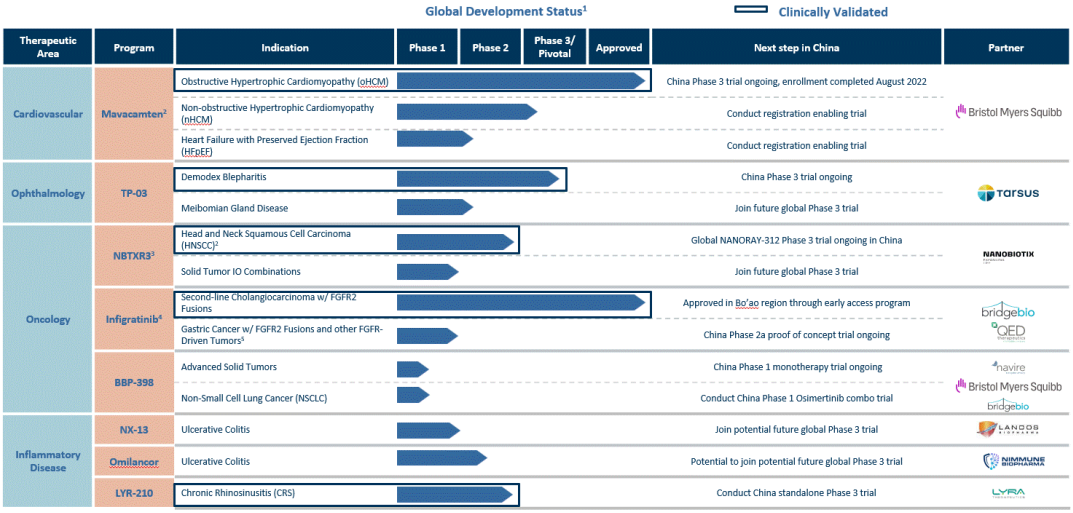
Overview

We are a clinical stage biopharmaceutical company dedicated to bringing innovative medicines to patients with unmet medical needs in Asia. Our initial focus is to in-license assets for development and commercialization in Greater China and other Asian markets. We have assembled a pipeline of eight therapeutic candidates across cardiovascular, oncology, ophthalmology, and inflammatory disease indications, each with its own distinct value proposition and the potential to drive new standards of care. With operations in China, Asia Pacific, and the United States, we have built a cross-border platform to provide our licensing partners access to our regulatory, development, and commercial expertise in China and other Asian markets. We have created a diverse, balanced portfolio of highly differentiated assets that represent our broad program scope and significant potential market opportunity across various stages of development, providing multiple avenues for value creation. We intend to continue to evaluate innovative, complementary product candidates with the potential to become new standards of care in Asia to deepen our pipeline.

We are currently conducting three registrational studies designed to support regulatory approval of our product candidates in our licensed territories, including the EXPLORER-CN trial of mavacamten in obstructive hypertrophic cardiomyopathy ("oHCM"), the LIBRA trial of TP-03 in Demodex blepharitis ("DB"), and the NANORAY-312 trial of NBTXR3 in elderly patients with locally advanced head and neck ("H&N") squamous cell carcinoma.

Today, China represents the second largest pharmaceutical market in the world, with estimated branded pharmaceutical market revenues of $174 billion in 2022, and which are expected to reach $196 billion by 2025. Recent regulatory reforms aimed at accelerating drug availability, a series of government development initiatives to support innovation and an improving reimbursement and access landscape have all increased the strategic importance of the Chinese pharmaceutical market. In addition, enhanced intellectual property protection, increasing healthcare coverage and capital inflows into life sciences have created a more favorable environment for providing access to innovative medicines. While China is becoming an increasingly critical component of biopharmaceutical companies' global development and commercialization strategies, challenges remain for Western companies to access this market. We have designed our company with fit-for-purpose cross-border infrastructure to navigate the complex regulatory and commercial landscape in China. It is our vision to serve as a gateway to China for Western biopharmaceutical companies focused on the large addressable market unlocked by these recent advances and reforms.

We are advancing a broad, robust pipeline of eight product candidates across four different therapeutic areas. We have sought to in-license programs that have established proof of concept, are highly innovative and can provide differentiated treatment options for patients both globally and in our target markets. Pending the results from our ongoing registrational clinical trials, we aspire to launch multiple commercial products and to become a leading biopharmaceutical company in Greater China and other Asian markets in the coming years. We will also continue to expand our pipeline by anchoring our therapeutic areas of focus with core assets and then building around them to drive development and future commercial and market access synergies.



1. The commercialization of each of our product candidates will require regulatory approval in the respective jurisdiction in which we intend to market such product candidate; however, obtaining and maintaining regulatory approval in one jurisdiction does not guarantee we will be successful in obtaining or maintaining regulatory approval of the product candidate in other jurisdictions that are material to the success of LianBio. For more information regarding the risks related to our business operations and clinical and regulatory strategies, see "Part I—Item 1A—Risk Factors—Risks Related to our Business and Industry."
2. Mavacamten has received FDA approval in the United States, which is not a part of our licensed territory, for the treatment of NYHA class II-III oHCM
3. NBTXR3 has received European market approval (CE mark) in the EU, which is not a part of our licensed territory, for the treatment of locally advanced soft tissue sarcoma ("STS"). At present, we are not pursuing NBTXR3 in relation to this STS indication.
4. Infigratinib has received FDA approval in the United States, which is not a part of our licensed territory, for the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with fibroblast growth factor receptor ("FGFR") 2 fusion or other rearrangement.
5. Ongoing Phase 2a gastric cancer and other FGFR-driven tumor standalone clinical trial in China. Separate investigator sponsored Phase 2 clinical trial of infigratinib in FGFR-driven tumors is ongoing in the United States.

Regulatory developments

Potential CSRC approval required

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly promulgated the Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law, pursuant to which Chinese regulators are required to accelerate rulemaking related to the overseas issuance and listing of securities, and update the existing laws and regulations related to data security, cross-border data flow, and management of confidential information. Numerous regulations, guidelines and other measures have been or are expected to be adopted under the umbrella of or in addition to the Cyber Security Law of the People's Republic of China (the "Cyber Security Law") and the Data Security Law of the People's Republic of China (the "Data Security Law"). As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

On February 17, 2023, the CSRC promulgated the Trial Measures and five supporting guidelines which will come into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form. According to the Trial Measures, we may be required to submit filings to the CSRC in connection with future offerings of our equity securities to foreign investors.

As of the date of this Annual Report on Form 10-K, we have not received any inquiry, notice, warning or sanction regarding obtaining approval, or completing filing with or other procedures in connection with previous offering of our equity securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. If it is determined in the future that the approval of, filing or other procedure with the CSRC or any other regulatory authority are required for previous offerings of our equity securities to foreign investors, or if we are required to complete relevant procedures for future offerings of our equity securities to foreign investors, it is uncertain whether we will be able and how long it will take for us to obtain the approval or complete the filing or other procedure or obtain a waiver for such procedures, despite our best efforts. If we, for any reason, are unable to obtain or complete, or experience significant delays in obtaining or completing, the requisite relevant approvals, filing or other procedures, we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in mainland China, limit our ability to pay dividends outside of mainland China, limit our operations in mainland China, delay or restrict the repatriation of the proceeds from our public offerings into mainland China or take other actions that could have a material adverse effect on our business and/or on the trading price of our ADSs. Furthermore, our ability to offer or continue to offer securities to investors in future overseas securities offerings may be significantly limited or hindered, and the value of our securities may significantly decline or be worthless.

For additional information, see "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—The approval of, or filing or other procedures with, the CSRC or other Chinese regulatory authorities may be required in connection with issuing our equity securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures. We are also required to obtain business licenses from Chinese authorities in connection with our general business activities currently conducted in China."

Other

To operate our general business activities currently conducted in China, each of our Chinese subsidiaries is required to obtain a business license from the State Administration for Market Regulation (the "SAMR"). Each of our Chinese subsidiaries has obtained a valid business license from the SAMR, and no application for any such license has been denied.

Corporate information

We are an exempted company incorporated in the Cayman Islands with limited liability under the Companies Act of the Cayman Islands on July 17, 2019. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The principal executive office of our research and development operations is located at 16F, 5 Corporate Avenue, 150 Hubin Road, Huangpu District, Shanghai, People's Republic of China, 200021. Our telephone number at this address is (021) 2308 1188. Our current registered office in the Cayman Islands is located at the offices of International Corporation Services Ltd., 2nd Floor, Harbour Place, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands. Our principal executive offices are located at 103 Carnegie Center Drive, Suite 309, Princeton, New Jersey 08540 and our telephone number is (609) 486-2308.

Dividends and other distributions

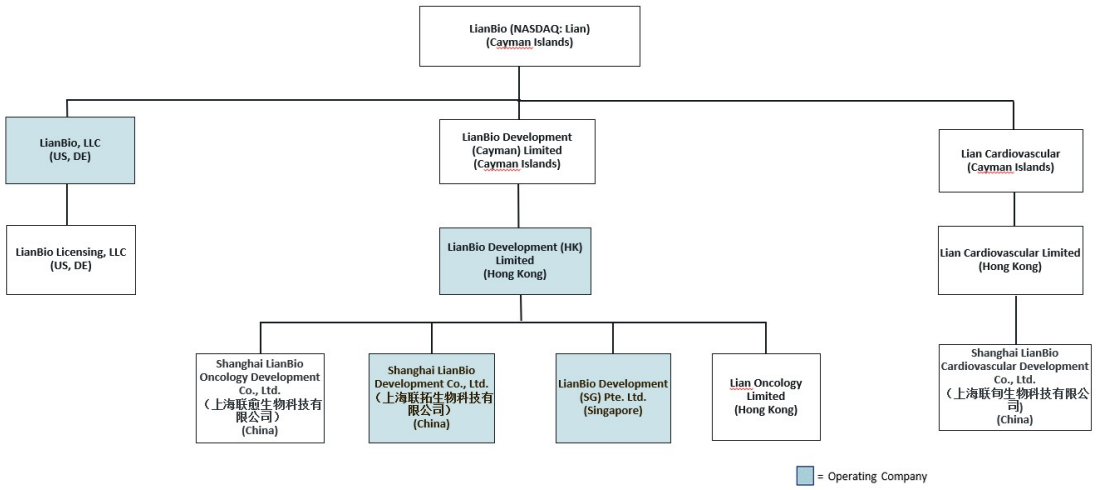
We are a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. If any of our Chinese subsidiaries incur debt on its own behalf in the future, the instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from our Chinese subsidiaries to our subsidiaries located outside of China. In addition, as of the date of this Annual Report on Form 10-K, none of our subsidiaries have ever issued any dividends or distributions to us or their respective shareholders outside of China. As of the date of this Annual Report on Form 10-K, neither we nor any of our subsidiaries have ever paid dividends or made distributions to U.S. investors. Our Chinese operating subsidiary, Shanghai LianBio Development Co., Ltd., received $5,000,000, $2,500,095, $17,499,905, $5,000,000, $9,999,995 and $14,999,995 in equity financing via capital contributions from its shareholder outside of China in February 2020, September 2020, December 2020, October 2021, December 2021 and January 2022, respectively, to fund its business operations in China. In the future, cash proceeds raised from overseas financing activities may be transferred by us to our Chinese subsidiaries via capital contribution or shareholder loans, as the case may be.

According to the Foreign Investment Law of the People's Republic of China (the "Foreign Investment Law") and its implementing rules, which jointly established the legal framework for the administration of foreign-invested companies, a foreign 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, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of China in renminbi or any foreign currency. According to the Company Law of the People's Republic of China (the "PRC Company Law") and other Chinese laws and regulations, our Chinese subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with Chinese accounting standards and regulations. In addition, each of our Chinese 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 Chinese 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 Chinese subsidiaries may allocate a portion of their after-tax profits based on Chinese accounting standards to a discretionary reserve fund.

Renminbi is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use their potential future renminbi revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our Chinese subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our Chinese subsidiaries may purchase foreign 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 Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. The Chinese government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in renminbi to fund our business activities outside of China or pay dividends in foreign currencies to holders of our securities. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries. See "Part I—Item 1A—Risks Related to Doing Business in China and Our International Operations—We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business" for a detailed discussion of the Chinese legal restrictions on the payment of dividends and our ability to transfer cash within our group. In addition, ADS holders may potentially be subject to Chinese taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes. See "Part II—Item 5—Taxation—Material Chinese Taxation" for more details.

Organizational structure

The following diagram depicts our corporate structure as of the date of this Annual Report on Form 10-K. As of the date of this report, the shares of each of our subsidiaries are 100% owned by the respective entity displayed immediately above that subsidiary. Certain warrant rights are outstanding and may be exercised in the future for equity interests in our Cayman parent entity, LianBio, and our subsidiary, Lian Cardiovascular, as described in "Note 10: Equity" in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Currently, our corporate structure contains no variable interest entities.



Within the organization, investor cash inflows have all been received by our parent Cayman entity, LianBio. Cash to fund our Chinese operations is transferred from our Cayman parent entity down through our Hong Kong entities and then into our Chinese entities through capital contributions. Cash to fund our operations in the United States is transferred from our Cayman parent entity down to our United States entity through a capital contribution.

Our pipeline

Cardiovascular

Mavacamten for the potential treatment of HCM

We have partnered with MyoKardia, Inc. ("MyoKardia," now a wholly owned subsidiary of Bristol-Myers Squibb ("BMS")) to develop and commercialize mavacamten in Greater China and other Asian markets. Mavacamten is an oral small-molecule allosteric modulator of cardiac myosin, which is approved in the United States for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) and is also being studied as a treatment for other diseases of diastolic dysfunction. Hypertrophic cardiomyopathy ("HCM") is a disease that leads to progressive deterioration of heart function and an increased risk of atrial fibrillation, stroke, heart failure and sudden cardiac arrest. There are currently no approved therapies for HCM in China. HCM can be segmented into two groups, oHCM and non-obstructive HCM ("nHCM"). In 2020, MyoKardia completed a global Phase 3 clinical trial of mavacamten for the treatment of symptomatic oHCM. This trial met its primary and all secondary endpoints and mavacamten was observed to be well-tolerated. In February 2022, we announced that the Center for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA") granted Breakthrough Therapy Designation in China for mavacamten for the treatment of patients with oHCM. In May 2022, we announced the completion of a pharmacokinetics ("PK") trial of mavacamten in healthy Chinese volunteers. The PK trial demonstrated a favorable safety, tolerability and PK profile. A single oral administration of mavacamten showed no new safety signals in Chinese subjects, and the data were comparable to those observed in the Phase 1 PK study of mavacamten conducted by MyoKardia in healthy volunteers in the United States. In August 2022, we announced that we completed enrollment of patients in a Phase 3 clinical trial of mavacamten, EXPLORER-CN, in China, and that we expect to report topline results in mid-2023. If the data are consistent with the data demonstrated in global clinical trials, we intend to use the China data in combination with data generated in global trials conducted by MyoKardia to seek regulatory approval in China. We also plan to develop mavacamten in nHCM and heart failure with preserved ejection fraction ("HFpEF").

Hypertrophic cardiomyopathy disease overview

HCM is an inherited form of cardiomyopathy mainly caused by genetic mutations that result in excessive cardiac muscle contraction and abnormally thick cardiac muscle growth. HCM is characterized by left ventricular hypertrophy unexplained by secondary causes and a nondilated left ventricle with preserved or increased ejection fraction. The histological features of HCM include hypertrophy and disarray of myocytes, cardiac muscle cells, as well as interstitial fibrosis. The hypertrophy is also frequently associated with left ventricular diastolic dysfunction.

Patients with HCM are at increased risk for developing arrhythmia, shortness of breath, chest pain, heart failure and sudden cardiac death. The most frequent arrhythmia observed is atrial fibrillation, which occurs in 22% to 32% of HCM patients. Atrial fibrillation is also a major risk factor for thromboembolic stroke. The combination of the loss of ventricular filling and the rapid ventricular contraction results in further elevations of left ventricular diastolic pressure and symptoms of heart failure. Although rare, HCM is the most common cause of sudden cardiac death in young people and athletes under the age of 35.

HCM patients can be segmented into two groups:

- ***Obstructive HCM:*** In two-thirds of HCM patients, the path through which blood exits the heart, known as the left ventricular outflow tract ("LVOT"), becomes obstructed by the enlarged and diseased heart muscle, restricting the flow of blood from the heart to the rest of the body. oHCM patients are at an increased risk of severe heart failure and death.
- ***Non-Obstructive HCM:*** Patients with nHCM do not have significant LVOT obstruction but have reduced cardiac output due to an enlarged and stiffened heart muscle. These patients can be difficult to manage medically as they often present with an advanced state of disease due to damage that accumulates before patients become symptomatic.

Most cases of HCM appear to be inherited, as family members of HCM patients are at increased risk of developing the disease. Mutations in more than a dozen genes have been linked to the development of HCM. However, in 40% of patients, the causal mutation is not known. A typical HCM patient presents with a range of symptoms, including shortness of breath, chest pain and heart palpitations. Diagnosis of HCM is generally by echocardiography, a noninvasive technique that allows key parameters such as the thickness of the heart wall, the size of the left ventricle and the output of the heart to be quantitatively and qualitatively measured. Most patients are diagnosed in middle age. We estimate there are approximately 1.1 million to 2.8 million HCM patients in China, with approximately two-thirds of patients having oHCM, and one-third of patients having nHCM.

Current standard of care for HCM

There are currently no approved pharmacologic therapies indicated for the treatment of HCM in China. Patients in China are typically prescribed one or more drugs indicated for the treatment of hypertension, heart failure or other cardiovascular disorders to address disease symptoms. These drugs, including beta blockers, such as metoprolol, and calcium channel blockers, such as verapamil, may help some patients manage the symptoms of HCM, but they do not directly address the underlying cause of disease or affect disease progression. In some countries, but not in China, disopyramide, a sodium channel blocker with significant side effects, is added if patients do not respond to other therapies.

Despite pharmacologic management, symptoms and disease burden persist for many patients, and therapeutic options are limited. For a subset of patients with advanced disease progression or more pronounced symptoms, invasive therapies may be appropriate, including use of an implantable cardioverter-defibrillator, open surgical myectomy, percutaneous alcohol septal ablation or, in rare cases, heart transplantation for end-stage HCM. However, these invasive therapies are associated with inherent risks and require expertise that is not universally available in China.

HFpEF disease overview and current standard of care

HFpEF is a disease in which the heart's ability to pump blood through the body is decreased due to the inability of the ventricle to fully relax and fill with blood. HFpEF can arise from multiple other conditions including diabetes, obesity, atrial fibrillation and high blood pressure. At a cellular level, cardiac myocytes in patients with HFpEF are thicker and shorter than normal myocytes, and collagen content is increased. Early symptoms of HFpEF include shortness of breath upon exertion and fatigue. Therapeutic management has typically been directed toward associated conditions such as hypertension and symptoms such as edema. Patients have historically been treated with standard medications for hypertension such as beta blockers or renin-angiotensin-aldosterone inhibitors, and in 2021 the United States Food and Drug Administration ("FDA") approved Novartis AG's Entresto for the treatment of HFpEF.

Approximately 41% of heart failure cases are attributed to HFpEF. We believe there are approximately four million HFpEF patients in China. In a subset of approximately 10-20% of HFpEF patients, the underlying cause of symptoms is similar to that of nHCM, and we believe mavacamten has the potential to address this underlying disease pathology in HFpEF patients.

Mavacamten development path

Mavacamten was designed to correct or address the impaired cardiac muscle contractility and relaxation that characterizes HCM by acting on cardiac myosin, a key myocyte protein, to allow the heart muscle to relax, thereby expanding the volume of the heart and enabling it to pump more blood. In 2020, MyoKardia announced results from a global Phase 3 clinical trial called EXPLORER-HCM, in which patients with symptomatic oHCM treated with mavacamten experienced statistically significant and clinically meaningful improvements in symptoms, functional status and key aspects of quality of life. In April 2022, the FDA approved mavacamten for the treatment of adults with symptomatic New York Heart Association ("NYHA") Class II-III oHCM to improve functional capacity and symptoms. We have an exclusive license to develop and commercialize mavacamten in Greater China and other Asian markets.

Results from the global EXPLORER-HCM trial

Per data published in the Lancet, the EXPLORER-HCM trial was a randomized, double-blind, placebo-controlled Phase 3 clinical trial that enrolled 251 patients with symptomatic NYHA functional Class II or III oHCM. Patients were randomized on a 1:1 basis to receive individualized once-daily dosing of mavacamten or placebo. Patients started on a dose of 5mg, with up to two opportunities for dose adjustments (to doses of 2.5mg, 5mg, 10mg or 15mg) based on a combination of residual LVOT gradient, drug plasma concentration and left ventricular ejection fraction levels. Patients were evaluated every two to four weeks for 30 weeks.

The primary endpoint for EXPLORER-HCM was a composite functional analysis designed to capture mavacamten's effect on both symptoms and cardiac function. The composite functional endpoint was defined by either (i) the achievement of a ≥1.5mL/kg/min improvement in peak oxygen consumption ("pVO_2") accompanied by an improvement of ≥1 NYHA functional class, or (ii) the achievement of a ≥3.0mL/kg/min improvement of pVO_2 with no worsening in NYHA functional class. The 30-week treatment with mavacamten resulted in a highly statistically significant outcome relative to placebo (p=0.0005) for the primary endpoint.

Additionally, mavacamten demonstrated beneficial results (p≤0.0006) for all secondary endpoints: post-exercise LVOT peak gradient, pVO_2, NYHA functional class, Kansas City Cardiomyopathy Questionnaire-Clinical Summary Score ("KCCQ-CSS") and HCM Symptom Questionnaire Shortness-of-Breath subscore.

The primary and all secondary endpoints of the EXPLORER-HCM trial were met with statistical significance (p≤0.0006 for all endpoints)
Results from the EXPLORER-HCM trial published in 2020

	Mavacamten Group (n=123)	Placebo Group (n=128)	Difference[1] (95% CI), p Value
Primary Endpoint[2]			
Either ≥1.5 mL/kg per Min Increase in pVO_2 with ≥1 NYHA Class Improvement or ≥3.0 mL/kg per Min Increase in pVO_2 with No Worsening of NYHA Class	45 (37%)	22 (17%)	19.4 (8.7 to 30.1; p=0.0005)
≥1.5 mL/kg per Min Increase in pVO_2 with ≥1 NYHA Class Improvement	41 (33%)	18 (14%)	19.3 (9.0 to 29.6)
≥3.0 mL/kg per Min Increase in pVO_2 with No Worsening of NYHA Class	29 (24%)	14 (11%)	12.6 (3.4 to 21.9)
Both ≥3.0 mL/kg per Min Increase in pVO_2 and ≥1 NYHA Class Improvement	25 (20%)	10 (8%)	12.5 (4.0 to 21.0)
Secondary Endpoints[3]			
Post-exercise LVOT Gradient Change from Baseline to Week 30, mm Hg	-47 (40), n=117	-10 (30), n=122	-35.6 (-43.2 to -28.1; p<0.0001)
pVO_2 Change from Baseline to Week 30, mL/Kg per Min	1.4 (3.1), n=120	-0.1 (3.0), n=125	1.4 (0.6 to 2.1; p=0.0006)
≥1 NYHA Class Improvement from Baseline to Week 30[4]	80 (65%)	40 (31%)	34% (22 to 45; p<0.0001)
Change from Baseline to Week 30 in KCCQ-CSS[4]	13.6 (14.4), n=92	4.2 (13.7), n=88	9.1 (5.5 to 12.7; p<0.0001)
Change from Baseline to Week 30 in HCMSQ-SoB[4]	-2.8 (2.7), n=85	-0.9 (2.4), n=86	-1.8 (-2.4 to -1.2; p<0.0001)

Note: Data are n (%) or mean (SD). HCMSQ-SoB=Hypertrophic Cardiomyopathy Symptom Questionnaire Shortness-of-Breath subscore. KCCQ-CSS= Kansas City Cardiomyopathy Questionnaire-Clinical Symptom Score. LVOT=Left Ventricular Outflow Tract. pVo_2 = Peak Oxygen Consumption. NYHA = New York Heart Association.

[1] Model estimated least-square mean differences were reported for continuous variable.

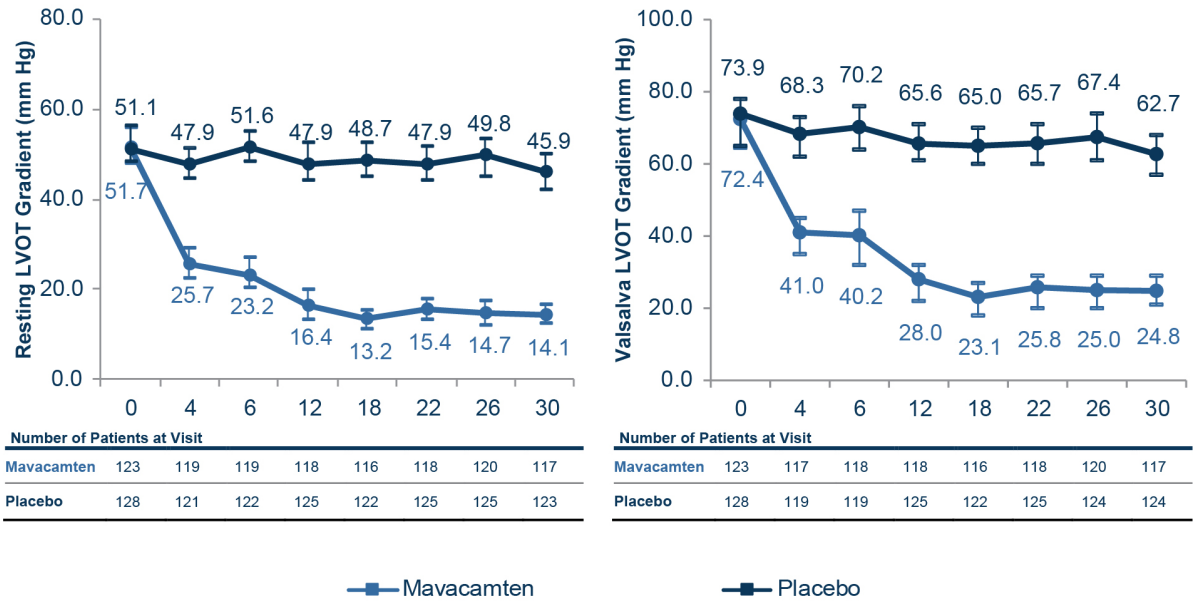
[2] Patients with a non-evaluable primary endpoint and NYHA secondary endpoint were considered as non-responders. The response rates were calculated with the N value as the denominator.

[3] N was the number analyzable for secondary endpoints based on availability of both baseline and week 30 values.

[4] Due to the smaller number evaluable for patient-reported outcome endpoints, additional post-hoc analyses compared the reasons for missing data.

Patients administered mavacamten showed rapid and sustained improvement in resting and Valsalva LVOT gradient compared with placebo. By week 30, 57% of mavacamten-treated patients had reductions in post-exercise LVOT peak gradient less than 30 mmHg compared to only 7% of patients on placebo.

Mavacamten led to rapid and sustained reductions in resting and Valsalva LVOT gradient compared to placebo



Mavacamten was well-tolerated in the clinical trial. Overall rates of adverse events ("AEs"), serious adverse events ("SAEs") and cardiac adverse events, including atrial fibrillation, were comparable for patients treated with mavacamten versus placebo. Over 97% of patients completed the trial with similar rates of discontinuation in the mavacamten treatment group relative to the placebo group.

In February 2022, BMS announced positive topline results from Phase 3 VALOR-HCM trial, evaluating mavacamten in patients with obstructive hypertrophic cardiomyopathy who are eligible for septal reduction therapy.

Our strategy to seek regulatory approval of mavacamten in China

Our goal is to bring mavacamten to market in China for the treatment of oHCM patients. To accomplish this goal, we conducted a PK trial and are currently conducting a Phase 3 trial in China to evaluate the safety, efficacy and pharmacokinetics in Chinese subjects and consistency with the corresponding data demonstrated in global trials. We completed a PK trial in May 2022 and completed subject dosing in the Phase 3 EXPLORER-CN clinical trial in August 2022.

- ***Phase 3 EXPLORER-CN clinical trial:*** We have designed our randomized, double-blind, placebo-controlled Phase 3 EXPLORER-CN clinical trial to assess the safety and efficacy of mavacamten in Chinese adults with symptomatic oHCM. We enrolled 81 patients, randomized 2:1. The primary endpoint is the change in Valsalva LVOT gradient from baseline to Week 30. Eligible patients will continue in a long-term extension treatment period.
- ***Pharmacokinetic trial in China:*** We also conducted a PK trial of mavacamten in healthy adults in China. We announced in May 2022 that a single oral administration of mavacamten showed no new safety signals in Chinese subjects, and the data were comparable to those observed in the Phase 1 PK study of mavacamten conducted by MyoKardia in healthy volunteers in the United States.

We are also planning to pursue the development of mavacamten for the treatment of nHCM and HFpEF:

- ***nHCM:*** In 2020, MyoKardia announced that a double-blind, placebo-controlled Phase 2 clinical trial of mavacamten in symptomatic nHCM patients demonstrated that patients dosed with mavacamten had significant reductions in N-terminal pro-B type natriuretic peptide and cardiac troponin I, biomarkers of cardiac stress and injury that correlate with poor prognosis in multiple cardiovascular diseases. We intend to develop mavacamten in our licensed territories for the treatment of nHCM.

- ***HFpEF:*** We believe that mavacamten has the potential to directly address a key underlying pathology in HFpEF and we intend to develop mavacamten in our licensed territories for the treatment of HFpEF.

Ophthalmology

TP-03 for the potential treatment of demodex blepharitis and meibomian gland disease

We have partnered with Tarsus Pharmaceuticals, Inc. ("Tarsus") to develop and commercialize TP-03 (lotilaner ophthalmic solution, 0.25%) in Greater China. TP-03 is a novel, topical ophthalmic formulation of lotilaner, that is an antagonist of insect and arachnid γ-aminobutyric-gated chloride channels ("GABA-Cl") and which is initially being studied for the treatment of Demodex blepharitis ("DB") and has potential therapeutic applications for Meibomian Gland Disease ("MGD"). DB is caused by an infestation of Demodex mites triggering inflammation and is characterized by a specific type of debris called "collarettes" that form at the base of the eyelash follicles, inflammation of the eyelid margin, redness and ocular irritation. We estimate DB affects approximately 43 million patients in China. TP-03 is designed to paralyze and eventually cause the death of Demodex mites through the inhibition of parasite-specific GABA-Cl channels. The active ingredient in TP-03 is lotilaner, an anti-parasitic that is part of a class of molecules named isoxazolines. Tarsus has completed two pivotal trials of TP-03 for the treatment of DB in the United States, Saturn-1 and Saturn-2. All pre-specified primary and secondary endpoints were met in Saturn-1 and Saturn-2, and complete resolution of DB signs was demonstrated in patients treated with TP-03. Tarsus submitted a New Drug Application ("NDA") to the FDA, with a target action date for the Prescription Drug User Fee Act ("PDUFA") of August 25, 2023. We plan to generate clinical data in China to be used in combination with clinical data generated in Saturn-1 and Saturn-2, if such data are positive, to seek regulatory approval in DB in Greater China. We also plan to develop TP-03 for the treatment of MGD. In November 2022, we began dosing patients in the registrational Phase 3 LIBRA trial of TP-03 in Chinese patients with DB. We expect to report topline results from the trial in the fourth quarter of 2023.

DB disease overview

Blepharitis is a disease characterized by eye inflammation, irritation, redness and lid margin disease. Symptoms can become severe if left untreated, and progress to blurred vision, missing eyelashes, corneal damage and even blindness in extreme cases. Demodex mites are a common underlying cause of blepharitis, and they are the most common ectoparasite found on humans. The Demodex parasite causes a significant portion of blepharitis cases through an infestation of the eyelash follicles. Demodex infestation may be accompanied by cylindrical dandruff on the eyelids called collarettes. The presence of collarettes is pathognomonic for Demodex infestation. Collarettes are composed of partially digested epithelial cells, mite waste and eggs, among other things. Aging is the main risk factor for DB. Relapse is common in patients who have had DB as the Demodex mites can stay in the skin of the face even after they have been eradicated from the eyelid. We estimate DB affected approximately 43 million patients in China in 2020. We believe there is a significant opportunity to raise awareness of and improve the diagnosis rate of DB through physician and patient education. The approval and introduction of an effective disease-modifying therapy may help encourage patient and physician awareness to grow the identifiable patient population.

Current standard of care for DB

DB in China is most commonly diagnosed through signs of collarettes, sparse eyelashes, missing eyelash and trichiasis, among other symptoms, which is similar to the diagnosis approach in the United States. Other symptoms of DB, including eyelid redness, itching and dry eye, are non-specific and unclear for diagnosis. Patients are often diagnosed when they visit eye care professionals for other conditions such as dry eye, cataracts or contact lens discomfort. Light microscopy and slit lamps are used to diagnose DB, and testing prevalence and accuracy are expected to increase in the coming years. There are currently no FDA-approved therapies for DB. The condition is currently treated in some cases with tea tree oil and metronidazole to repel mites, along with a topical steroid to control inflammation. Key opinion leader ("KOL") research indicates treatment typically is not efficacious, lasting two to three months, and 60% of patients relapse within six months, assuming any improvement to begin with. Many patients are not able to tolerate these treatments long-term. We believe the absence of a currently available FDA-approved treatment and a large existing patient population create a significant market opportunity in China.

MGD disease overview and current standard of care

MGD is a common eye condition where the glands do not secrete enough oil or when the oil they secrete is of poor quality. MGD is a leading cause of dry eye disease. In the early stages of the disease, patients are often asymptomatic but, if left untreated, MGD can cause exacerbated dry eye symptoms and eyelid inflammation. Symptoms include dryness, burning, itching, stickiness or crustiness, watering, light sensitivity, red eyes and foreign body sensation. Clinical signs of MGD have been shown to be correlated with infestation of a certain species of Demodex mite. We estimate 50% of diagnosed Demodex-driven MGD patients also have DB. The standard of care for the treatment of Demodex-driven MGD is similar to that of DB. Demodex-driven MGD patients are currently treated with tea tree oil and metronidazole to repel mites, along with a topical steroid to control inflammation. We believe, based on KOL research, there were an estimated 73 million Demodex-driven MGD patients in China in 2020. There are no currently approved therapies for MGD in China.

TP-03 development path

Tarsus has completed two pivotal trials of TP-03 for the treatment of DB in the United States, Saturn-1 and Saturn-2. All pre-specified primary and secondary endpoints were met in the trials, and complete resolution of DB signs was demonstrated in patients treated with TP-03. Tarsus submitted an NDA to the FDA, with a PDUFA target action date of August 25, 2023. In August 2022, Tarsus initiated a Phase 2a clinical trial of TP-03 for the treatment of MGD.

Results from pivotal Phase 2b/3 Saturn-1 clinical trial

In June 2021, Tarsus announced positive results of the pivotal Phase 2b/3 Saturn-1 trial. All pre-specified primary and secondary endpoints were met, and complete resolution of DB signs was demonstrated in patients treated with TP-03.

- 44% of patients on TP-03 achieved the primary endpoint of complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 7% on vehicle ($p<0.0001$).
- 81% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared to 23% of those on vehicle ($p<0.0001$).
- 68% of patients on TP-03 achieved mite eradication defined as 0 mites per lash at day 43, compared to 18% on vehicle ($p<0.0001$).

Additionally, significant efficacy in lid erythema (redness) was demonstrated across multiple measures including complete and clinically meaningful composite cures, and in erythema alone. Results showed 45% of patients improved erythema by one grade or more (compared to 28% of patients on vehicle, $p=0.0002$) and 19% of patients on TP-03 achieved a complete erythema cure (compared to 7% of patients on vehicle, $p=0.0001$).

TP-03 was well tolerated with a safety profile similar to the vehicle group. Additionally, most TP-03 patients (92%) reported that the drop comfort was neutral to very comfortable. There were no serious treatment-related AEs nor any treatment-related AEs leading to treatment discontinuation.

Results from pivotal Phase 3 Saturn-2 clinical trial

In May 2022, Tarsus announced positive results of the pivotal Phase 3 Saturn-2 trial. All pre-specified primary and secondary endpoints were met, TP-03 was well tolerated, and complete resolution of DB was demonstrated in patients treated with TP-03.

Primary Endpoint:

- 56% of patients on TP-03 achieved complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 13% on vehicle ($p<0.0001$).

Secondary Endpoints:

- 52% of patients on TP-03 achieved mite eradication defined as zero mites per lash at day 43, compared to 15% on vehicle ($p<0.0001$).
- 31% of patients on TP-03, as compared to 9% of patients on vehicle ($p<0.0001$), achieved complete lid erythema cure at day 43.
- 19% of patients on TP-03 achieved a complete composite cure, based on achieving both complete collarette cure and complete lid erythema cure, compared to 4% on vehicle ($p<0.0001$) at day 43.

Additional Analysis:

- 89% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared to 33% of those on vehicle ($p<0.0001$).

Safety Profile:

- Consistent with Saturn-1, Saturn-2 demonstrated that TP-03 was well tolerated with a safety profile similar to the vehicle group.
- 91% of TP-03 patients reported that the drop comfort was neutral to very comfortable.
- There were no serious treatment-related AEs nor any treatment-related AEs leading to treatment discontinuation.

Tarsus has also completed four Phase 2 clinical trials in which TP-03 achieved efficacy endpoints including collarette grade, mite density, collarette cure rate and/or mite eradication rate. TP-03 was generally well-tolerated in all four trials. Based on the strength and consistency of the TP-03 clinical data, we believe TP-03 has the potential to have a global impact.

Our strategy to seek regulatory approval of TP-03 in DB and MGD in China

We believe TP-03 has the potential to become the new standard of care for the treatment of DB, and our goal is to bring TP-03 to market for patients in China. To accomplish this goal, we are conducting the Phase 3 LIBRA clinical trial to evaluate the safety, efficacy and pharmacokinetics in Chinese patients with DB and consistency with the corresponding data demonstrated in the United States. We expect to report topline data from LIBRA in the fourth quarter of 2023.

Phase 3 LIBRA clinical trial: We have designed our randomized, double-blind, placebo-controlled Phase 3 LIBRA clinical trial to assess the safety and efficacy of TP-03 in Chinese patients with DB. We plan to enroll approximately 162 patients, randomized 1:1. The co-primary endpoints are complete collarette cure (0-2 collarettes per eyelid) and mite eradication (mite density of 0 mites per lash) at day 43. Secondary endpoints include composite cure of collarette and erythema (0-2 collarettes per eyelid and grade 0 erythema) at day 43.

We also intend to pursue the development of TP-03 in Greater China for the treatment of MGD. We plan to join any future global pivotal trial of TP-03 in MGD conducted by Tarsus. We believe that enrolling patients in China in a global Phase 3 clinical trial may expedite the global development program as well as enable us to seek regulatory approval in China.

Oncology

NBTXR3, a radioenhancer for the potential treatment of H&N cancer and other solid tumors

We have partnered with Nanobiotix S.A. (“Nanobiotix”) to develop and commercialize NBTXR3, a radioenhancer designed to be injected directly into a malignant tumor prior to standard radiotherapy (“RT”). When exposed to ionizing radiation, NBTXR3 has been shown to enhance the localized effect of RT, in our licensed territories of Mainland China, Hong Kong, Taiwan, Macau, South Korea, Singapore and Thailand. NBTXR3 is designed to increase the dose of RT delivered within the tumor without increasing the dose in surrounding healthy tissue. NBTXR3 may also prime the body’s immune response against cancer. We believe that NBTXR3 has a broadly applicable mechanism of action that has the potential to be used in conjunction with RT in the treatment of various solid tumor types. Clinical proof of concept for NBTXR3 has been demonstrated in soft tissue sarcoma, for which Nanobiotix received CE mark approval in the European Union, which is not a part of our licensed territory. Nanobiotix is currently prioritizing registration of NBTXR3 for the treatment of locally advanced H&N cancer, for which the FDA has granted Fast Track designation for the treatment of elderly patients ineligible for platinum-based chemotherapies. Additionally, in a Phase 1 clinical trial (Study 1100), NBTXR3 has shown the potential to convert patients who initially failed checkpoint inhibitor therapy into responders while also displaying a potential abscopal effect. Nanobiotix and its collaborators are currently conducting clinical trials to evaluate NBTXR3 as a potential treatment in various cancer indications. We plan to join the NBTXR3 development program by enrolling patients in China in five of Nanobiotix’s current and potential future global pivotal trials across indications and therapeutic combinations including immunotherapy, beginning with Nanobiotix’s ongoing Phase 3 NANORAY-312 clinical trial in locally advanced H&N cancer. We announced in September 2022 that we had begun enrolling patients in LianBio’s licensed territories in the NANORAY-312 clinical trial.

Radiotherapy overview

Radiotherapy is an essential component of cancer care and may be used alone or in combination with other treatments, including surgery, chemotherapy and targeted therapies. RT can cure cancer, prevent its recurrence or stop or slow its growth. Nevertheless, many cancer patients still experience progressive disease, because, among other reasons, they are not able to receive a high enough radiation dose to completely destroy their tumor without resulting in an unacceptable level of damage to surrounding healthy tissues. We believe that by easing this limitation, NBTXR3 has the potential to improve the survival rate for cancer patients.

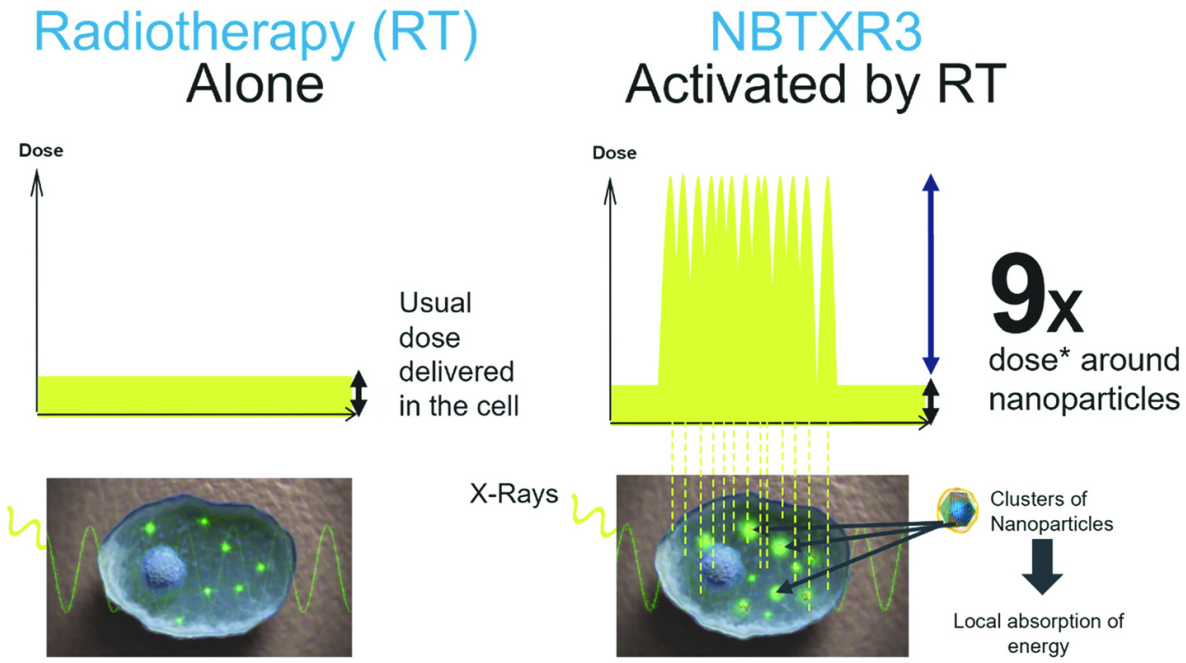
In developed countries, more than half of cancer patients receive RT as part of their treatment protocol. Currently, 20-25% of cancer patients in China are treated with RT, due in part to a shortage of equipment. In recent years, the government has issued policies aimed at expanding the availability of RT in China. We believe access to RT is improving in China due to policies supporting its use, hospital capability expansion and new training requirements. In 2018, a total of 1.3 million patients received RT in China, an increase of 37% compared to 2015.

NBTXR3 overview

NBTXR3 is an aqueous suspension of functionalized crystalline hafnium oxide nanoparticles designed for injection directly into a solid tumor prior to standard RT. NBTXR3's approach brings a universal, physics-based mechanism of action to destroy cancer cells from within.

When NBTXR3 nanoparticles are directly injected into a malignant tumor before standard RT, they are internalized through endocytosis to function as radioenhancers. The nanoparticles contain an inorganic core of crystallized hafnium oxide which has a high electron density, thus allowing the nanoparticles to absorb more energy than would otherwise be absorbed by the surrounding water molecules. Greater energy absorption generates more electrons, and, in turn, more free radicals thereby enhancing damage within the tumor cell and leading to greater cell death. NBTXR3 nanoparticles are pharmacologically inert, meaning that they do not interact with cellular or molecular systems in the absence of ionizing radiation. After radiation exposure, nanoparticles return to their inactive state, meaning that multiple RT procedures can be performed after a single NBTXR3 injection.

NBTXR3 Nanoparticles Enabling Hyper-Focused Radiation Dose Delivery



*Dose enhancement determined by Monte Carlo simulation (CEA Saclay, France).

Preclinical and early clinical data also suggest that the use of NBTXR3 activated by RT could trigger the destruction of metastatic cells through an abscopal effect, and that NBTXR3 could be effective in making tumors visible to the immune system and increasing patient responses to immunotherapy by turning “cold” tumors “hot.”

NBTXR3 received European market approval (CE mark) in 2019 for the treatment of locally advanced soft tissue sarcoma based on the results of a registrational Phase 2/3 clinical trial (Study 301) in patients with locally advanced soft tissue sarcoma of the extremity or trunk wall. Study 301 achieved its primary endpoint with a pathological complete response (<5% viable cancer cells) rate of 16.1% in the NBTXR3 arm compared to 7.9% in the control arm (p=0.0448). In the subgroup of patients with more aggressive disease (histologic grade 2 and 3), a pathological complete response was achieved in 17.1% of patients in the NBTXR3 arm compared to 3.9% in the control arm. Similar rates of SAEs were observed in the NBTXR3 and control arms (39% and 30% respectively), including the rate of postsurgical wound complications, which were the most common treatment-emergent adverse event (9% in both arms). NBTXR3 administration did not show an impact on the severity or incidence of RT-related AEs.

Head and neck cancer overview

H&N cancers include cancers of the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity and salivary glands. Tobacco use, heavy alcohol use, human papillomavirus infection, Epstein-Barr virus infection, poor oral hygiene and certain industrial exposures increase the risk of H&N cancer. Globally, the five-year survival rate for patients with H&N cancer is approximately 40-50%.

In China, we estimate that approximately 90,000 non-nasopharyngeal cancer H&N cancer patients are diagnosed each year. Due to the aging of the population, we believe H&N cancer incidence will continue to grow in China over the coming decade.

Current standard of care for locally advanced H&N cancer

Chemotherapy in combination with concomitant radiation is the current standard of care for inoperable locally advanced H&N cancer. In China, KOL research indicates most patients with inoperable locally advanced H&N cancer are eligible to be treated by RT. This presents limitations in elderly patients, for whom these cancers are more prevalent, due to their reduced ability to withstand chemotherapy and its associated AEs. Cetuximab and RT can sometimes be offered as an alternative to chemoradiation but has shown limited efficacy in elderly patients. Data presented at the Multidisciplinary H&N Cancers Symposium 2020 showed that elderly patients treated with RT alone or RT plus cetuximab had a median progression-free survival ("PFS") of 7.3 months. These patients reported poor quality of life due to high unmet medical need as well as limited availability of therapeutic options.

Other solid tumor indications

Nanobiotix is also studying NBTXR3 in other solid tumor types as both a single agent and in combination with programmed cell death protein 1 ("PD-1") inhibitors and with chemotherapy.

Phase 1 dose escalation and expansion study in head & neck cancer (Study 102)

In March 2022, Nanobiotix announced an updated analysis of overall survival ("OS") from the ongoing Phase 1 trial of NBTXR3 in elderly and frail locally advanced head and neck squamous cell carcinoma ("HNSCC") patients ineligible for cisplatin and intolerant to cetuximab (Study 102) demonstrating median OS of 17.9 months in the all-treated population (n=56) and 23.0 months in evaluable patients (n=44) from the dose expansion part of the study. NBTXR3 administration was feasible and well-tolerated overall. The most recently reported safety data, as of September 2021, showed that a total of 8 Grade 3-4 NBTXR3-related AEs were observed in 8 patients. Of these AEs related to NBTXR3, 5 SAEs were observed across 5 patients: one Grade 4 tumor hemorrhage (also related to RT), one Grade 3 stomatitis (also related to RT), one Grade 3 soft tissue necrosis (also related to RT), one Grade 4 dysphagia (also related to RT) and one Grade 4 sepsis (also related to RT and disease). Of the SAEs, one death from sepsis occurred, which the investigator assessed as possibly related to NBTXR3, RT, and cancer.

Phase 3 registrational trial (NANORAY-312)

Based on the preliminary Phase 1 data demonstrated in Study 102, Nanobiotix has designed a global pivotal Phase 3 clinical trial of NBTXR3 in elderly patients with locally advanced HNSCC who are ineligible for platinum-based chemotherapy (cisplatin). In January 2022, Nanobiotix randomized the first patient in the study in Europe. Enrollment in the United States by Nanobiotix was initiated in the fourth quarter of 2022.

NBTXR3 in immuno-oncology

Nanobiotix has generated preclinical data demonstrating that RT-activated NBTXR3 resulted in greater tumor cell death than RT alone due to higher tumor recognition by the patient's immune system.
In March 2021, Nanobiotix presented preclinical data at the American Association for Cancer Research Annual Meeting which demonstrated that a combination therapy of RT-activated NBTXR3 and checkpoint inhibitors (anti-PD-1, anti-LAG3, anti-TIGIT) significantly promoted the proliferation of CD8+ T-cells and improved local and distal tumor control, as well as increased survival rate. Moreover, survivor mice were immune to re-injections of tumor cells and maintained significantly higher levels of memory T-cells compared to control mice. This combination therapy approach also augmented antitumor response in abscopal tumors. These data suggest that NBTXR3 could modulate the immunogenicity of cancer tumor cells and that NBTXR3 could potentially be used in combination with existing immunotherapies.

Phase 1 basket trial (Study 1100)

Nanobiotix is currently conducting Study 1100, a Phase 1 prospective, multi-center, open-label, non-randomized basket trial of NBTXR3-enhanced RT in combination with anti-PD-1 immune checkpoint inhibitors nivolumab or pembrolizumab in patients with inoperable local-regional recurrent or metastatic HNSCC eligible for re-irradiation and patients with lung or liver metastases from any primary cancer that is amenable to anti-PD-1 therapy. In November 2022, Nanobiotix presented updated data from Study 1100 at the 37th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC"). Objective reduction in target lesion(s) from baseline was observed in 71.43% of evaluable patients (15/21), 67% of prior anti-PD-1 resistant patients (10/15) and 83% of anti-PD-1 naive patients (5/6). The results suggest that NBTXR3 administration was feasible and well-tolerated and the recommended Phase 2 dose was established at 33% of Gross Tumor Volume in each of the 3 cohorts.

Based on available outcomes from Study 1100, Nanobiotix initiated discussion with FDA and subsequently received preliminary feedback in the first half of 2022 regarding a potential registrational program for patients with unresectable relapsed or metastatic head and neck squamous cell carcinoma (R/M HNSCC) that developed primary or secondary resistance to previous anti-PD-1/PD-L1 therapy. Feedback from the agency suggested a single, randomized, controlled trial including a pre-specified comparative analysis of overall response rate (ORR) may be suitable to support an accelerated approval, subject to confirmation of clinical benefit based on overall survival (OS) results from the same trial.

Our strategy to seek regulatory approval of NBTXR3 in China

We believe NBTXR3 has the potential to be broadly applicable against solid tumors where RT can be used. We have the potential to join five of Nanobiotix's planned global registrational trials by enrolling patients in China. We believe that enrolling patients in China in global Phase 3 clinical trials may expedite the global development program as well as support regulatory approval in China. The initial cancer indication we are pursuing for NBTXR3 in China is locally advanced HNSCC as part of the ongoing Phase 3 NANORAY-312 clinical trial. We initiated enrollment in the NANORAY-312 trial in LianBio territories in September 2022. Additionally, we plan to join potential future pivotal studies in other solid tumor indications. We believe that NBTXR3 activated by RT has the potential to modulate antitumor immune response, and we may join Nanobiotix's future registrational trials of NBTXR3 in combination with anti-PD-1 antibodies for the treatment of certain solid tumors. We believe NBTXR3 has the potential to be used in the treatment of up to 925,000 patients in China each year across our current potential solid tumor target indications, including an estimated 25,000 patients with locally advanced H&N cancer, up to 150,000 patients with other solid tumors (with or without additional chemotherapy), and up to 750,000 patients in combination with RT and immunotherapy.

Infigratinib, a targeted FGFR1-3 inhibitor for the potential treatment of gastric cancer

We have partnered with BridgeBio Pharma, Inc. ("BridgeBio") and its affiliate QED Therapeutics, Inc. ("QED") to develop and commercialize infigratinib in Mainland China, Hong Kong and Macau for FGFR-driven tumors. Infigratinib is an orally administered, ATP-competitive, FGFR1-3 tyrosine kinase inhibitor in development for the treatment of individuals with FGFR-driven diseases. Infigratinib is approved in the United States for the treatment of patients with previously-treated, unresectable locally advanced or metastatic cholangiocarcinoma ("CCA") harboring an FGFR2 fusion or rearrangement. Infigratinib has also shown clinical activity in advanced and/or metastatic urothelial carcinoma with FGFR3 genomic alterations, and FGFR1-amplified lung cancer. We believe infigratinib has the potential to become an important treatment option for patients with FGFR-driven cancers, including those with high prevalence rates across Asia, such as gastric and related cancers.

Incidence and Mutation Rate of Gastric Cancer in the United States and China

	United States		China		
	Diagnosed Incidence	Estimated Occurrence of FGFR2 Genomic Alterations	Diagnosed Incidence	Estimated Occurrence of FGFR2 Genomic Alterations	FGFR Genomic Alterations
GC.....	~26k	4.0 %	~480k	4.6 %	FGFR2 amplification

Gastric cancer overview

Gastric cancer develops from the cancerous transformation of cells that line the stomach. There are geographic and ethnic differences in the incidence of gastric cancer around the world, suggesting that environmental factors, including *Helicobacter pylori* infection, salt intake and concentrated use of nitrates as food preservatives, have an important role in its development.

Gastric cancer is the second most common type of cancer in China and the third leading cause of cancer-related deaths. Worldwide, there are approximately 1.2 million newly diagnosed cases of gastric cancer yearly and an estimated 480,000 newly diagnosed cases annually in China. The five-year survival rate for gastric cancer in China is 27.4%. Globally, the five-year survival rate for gastric cancer patients with distant metastatic disease is 6%.

Complete surgical removal of the tumor in early-stage disease can be curative. However, by the time of diagnosis, the majority of patients have advanced disease and are treated with systemic chemotherapy. First-line chemotherapy is typically with cytotoxic agents used in combination, such as fluorouracil, cisplatin, epirubicin and oxaliplatin.

Approximately 22,000 patients with gastric cancer in China have tumors with FGFR2 gene amplification. FGFR1, FGFR2 and FGFR3 are tyrosine kinase receptors that play a pivotal role in the regulation of cell growth, with important functions in tissue repair, angiogenesis and inflammation in adults. However, given the role in these functions, FGFR dysregulation is believed to be involved in cancer pathogenesis. Genetic alterations in the FGFR pathway have been found in over 7% of all tumor types, making it one of the most frequently altered pathways. Patients with gastric cancer expressing FGFR2 gene amplification have significantly reduced survival rates compared to other patients with gastric cancer. We believe that FGFR inhibitors have the potential to provide therapeutic benefit to patients in China.

Infigratinib development path

Infigratinib has demonstrated encouraging clinical activity in chemotherapy-refractory CCA with FGFR2 fusions, advanced urothelial carcinoma with FGFR3 genomic alterations, and FGFR1-amplified lung cancer. In May 2021, the FDA approved infigratinib for the treatment of patients with previously-treated, unresectable locally advanced or metastatic CCA harboring an FGFR2 fusion or rearrangement under the accelerated approval program. We licensed infigratinib from QED as part of our collaboration with BridgeBio for development and commercialization in Mainland China, Hong Kong and Macau. We plan to pursue local development strategies in China with a focus on gastric cancer, with the possibility of leading infigratinib's global development in gastric cancer indications. We initiated a Phase 2a proof of concept clinical trial in patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 genetic amplification and other solid tumors with FGFR alterations in August 2021.

In October 2022, we reported that our partner, BridgeBio, informed us that Helsinn Healthcare SA, which holds the Truseltiq (infigratinib) NDA in the United States, is permanently discontinuing distribution of the drug and anticipates requesting withdrawal of the NDA in the United States due to business reasons. Due to the planned withdrawal of the NDA, BridgeBio informed us that it intends to close the ongoing global Phase 3 PROOF-301 clinical trial of infigratinib in first-line CCA. Consequently, we are terminating activities related to the PROOF-301 clinical trial in China and no longer plan to pursue development and commercialization of infigratinib in CCA indications in our licensed territories. Subject to physician determination, we intend to continue to support patients who are currently being treated with infigratinib under the special pilot program implemented in the Bo'ao Lecheng pilot zone in Hainan Province.

We expect to continue the ongoing Phase 2a China standalone proof of concept clinical trial of infigratinib in patients with locally advanced, metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 genetic amplification and other solid tumors with FGFR alterations. We expect to report topline data from this clinical trial in the second half of 2023.

Results from phase 2 and phase 1 clinical trials

A Phase 2 global, open-label, single arm clinical trial of infigratinib was conducted by QED in advanced CCA patients with FGFR2 fusions or translocations who previously failed gemcitabine-based chemotherapy. The primary endpoint was overall response rate. A final analysis conducted in 108 patients demonstrated an overall response rate of 23%, most of which were partial responses. One patient had a complete response. Median PFS was 7.3 months and median OS was 12.2 months.

Clinical Activity of Infigratinib in Advanced CCA

Activity Endpoints in the Full Analysis Set	**N=108**
BICR-assessed objective response rate, % (95% CI)	**23.1% (15.6-32.2)**
≤1 previous line of therapy (n=50)	34.0%
≥2 previous lines of therapy (n=58)	7.4%
BICR-assessed best overall response	
Complete response, n (%)	1 (1%)
Partial response, n (%)	24 (22%)
Stable disease, n (%)	66 (61%)
Unconfirmed complete response or partial response	12 (11%)
Progressive disease, n (%)	11 (10%)
Unknown, n (%)	6 (6%)
BICR-assessed confirmed or unconfirmed response, % (95% CI)	34.3% (25.4-44.0)
BICR-assessed disease control rate, % (95% CI)	84.3% (76.0-90.6)
BICR-assessed median duration of response (IQR), months	5.0 (3.7-9.3)
BICR-assessed median PFS (95% CI), months	7.3 (5.6-7.6)
Median overall survival (95% CI), months	12.2 (10.7-14.9)

* BICR=blinded independent central review

Infigratinib-associated toxicity was manageable, with expected on-target class effects, which include hyperphosphatemia, the most common adverse event reported in trials of infigratinib. Development of hyperphosphatemia in clinical trials of infigratinib was generally reversible and managed using standard phosphate binders.

Treatment-Emergent AEs reported in Infigratinib Phase 2 clinical trial in advanced CCA: any grade AEs > 20%

Number of Patients (%)	Any Grade
Hyperphosphatemia	83 (77%)
Stomatitis	59 (55%)
Fatigue	43 (40%)
Alopecia	41 (38%)
Dry Eye	37 (34%)
Palmar-plantar Erythrodysesthesia Syndrome	36 (33%)
Arthralgia	34 (31%)
Dysgeusia	34 (31%)
Constipation	32 (30%)
Dry Mouth	27 (25%)
Hypercalcemia	27 (25%)
Blood creatinine concentration increased	26 (24%)
Diarrhea	26 (24%)
Dry skin	25 (23%)
Decreased appetite	24 (22%)
Hypophosphatemia	24 (22%)
Vision Blurred	23 (21%)
AST concentration increased	23 (21%)
Vomiting	23 (21%)

Similar antitumor activity was reported from a Phase 1 open label trial of infigratinib conducted by Novartis AG in 67 patients with advanced, unresectable or metastatic urothelial carcinoma. In this trial, patients had an objective response rate of 25.4% when treated with infigratinib as first-line or later therapy. In addition, one patient achieved a complete response.

Infigratinib has been studied in over 700 patients to date. It has shown acceptable tolerability with expected on-target class effects, which include hyperphosphatemia, the most common adverse event reported in trials of infigratinib. Most patients with hyperphosphatemia have no symptoms. However, in rare cases, some patients develop calcium deposits in soft tissue. Hyperphosphatemia is believed to be a class-specific, mechanism-based toxicity caused by FGFR inhibition leading to dysregulation of FGF23, resulting in phosphorus retention. Development of hyperphosphatemia in clinical trials of infigratinib was generally reversible and managed using standard phosphate binders.

Our strategy for the development of infigratinib in gastric cancer in China

We initiated a Phase 2a proof of concept trial in China for FGFR2 amplified gastric cancer and other solid tumors with FGFR alterations in August 2021. The results of the Phase 2a trial will inform our development strategy moving forward. As part of our Phase 2a trial, we are including a cohort of patients with tumors that have FGFR alterations that are not related to gastric cancer, gastroesophageal junction cancer, urothelial cancer or CCA. The results of this cohort may guide our further development strategy in tumor-agnostic treatment. We expect to report topline data from this trial in the second half of 2023.

In December 2021, infigratinib was approved by the Health Commission and Medical Products Administration of Hainan Province, under the special Named Patient Program ("NPP"), for the treatment of patients with previously treated, unresectable locally advanced or metastatic CCA with a FGFR2 fusion or other rearrangement. The special NPP was enacted by the State Council of PRC as a pilot program implemented in the Bo'ao Lecheng International Medical Tourism Pilot Zone to accelerate patient and physician access to urgently needed medicines that are approved in certain jurisdictions, but not yet approved in Mainland China. Subject to physician determination, we intend to continue to support patients who are currently being treated with infigratinib under the special pilot program implemented in the Bo'ao Lecheng pilot zone in Hainan Province.

We plan to initiate a Phase 2 trial of infigratinib in locally advanced or metastatic gastric cancer with FGFR2 gene amplification in the first half of 2024 to support regulatory approval in China.

BBP-398, a SHP2 inhibitor for the potential treatment of MAPK-driven solid tumors

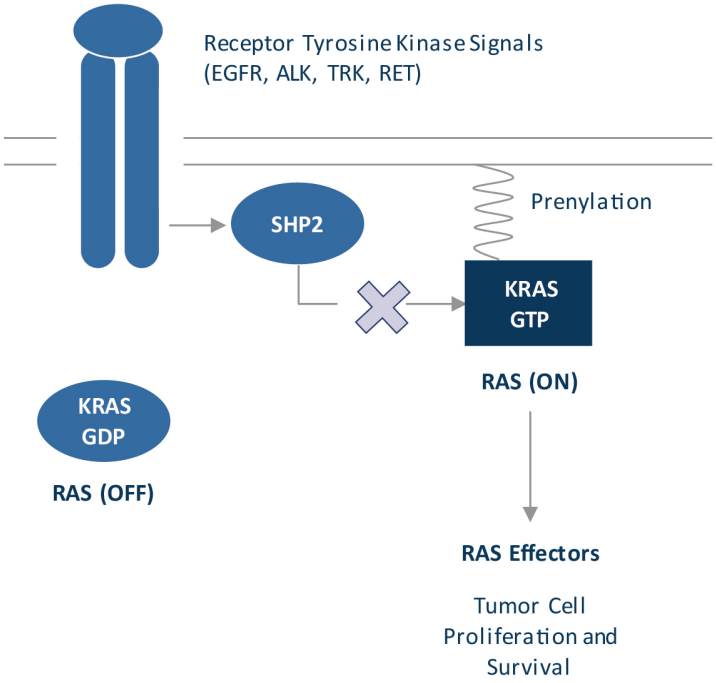
BBP-398 is an orally available allosteric inhibitor of SHP2, a tyrosine phosphatase that plays a key role in the RTK-mediated MAPK signal transduction pathway. We have partnered with BridgeBio and its affiliate Navire Pharma, Inc. ("Navire") to develop and commercialize BBP-398 in Greater China, Thailand, Singapore and South Korea. We plan to develop BBP-398 in combination with an epidermal growth factor receptor ("EGFR")-inhibitor and in combination with PD-1 inhibitors for the treatment of drug-resistant and other hard-to-treat MAPK-driven solid tumors, including non-small-cell lung carcinoma ("NSCLC"). We initiated a Phase 1 monotherapy dose escalation trial of BBP-398 in Chinese patients with advanced solid tumors in November 2022. We received clearance from the NMPA to enroll patients in China in a local Phase 1a/1b clinical trial of BBP-398 in combination with osimertinib, and we plan to initiate this study in the second half of 2023.

NSCLC disease overview

An estimated 1.8 million people die of lung cancer each year. Lung cancer is the leading cause of cancer-related death, accounting for approximately 18% of all cancer deaths globally. NSCLC accounts for 80% to 85% of lung cancer cases. There are an estimated 670,000 patients diagnosed with NSCLC each year in China.

Genetic profiling of tumors has identified a number of genes that are altered in NSCLC, including MAPK, which has been identified as one of the most important signaling pathways in promoting tumor growth in many types of cancer. Upregulation of MAPK signaling is a common mechanism of resistance to targeted therapies. SHP2 is a protein tyrosine phosphatase that positively regulates MAPK signaling. Additionally, SHP2 has a role in regulating immune checkpoint inhibition, whereby tumors can suppress patients' anti-tumor immune responses.

Signaling Through Receptor Tyrosine Kinases and RAS Converge on SHP2



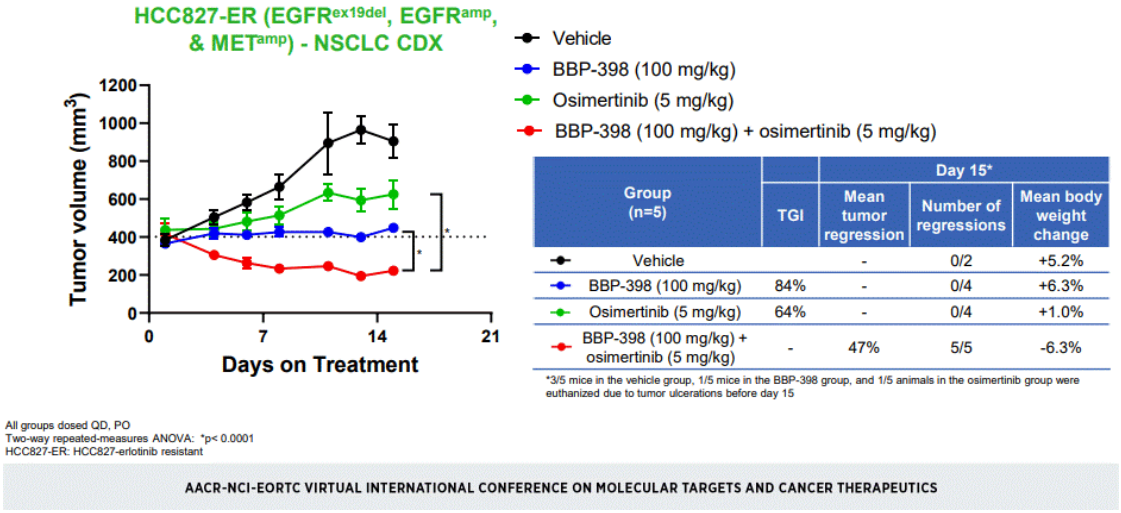
NSCLC current standard of care

Targeted therapies developed for the proteins encoded by some of the genes most commonly upregulated in NSCLC, such as EGFR and the anaplastic lymphoma kinase gene ("ALK"), have been approved and are now part of the standard of care. In China, approximately 36-39% of NSCLC cases contain mutations in EGFR, double the rate found in the United States. EGFR-targeted therapies such as osimertinib lead to clinical benefit in more than 65% of patients treated. However, almost all of these patients will acquire resistance to these therapies. Up to two-thirds of NSCLC patients who do not have EGFR or ALK gene alterations or who develop resistance to targeted therapies have tumors that express PD-L1 and are candidates for checkpoint inhibitor therapies. Despite the availability of targeted agents and immunotherapies, the prognosis in NSCLC remains poor, with an overall five-year survival rate for all patients diagnosed with NSCLC of 19%.

One method by which tumors develop resistance to therapeutic inhibitors of kinases such as EGFR is by shifting growth factor signaling to an alternate receptor. However, signaling from many of these pathways converges on SHP2, making it a highly attractive target for oncology drug development. Inhibition of SHP2 may be an effective way to restore sensitivity to kinase inhibitors by blocking signaling through common resistance pathways as confirmed by cellular and animal model experiments. We believe an inhibitor of SHP2 has the potential to be used as a targeted cancer therapy both as a monotherapy as well as in combination with multiple therapies targeted against the RAS pathway or receptor tyrosine kinases, as well as in combination with immunotherapies including PD-1 inhibitors. We believe that BBP-398's favorable tolerability profile with no major overlapping AEs with key targeted therapies positions this agent as an attractive combination partner.

BBP-398 development path

In preclinical studies, BBP-398 blocked RAS and MAPK signaling and inhibited cell growth of tumor cell lines containing EGFR amplification and KRAS activating mutations. As a monotherapy in mouse xenograft models, BBP-398 prevented tumor growth of EGFR amplified and KRAS-mutant tumors. In a model of EGFR tyrosine kinase inhibitors ("TKI")-resistant NSCLC, neither IACS-13909, a preclinical compound with a profile similar to BBP-398, nor osimertinib led to tumor shrinkage in most mice. However, the combination of IACS-13909 with osimertinib led to tumor shrinkage in all treated mice.



Group (n=5)	TGI	Day 15*		
		Mean tumor regression	Number of regressions	Mean body weight change
Vehicle		-	0/2	+5.2%
BBP-398 (100 mg/kg)	84%	-	0/4	+6.3%
Osimertinib (5 mg/kg)	64%	-	0/4	+1.0%
BBP-398 (100 mg/kg) + osimertinib (5 mg/kg)	-	47%	5/5	-6.3%

*3/5 mice in the vehicle group, 1/5 mice in the BBP-398 group, and 1/5 animals in the osimertinib group were euthanized due to tumor ulcerations before day 15

All groups dosed QD, PO
Two-way repeated-measures ANOVA: *p< 0.0001
HCC827-ER: HCC827-erlotinib resistant

AACR-NCI-EORTC VIRTUAL INTERNATIONAL CONFERENCE ON MOLECULAR TARGETS AND CANCER THERAPEUTICS

Our partner Navire is currently dosing patients in a Phase 1/1b clinical trial of BBP-398 in approximately 60 patients with advanced solid tumors. Navire announced in October 2022 that the company had begun dosing patients in a Phase 1/2 clinical trial of BBP-398 in combination with sotorasib in advanced solid tumors with the *KRAS* G12C mutation. BridgeBio has also indicated its plans to study BBP-398 in combination with nivolumab in advanced solid tumors with *KRAS* mutations.

In May 2022, BridgeBio entered into an exclusive license agreement with BMS to develop and commercialize BBP-398 outside of LianBio's licensed territories. Under the terms of the agreement, BridgeBio will lead its ongoing Phase 1 trials, and BMS will lead and fund all other development and commercial activities outside of LianBio's licensed territories.

Our clinical development strategy for BBP-398 in China

We intend to develop BBP-398 in China as part of a global development plan in partnership with Navire. Our strategy is to initially conduct an abbreviated monotherapy dose escalation trial in China followed by a monotherapy expansion arm. We then plan to lead a local trial of BBP-398 in combination with osimertinib in NSCLC. We believe the higher rate of EGFR mutations in China compared to the United States confers key advantages and we plan to leverage the anticipated large addressable patient population and augmented enrollment capabilities to inform the development strategy of BBP-398 in our licensed territories. We believe there are approximately 250,000 patients diagnosed with EGFR-mutant NSCLC in China each year.

We also plan to conduct a local Phase 1/2a trial in combination with a PD-1 inhibitor in solid tumor indications, leveraging the unique PD-1 landscape in China to seek out opportunities that otherwise may be inaccessible within the United States and other major markets. Key market advantages in China include a wide variety of potential PD-1 combination partners, a differentiated set of indications for which PD-1s are approved or in development in China and differences in epidemiology of target indications. We have prioritized indications for development based on strong scientific rationale for BBP-398/PD-1 combination. We believe there are approximately 900,000 PD-L1 positive patients (defined as those with PD-L1 expression >1%) across select high-incidence tumor types in which PD-1s are approved in China. SHP2i has the potential to impact the tumor cells directly as well as reshape the tumor microenvironment through effects on T-cells and macrophages, among other factors. We have selected several tumor types with evidence of SHP2i impacting both tumor cells and microenvironment for inclusion in an exploratory Phase 1 dose escalation trial. We may also in the future join global combination trials with inhibitors of KRAS, BRAF, MEK or CDK4/6 conducted by our partner Navire.

In November 2022, we announced that we began dosing Chinese patients in a two-part Phase 1 dose escalation and dose expansion clinical trial of BBP-398 in advanced solid tumors. Part 1 is a dose escalation to establish the recommended Phase 2 dose of BBP-398 and assess the pharmacokinetic profile of BBP-398 in Chinese patients. Part 2 is a dose expansion to examine preliminary antitumor activity in patients with advanced or metastatic EGFR-mutant NSCLC.

We also received clearance from the NMPA to enroll patients in China in a local Phase 1a/1b clinical trial of BBP-398 in combination with osimertinib. We expect to initiate this trial in the second half of 2023.

LYR-210 for the potential treatment of chronic rhinosinusitis

We have partnered with Lyra Therapeutics, Inc. ("Lyra") to develop and commercialize LYR-210 in Greater China, South Korea, Singapore and Thailand. LYR-210 is an anti-inflammatory implantable drug matrix that is designed to consistently and locally elute mometasone furoate ("MF") to inflamed mucosal sinus tissue for up to six months with a single administration. Chronic rhinosinusitis ("CRS") is an inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. CRS constitutes a substantial disease burden in Asia, with 88 million cases in Chinese adults ages 18-74 alone, an estimated 3.4 million of whom have failed currently available medical management. In December 2020, Lyra announced positive topline results from its Phase 2 LANTERN clinical trial demonstrating statistically significant improvement in symptom scores. Lyra has announced the initiation of its Phase 3 ENLIGHTEN I clinical trial of LYR-210 in adult, surgically naïve CRS patients and plans to initiate ENLIGHTEN II, the second Phase 3 clinical trial, in the third quarter of 2023. We plan to conduct a Phase 3 China standalone trial to support regulatory approval in China, leveraging the results of Lyra's Phase 3 program.

CRS disease overview

CRS is an inflammatory disease of the paranasal sinus in which the mucosa lining the sinuses become swollen and inflamed, leading to significant patient morbidities. Inflammation may be caused by infections, allergies or environmental factors, as well as structural issues such as blockages of an ostium. If the sinus drainage pathways become blocked, normal mucus drainage is prevented and damage to ciliary function may occur. The four cardinal symptoms of CRS are nasal obstruction and congestion, facial pain and pressure, nasal discharge and olfactory loss (loss of sense of smell). Other symptoms include chronic headaches, bodily pain, fatigue, sleep deprivation, depression and recurrent infections. CRS may be diagnosed when two of the four cardinal symptoms persist for 12 weeks or longer and when inflammation is confirmed via endoscopy or CT scan.

CRS has two phenotypes: CRS with nasal polyps, which are teardrop-shaped benign masses arising from the mucosa, and CRS without nasal polyps, with the non-polyp form representing approximately 70% to 90% of CRS patients. Patients with polyps develop non-cancerous polyps on the chronically inflamed surfaces, but both subgroups typically share the same symptoms and level of severity. Currently, the majority of therapies target CRS patients with polyps and there are no approved treatments for CRS patients without polyps who have failed medical therapy, creating a vast untapped market opportunity for a more effective treatment solution.

Current standard of care for CRS

Current treatments are directed towards managing the symptoms of CRS through a combination of medical management and surgical intervention techniques. The first line of therapy is medical management involving nasal saline irrigation, intranasal corticosteroid sprays and oral steroids. Antibiotics are employed for patients with an active sinus infection. It is estimated that at least 40% of CRS patients in China who are seen by ENT physicians and receive medical management remain symptomatic. In addition to its use as a first line of therapy, medical management is utilized as a maintenance therapy for patients who receive surgery.

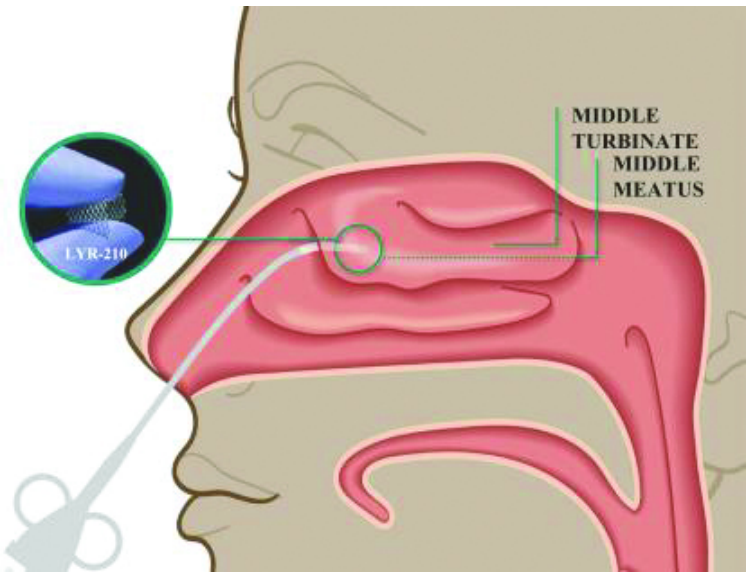
CRS patients whose symptoms persist despite medical management are generally recommended to undergo functional endoscopic sinus surgery ("FESS") or balloon sinus dilation ("BSD"), or both. FESS is a highly invasive surgery performed in the operating room, under full anesthesia, to open the blocked sinus pathways by removing inflamed tissue and bone. Approximately 65% of patients have recurrent symptoms post-FESS and up to 20% require a revision surgery. BSD is a less severe form of endoscopic sinus surgery, often used in combination with FESS, in which small balloon catheters are inserted and inflated to drain the large nasal sinuses. Although FESS and BSD can improve symptoms and quality of life, limitations remain. Neither corrects the underlying cause of the inflammation and patients who undergo either or both procedures often experience significant pain and require continued post-operative medical therapy to maintain improvements, with a high incidence of repeat symptoms and surgeries. Physicians report that many patients, when presented with sinus surgery as a treatment option, opt to forego the procedure, as some patients regard the often temporary benefits provided by surgery as not worth the expense, recovery time or use of general anesthesia.

For refractory patients with nasal polyps, who remain symptomatic following surgery, certain non-surgical options are available. A steroid-eluting implant that continuously delivers three months of low-dose MF was approved in the United States, although not in China, to treat adults with nasal polyps. However, this stent only has a two- to three-month elution profile, requiring frequent visits to an ENT's office. Monoclonal antibodies ("mAbs"), targeting type 2 inflammation, including Dupixent, Xolair and Nucala, have been approved in the United States for the treatment of adults with nasal polyps. Dupixent and Xolair have been approved in China for atopic dermatitis and for asthma, respectively, and, while not approved in China for polyps, they have been included in the treatment guidelines for CRS with nasal polyps. Nasal polyps are a condition of local inflammation and physicians prefer to treat them locally before moving on to systemic treatments, due in part to limited data regarding long-term safety of systemic biologics in the treatment of CRS. In addition to the limitations described, these treatment options are only used for the treatment of nasal polyps, leaving non-polyp patients who are refractory with no approved treatment options.

LYR-210 overview

We believe LYR-210, if successfully developed and approved, has the potential to become a treatment for patients that have failed medical management as an alternative to surgery for CRS patients, both with and without polyps. We believe it is the only product candidate that may provide up to six months of local delivery of anti-inflammatory medication with a single administration. LYR-210 is designed to enhance patient comfort and physician experience and to eliminate patient compliance issues associated with other CRS treatments, such as intranasal steroid sprays. The brief, non-invasive, in-office procedure allows for implantation without the need for surgery.

Illustration of Placement of LYR-210 in Middle Meatus



LYR-210 is an investigational local drug delivery system based on Lyra's XTreo™ platform, which is a proprietary drug delivery technology designed to locally and continuously deliver drugs to affected tissue over a sustained period of time from a single administration. It is designed to fit within, and conform to, the confined space of a surgically-naïve patient's middle meatus, a space that plays a fundamental role in drainage of the paranasal sinuses. LYR-210 consists of MF, which has been an active ingredient in a number of FDA-approved drugs. MF is embedded in biocompatible polymers to aid in the controlled and sustained delivery of the active ingredient to the sinonasal mucosal tissue from a single drug administration. LYR-210 has a tubular braid configuration with a uniform diamond pattern throughout and is 13mm in diameter and 10mm in length in the unconstrained state. It has elastic properties to promote patient comfort and is designed to be self-retaining against the mucosal tissue to allow effective drug transfer.

LYR-210 is intended to be administered bilaterally into the non-operated middle meatus by an ENT physician under endoscopic visualization via a provided, single-use applicator. It is designed for office-based administration performed with topical anesthesia. Once administered, LYR-210 is designed to gradually release MF to the inflamed mucosal tissue for up to six months from a single administration. LYR-210 can be removed at six months or earlier at the physician's discretion using standard instruments and, if needed, replaced with a new LYR-210. LYR-210 is made with bioresorbable polymers that, if left in place, gradually dissolves over time.

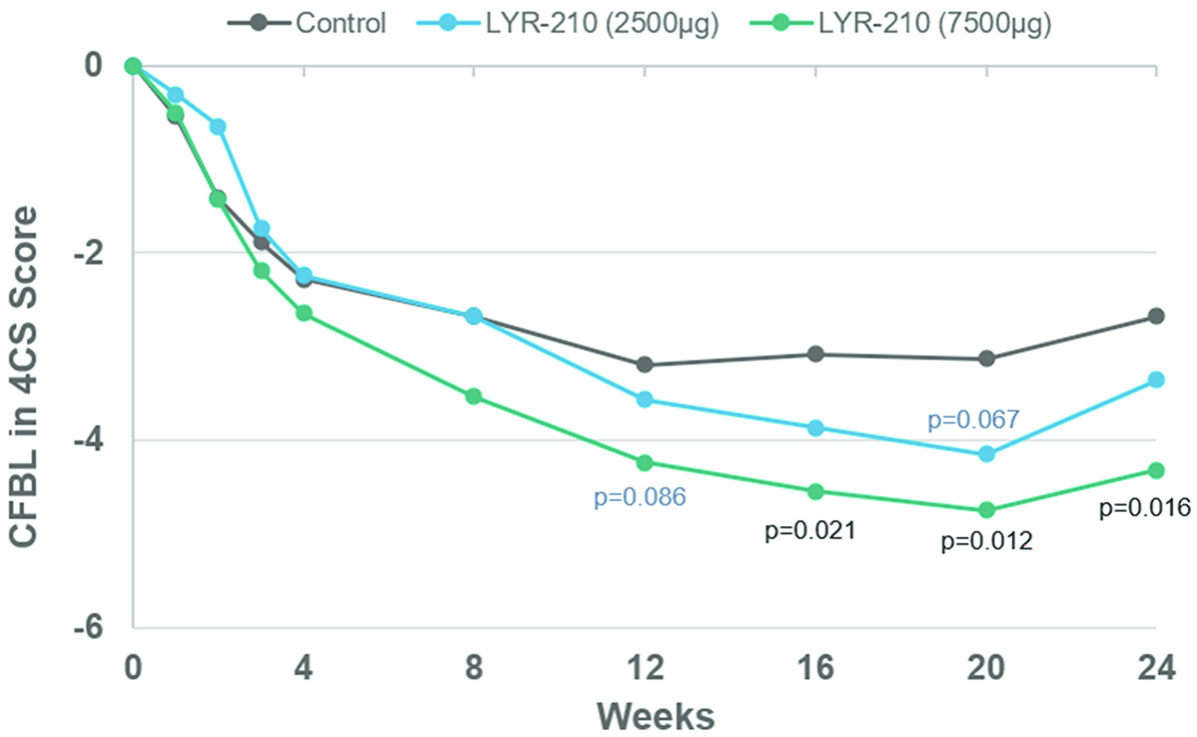
LYR-210 development path

Lyra plans to conduct two Phase 3 trials of LYR-210, ENLIGHTEN I and ENLIGHTEN II, to support regulatory approval in its territories. Lyra expects to complete enrollment in ENLIGHTEN I in mid-2023. Lyra expects to resume enrollment in ENLIGHTEN II in the third quarter of 2023 following a temporary pause in enrollment to align with internal manufacturing timelines for clinical trial supply.

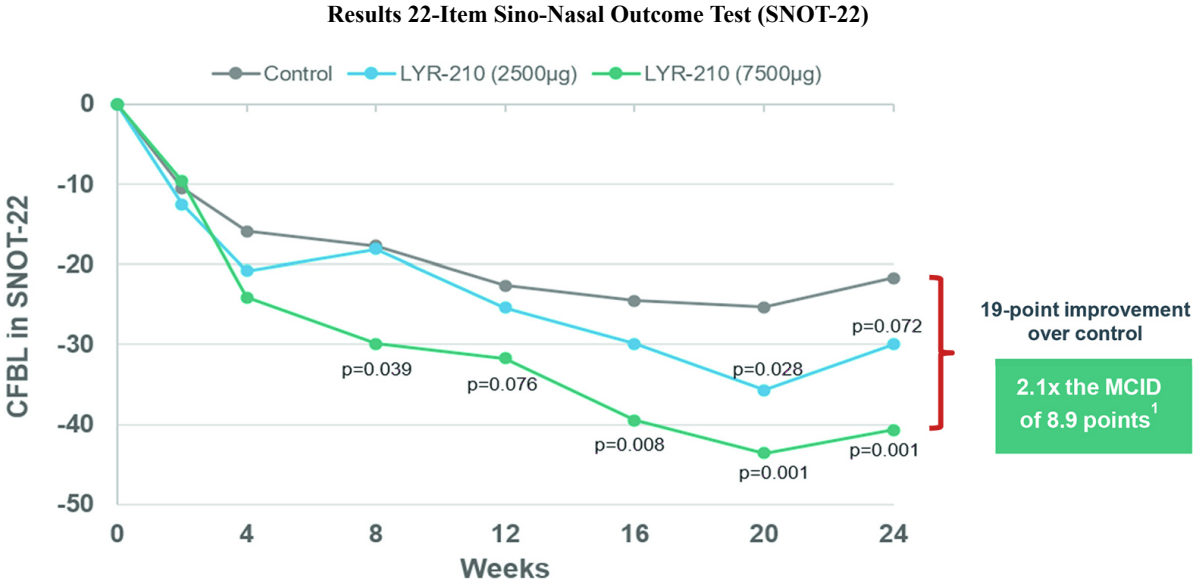
Results from phase 2 LANTERN clinical trial

Lyra presented positive topline and full results from its Phase 2 LANTERN clinical trial in December 2020 and April 2021. The LANTERN clinical trial was a randomized, sham procedure-controlled, patient-blinded study that evaluated adult patients with CRS who had failed previous medical management and had not undergone FESS. The clinical trial enrolled 67 patients, with enrollment curtailed due to the COVID-19 pandemic, across Australia, Czech Republic, New Zealand and Poland. The clinical trial consisted of three arms with a 1:1:1 randomization: an experimental arm with bilateral placement of 2,500 µg of LYR-210; an experimental arm with bilateral placement of 7,500 µg of LYR-210; and a control arm with bilateral sham procedure only. Patients were also supplied with saline for daily nasal irrigation treatment during the course of the treatment period.

Results from 4 Cardinal Symptoms Composite Score (4CS)



The primary endpoint of the clinical trial was the change from baseline in the 7-day average scores of the 4 cardinal symptoms composite score ("4CS") at week 4. The 4CS is comprised of the four cardinal symptoms of CRS, as described earlier, that are scored 0-3 with a total score of up to 12. At the 7,500 µg dose, LYR-210 achieved statistically significant improvement in the 4CS composite score in favor of the treatment arm at weeks 16 (-1.47) (p=0.021), 20 (-1.61) (p=0.012) and 24 (-1.64) (p=0.016).



Mean change from baseline (CFBL) in SNOT-22 total score. Data represents LSM. P<0.05 is considered statistically significant to control MCID = Minimal Clinically Important Difference. [1]Hopkins et al., Clinical Otolaryngology 2009, 34, 447–454.

The secondary endpoints of the LANTERN clinical trial included the Sino-Nasal Outcomes Test score (the "SNOT-22 score"), symptom improvement at week 24, sinus imaging to assess reduction in inflammation, time to treatment failure, reduction in inflammation, frequency of exacerbations and plasma PK. A single administration of LYR-210 7500 µg achieved statistically significant improvement in the SNOT-22 score in favor of the treatment arm at weeks 8 (-12.2) (p=0.039), 16 (-15.0) (p=0.008), 20 (-18.4) (p=0.001) and 24 (-19.0) (p=0.001). Furthermore, all patients, both with and without polyps, receiving the 7500 µg dose of LYR-210 achieved the minimal clinically important difference ("MCID") of 8.9 points for SNOT-22 by week 24.

LYR-210 was observed to be well-tolerated at all doses in the study, and no treatment related SAEs were reported. AEs were generally mild to moderate in nature and in line with the known safety profile of MF. While there was one subject in the 2500 µg group that experienced an SAE of increased viscosity of upper respiratory secretion, treatment-related AEs in the control and 7500 µg groups occurred at comparable rates. LYR-210 had high levels of intranasal retention out to 24 weeks. There were no AEs associated with the matrices that were dislodged.

In the LANTERN 24-week post-treatment follow-up, approximately 50% of patients experienced a durable response post-removal of LYR-210 (7500 µg), with no worsening of 4CS scores from Week 24, compared to approximately 90% of control patients who either experienced a worsening of 4CS scores or required a rescue treatment. LYR-210 continued to show strong safety post removal with no increased incidence of treatment related AEs.

Our strategy to seek regulatory approval in China

We plan to conduct a Phase 3 China standalone trial to support regulatory approval in China, leveraging the results of Lyra's Phase 3 program.

Inflammatory disease

NX-13 and omilancor for the potential treatment of inflammatory bowel disease

In 2021, we partnered with Landos BioPharma, Inc. ("Landos") to develop and commercialize NX-13 and omilancor in Greater China, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand, and Vietnam in inflammatory bowel disease ("IBD").

NX-13 is an oral, gut-restricted small molecule targeting the novel NLRX1 pathway. NX-13 works to decrease inflammasome activity and reduce reactive oxygen species, resulting in reduced differentiation of effector CD4 T-cells as well as promoting maintenance of intestinal barrier integrity. NX-13 has the potential to target moderate to severe ulcerative colitis ("UC") and Crohn's Disease ("CD"). Landos announced topline results from a Phase 1b trial of NX-13 in UC patients in August 2022. The data showed favorable safety and tolerability profiles across a range of doses, as well as signals of clinical improvement in as few as two weeks in patient symptoms and four weeks by endoscopy in exploratory endpoints.

Omilancor is an orally administered, gut-restricted small molecule activator of the lanthionine synthetase C-like protein 2 ("LANCL2") pathway, which is upstream of multiple key regulators of inflammation that can intercept autoimmune disease at multiple levels. Activation of LANCL2 enhances CD25/STAT5 signaling and increases oxidative metabolism to support the anti-inflammatory functionality of regulatory T-cells while decreasing TNF-α and IFN-γ production.

IBD overview

IBD is a chronic autoimmune inflammatory condition that primarily affects the intestines and colon. It is believed to be caused by a mix of genetic and environmental factors in which immune response is triggered from various potential stimulants such as bacteria crossing the intestinal lumen barrier. Diet and lifestyle are hypothesized to be key drivers of IBD, and IBD produces a variety of signs and symptoms ranging from mild to severe that negatively impact quality of life. The most common symptoms include abdominal pain, diarrhea, weight loss and anemia. IBD can lead to severe adverse outcomes including colectomy, disability and colorectal cancer. We estimate that there are 590,000 IBD patients in China.

IBD can be further classified into UC, which affects the large intestine (colon) and rectum, and CD, which can affect any part of the gastrointestinal tract but most commonly affects the small bowel. UC is more prevalent in ages 30-40 while CD is more prevalent in ages 20 to 30.

Both UC and CD can be classified as mild, moderate or severe, with treatments differing based on severity. In China, approximately 35% of active UC patients are classified as mild, 43% as moderate and 22% as severe. Additionally, 20% of patients experience at least one severe exacerbating symptom that requires hospitalization. In CD, approximately 30% of patients are classified as moderate and 17% as severe.

Current standard of care for IBD

The approach to diagnosis in China is similar to the United States, although the diagnosis rate is lower. A combination of fecal culture and imaging are used, and endoscopy and histopathology are deployed if the diagnosis is unclear after six months. The median time from symptom onset to diagnosis is three months for UC patients and 10 months for CD patients, and misdiagnosis is common. However, diagnosis has been improving in China, and there are now specialty medical centers established to focus on IBD, with additional treatment centers expected to be established in the future. China's IBD treatment guidelines were more recently updated in 2018 and reference global guidelines. The treatment paradigm in China is similar to that in the United States. For mild UC patients, aminosalicylic acid ("ASA") is commonly used for both induction and maintenance, while oral steroids are used for induction if ASA is not effective. Treatment of moderate UC starts with the same path as mild UC, and progresses to thiopurines if oral steroids are not effective, and chronic use may lead to multiple significant side effects. Infliximab can be used if thiopurines fail. In severe UC, IV steroids are used for the induction phase and can progress to infliximab if IV steroids are not effective. Other alternatives include cyclosporine, tacrolimus or surgery.

Similar to UC, mild CD is most often treated with ASA. Moderate CD is treated with oral steroids or thiopurines if oral steroids are not effective. Infliximab or adalimumab can be deployed if thiopurines are ineffective. In severe CD, surgery is recommended along with the aforementioned therapies.

While many therapies exist for UC and CD, unsatisfactory efficacy, side effects and inconvenient administration leave significant unmet need. There is a therapeutic gap for patients with mild to moderate disease. For these patients, steroids are not recommended for maintenance therapy due to the significant side effects, and ASA may be sub-optimal, but progressing to thiopurines may not offer an attractive benefit / risk profile. Certain biologics are associated with potentially SAEs, including leukopenia, immunosuppression, cancer, infection and death. We believe the gut-restrictive nature of omilancor and its potential to have a more benign safety profile than systemic biologics may result in a differentiated safety profile and could make it an important therapeutic option.

NX-13 development path

Landos announced the completion of a Phase 1b trial of NX-13 in UC patients in August 2022. The data showed favorable safety and tolerability profiles across a range of doses, as well as signals of clinical improvement as few as two weeks in patient symptoms and four weeks by endoscopy in exploratory endpoints.

Landos plans to conduct a Phase 2 proof-of-concept clinical trial of NX-13 in UC, which will be dose-ranging, blinded, placebo-controlled, and statistically powered. Landos expects to achieve first site activation and initiate patient enrollment in the second quarter of 2023, and expects to report topline results from the trial by the fourth quarter of 2024.

Our strategy to seek regulatory approval in China

Should NX-13 advance into Phase 3 studies, we plan to join Landos's potential future global pivotal trials of NX-13 by enrolling patients in LianBio territories.

Omilancor for the potential treatment of IBD

Omilancor is an orally administered, gut-restricted small molecule activator of the lanthionine synthetase C-like protein 2 ("LANCL2") pathway, which is upstream of multiple key regulators of inflammation that can intercept autoimmune disease at multiple levels. Activation of LANCL2 enhances CD25/STAT5 signaling and increases oxidative metabolism to support the anti-inflammatory functionality of regulatory T-cells while decreasing TNF-α and IFN-γ production.

Landos completed a global Phase 2 trial in mild-to-moderate UC, which confirmed the safety and tolerability characteristics observed in an earlier Phase 1a trial. While this study showed a clinical remission rate of over 30%, it did not reach statistical significance due to a higher-than-expected placebo remission rate of over 20%.

Landos announced in January 2023 that following an in-depth review of their pipeline and overall development plans, omilancor was poised for partnering and continued clinical development in the future and that Landos would continue to explore collaborations and other arrangements that would provide additional resources and/or capabilities to advance omilancor. In February 2023, Landos announced the transfer of omilancor to Dr. Josep Bassaganya-Riera, Ph.D., the founder of Landos who previously served as its Chairman, President and CEO, and certain affiliated individuals and entities. Dr. Bassaganya-Riera subsequently launched NImmune Biopharma, Inc. ("NImmune") to continue the development of its LANCL portfolio including omilancor.

In February 2023, we entered into an amendment to the Landos Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor, and we have entered into a direct license agreement with NImmune setting forth the terms of our continued development and commercialization of omilancor in LianBio territories.

Our strategy to seek regulatory approval in China

Should omilancor advance into Phase 3 studies, we have the option to join potential future global pivotal trials of omilancor.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. There are many companies, including biotechnology and pharmaceutical companies, engaged in developing products for the indications our product candidates are designed to treat and in the therapeutic areas we are targeting. Many of our competitors may have substantially greater scientific, research and product development capabilities as well as greater financial, marketing and sales and human resources than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Accordingly, our competitors may be more successful than we may be in developing, commercializing, and achieving widespread market acceptance for their products.

An important part of our corporate strategy is to build a diversified product pipeline by acquiring or in-licensing and developing, or partnering to license and develop, product candidates that we believe are highly differentiated and have significant commercial potential. The acquisition or licensing of product candidates is very competitive and more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages over us, as may other emerging companies that take similar or different approaches to product acquisitions. We are aware of certain companies, including Zai Lab Limited and BeiGene, Ltd., that have business models that may compete directly with our own.

We expect that our ability to compete effectively will depend on our ability to advance our existing product candidates through clinical development and regulatory approval in our licensed territories on a timely basis, license additional product candidates to build on our existing platform, establish and maintain patent and other proprietary positions in our technologies and products, and the efficacy, reliability, product safety, price and patent position of our product candidates approved for sale, if any. Our ability to achieve a leadership position in our licensed territories will depend largely upon our ability to maximize the approval, acceptance and use of our product candidates and the availability of adequate financial resources to fund our personnel costs, clinical testing and development initiatives and marketing efforts. Another key aspect of remaining competitive in the industry is recruiting and retaining leading scientists to advance our development programs and personnel with the commercial expertise to effectively market our products.

We believe our long-term competitive position will depend upon our success in developing, obtaining regulatory approval for and commercializing innovative, cost-effective product candidates that serve critical unmet needs, along with our ability to launch and market products effectively in a highly competitive environment.

For additional information about the competition that our product candidates face, see "Part I—Item 1A—Risk Factors."

License and collaboration agreements

License Agreement with MyoKardia

In August 2020, we, together with our wholly owned subsidiary LianBio Licensing, LLC, entered into an exclusive license agreement with MyoKardia (as subsequently amended, the "MyoKardia Agreement"), under which we obtained an exclusive license under certain patents and know-how of MyoKardia to develop, manufacture, use, sell, import and commercialize MyoKardia's proprietary compound, mavacamten, in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore, and in the licensed field of any indication in humans, which includes any prophylactic or therapeutic use in humans. The MyoKardia Agreement was subsequently assigned to Lian Cardiovascular and then to Lian Cardiovascular Limited. Under the MyoKardia Agreement, we agreed not to develop and commercialize certain competing products for a certain specified period.

We are obligated to use commercially reasonable efforts to develop and commercialize mavacamten in our licensed field and licensed territory under a development plan and a commercial plan.

Under the terms of the MyoKardia Agreement, we paid to MyoKardia an upfront payment of $40.0 million and paid an additional $35.0 million upon a specified financing event, which occurred on October 29, 2020. In conjunction with entering into the MyoKardia Agreement, we also granted a warrant (the "MyoKardia Warrant") to MyoKardia as partial consideration for the grant of certain licenses and rights to us pursuant to the MyoKardia Agreement. The MyoKardia Warrant is exercisable for 170,000 ordinary shares of Lian Cardiovascular, our wholly owned subsidiary, at any time and from time to time at the option of the holder. In accordance with the terms of that certain Amended and Restated Option Agreement dated as of August 10, 2020, by and among the Company, QED, MyoKardia and certain other parties thereto (the "Option Agreement"), MyoKardia had an option to (i) convert the 170,000 ordinary shares of Lian Cardiovascular into 2,924,011 of the Company's ordinary shares or (ii) convert the MyoKardia Warrant into a warrant to purchase 103,805 of the Company's ordinary shares, with an exercise price of $47.03 per share, in connection with the completion of our initial public offering. MyoKardia elected not to exercise this option and continues to hold the MyoKardia Warrant to purchase ordinary shares in Lian Cardiovascular. The Option Agreement, and MyoKardia's option to convert the MyoKardia Warrant, irrevocably terminated upon the completion of our initial public offering.

In addition, under the terms of the MyoKardia Agreement, if we achieve specified development and commercialization milestones, we will be required to pay to MyoKardia development milestone payments of up to $60.0 million and sales milestone payments based on cumulative sales of mavacamten of up to $87.5 million. In addition, if we successfully develop and commercialize mavacamten, we will pay MyoKardia tiered royalties on the sales of mavacamten at percentage rates ranging from the low- to upper-teens until the latest of the last-to-expire licensed patent covering mavacamten, the expiration of regulatory exclusivity for mavacamten, or the tenth anniversary of the first commercial sale of mavacamten, in each case on a product-by-product and region-by-region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement in Taiwan will have a twenty-year statutory expiration date in 2040 if allowed, and in each of the other licensed territories the last-to-expire patent is a Patent Cooperation Treaty ("PCT") application and will have a twenty-year statutory expiration date in 2040, provided that such PCT application would be allowed in each of such licensed territories. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. We also have entered into a clinical supply agreement and agreed to enter into a commercial supply agreement, pursuant to which we will purchase mavacamten exclusively from MyoKardia for the clinical supply and commercial supply, respectively. However, we also have the right to have a third party manufacture mavacamten in the licensed territory in certain circumstances, including if MyoKardia fails to supply certain amounts of mavacamten.

The term of the MyoKardia Agreement will depend on the patent coverage we and MyoKardia may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The MyoKardia Agreement will remain in effect until the expiration of all payment obligations, and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy, or insolvency. MyoKardia may also terminate the agreement for our failure to achieve certain key milestones, or if we challenge any of the licensed patents. We have the right to terminate the MyoKardia Agreement for convenience upon advance notice to MyoKardia.

On October 8, 2020, we entered into an amendment with MyoKardia to change the timing for the parties to enter into the development supply agreement. On January 4, 2021, we entered into a second amendment with MyoKardia to change the timing for the parties to enter into the development supply agreement and pharmacovigilance agreement; we have subsequently entered into those agreements.

License Agreement with QED Therapeutics, Inc.

In October 2019, we entered into a license agreement with QED (as subsequently amended, the "QED Agreement"), under which we obtained an exclusive, sublicensable license under certain patents and know-how (including patents and know-how that QED licensed from QED's upstream licensor) to develop, manufacture, use, sell, import, and commercialize QED's ATP-competitive, FGFR1-3 tyrosine kinase inhibitor, infigratinib, in pharmaceutical products in the licensed territory of Mainland China, Macau, Hong Kong, Taiwan, Thailand, Singapore and South Korea, in the licensed field of human prophylactic and therapeutic uses in cancer indications. In September 2020, we entered into an amendment with QED to reduce the licensed territories to include Mainland China, Macau and Hong Kong. In December 2021, we entered into a second amendment with QED to modify our development obligations with respect to certain clinical trials, and change the development milestone payments we owe to QED and the royalty rates for the tiered royalties on net sales of licensed products we will pay to QED.

Under the QED Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products in our licensed field and licensed territory under a development plan. Under the terms of the QED Agreement, we are also responsible for funding all development and commercialization of the licensed products in our licensed territory. Our rights under the QED Agreement are subject to QED's upstream licensor's license to a third party to use infigratinib in combination with such third party's proprietary compounds in clinical trials for oncology. If we (or QED) do not promptly respond to an inquiry from QED's upstream licensor about whether we intend to seek regulatory approval for and commercialize infigratinib in a particular indication, then QED's upstream licensor may grant such third party an exclusive, worldwide license commercialize infigratinib in combination with such third party's proprietary compounds in the field of oncology.

Under the terms of the QED Agreement, we made an upfront payment of $10.0 million. We also granted three warrants (collectively, the "QED Warrants"), valued at $1.0 million, to QED, exercisable for an aggregate of 100,000 ordinary shares of Lian Oncology, our wholly owned subsidiary, at an exercise price of $0.0001 per share. The QED Warrants subsequently vested and each underlying warrant was exercisable at any time and from time to time at the option of the holder. Pursuant to the Option Agreement, QED had an option to convert the QED Warrants into a warrant to purchase a certain number of our ordinary shares. On October 5, 2021, QED exercised its option to convert the QED Warrants. Accordingly, on October 18, 2021, we issued to QED a warrant to purchase 347,569 of our ordinary shares at an exercise price of $0.000017100448 per share and, concurrently with such issuance, the QED Warrants were deemed to be performed and settled in full and were irrevocably terminated.

In addition, under the terms of the QED Agreement, we will be required to pay QED development milestone payments of up to $7.0 million if we achieve specified development milestones, and sales milestone payments of up to $87.5 million if we achieve specified commercialization milestones. Additionally, if we successfully develop and commercialize the licensed products, we will pay QED tiered royalties on net sales of licensed products at the greater of (a) percentage rates in the mid- to high-teens on the net sales of the licensed products, or (b) the applicable rate payable under QED's agreement with its upstream licensor (capped in the mid-teens), until the latest of the last-to-expire licensed patent, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement is a Chinese priority application and will have a twenty-year statutory expiration date no later than 2043 in each licensed territory, provided such Chinese priority application will be converted to a non-provisional PCT application, enter each of the licensed territories and be allowed therein. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. We also entered into a clinical supply agreement and will enter into a commercial supply agreement pursuant to which we will purchase licensed products from QED or its assignee. We also have the right to manufacture licensed products in the licensed territory for development and commercialization of the licensed products in the licensed territory and licensed field.

The term of the QED Agreement will depend on the patent coverage we and QED may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The QED Agreement will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. We have the right to terminate the QED Agreement for convenience at any time upon advance notice to QED, and QED may terminate the agreement if we challenge any of the licensed patents.

In October 2020, we, together with our wholly owned subsidiary, LianBio Licensing, LLC, entered into a novation agreement with QED, pursuant to which the QED Agreement was novated and transferred from us to our wholly owned subsidiary LianBio Licensing, LLC. The QED Agreement was subsequently assigned to Lian Oncology and then to Lian Oncology Limited.

License Agreement with Navire

In August 2020, we, together with our wholly owned subsidiary, LianBio Licensing, LLC, entered into an exclusive license agreement with Navire (as subsequently amended, the "Navire Agreement"), under which we obtained an exclusive, sublicensable license under certain patents and know-how of Navire to develop, manufacture, use, sell, import and commercialize Navire's proprietary SHP2 inhibitor, BBP-398 (formerly known as IACS-15509) in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand, Singapore, and South Korea, in the licensed field of diagnostic, prophylactic, palliative, and therapeutic uses or indications in humans. We also have certain option rights to take licenses to certain compounds or products that Navire or its affiliates may acquire during the term of the Navire Agreement to develop combination products or therapies in combination with the licensed compound. The Navire Agreement was subsequently assigned to Lian Oncology and then to Lian Oncology Limited.

Under the Navire Agreement, each party agreed not to develop and commercialize certain competing products for specified time periods. This obligation also extends to certain affiliates of each party.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory under a development plan.

We also have the right to request to participate in certain clinical studies conducted by Navire intended to support development of licensed products outside of the licensed territory. If we do participate in such studies, we would include clinical study sites within the licensed territory and be responsible for the costs of such studies for the licensed territory.

We also have the right to conduct our own local combination study for the licensed products within the licensed territory. Navire has the option to participate in such combination study and obtain a license to the resultant data in exchange for being responsible for a portion of the costs of such study.

Under the terms of the Navire Agreement, we made an upfront payment of $8.0 million, as well as an additional $8.5 million upon the occurrence of a specified milestone event, which occurred on June 29, 2021. We will be required to pay Navire development milestone payments of up to $24.5 million if we achieve specified development milestones, including the $8.5 million milestone payment referenced above, and sales milestone payments of up to $357.6 million if we achieve specified commercialization milestones. In addition, if we successfully develop and commercialize the licensed products, we will pay Navire tiered royalties on net sales of licensed products at percentage rates ranging from approximately 5-15% on the net sales of the licensed products until the latest of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement will have a twenty-year statutory expiration date in 2039 in Mainland China, Hong Kong, Taiwan, Thailand, Singapore, and South Korea, if allowed. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. We have agreed to enter into separate supply agreements pursuant to which we will purchase licensed products exclusively from Navire. We also have the right to manufacture licensed products in the licensed territory for development and commercialization of the licensed products in the licensed territory and licensed field.

The term of the Navire Agreement will depend on the patent coverage we and Navire may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The Navire Agreement with Navire will remain in effect until the expiration of all payment obligations, and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy, or insolvency. In addition, we have the right to terminate the agreement for convenience upon advance notice to Navire, and Navire may terminate the agreement if we challenge any of the licensed patents. Upon termination of the Navire Agreement, we must grant to Navire an exclusive license under certain of our intellectual property to develop, manufacture, and commercialize the licensed products in the licensed territory.

In September 2020, we entered into two amendments with Navire to change the timing of the upfront payment, and to include the chemical structure for the licensed compound as an exhibit to the Navire Agreement. In December 2020, we entered into an amendment with Navire to change the timing for the parties to enter into the pharmacovigilance agreement and we have subsequently entered into such agreement.

Pfizer Strategic Collaboration

In November 2020, we entered into a strategic collaboration agreement (the "Pfizer Agreement") with Pfizer, pursuant to which Pfizer agreed to contribute up to $70.0 million of restricted, non-dilutive capital (the "Funds"), $20.0 million of which was paid upfront, toward our in-licensing and co-development activities in Greater China. Under the Pfizer Agreement, Pfizer and we will form a joint collaboration committee to discuss potential third party in-license opportunities and development and commercialization of our products in Greater China for up to five products. In the event we seek to engage a third-party commercialization partner with respect to the commercialization of our future products in Greater China, Pfizer will have a right to opt into such product. Upon opting in, a portion of the Funds will become available for our use for development and commercialization costs of such product ("Opted-In Product") and Pfizer will thereafter have a right of first negotiation and right of last refusal ("Options") to obtain the commercialization rights of such Opted-In Product in Greater China, in each instance for additional, separate financial consideration, further details of which will be separately agreed and set forth in a separate commercialization agreement to be executed between us and Pfizer at such time (each, a "Commercialization Agreement"). During the collaboration, Pfizer may provide in-kind support to us for marketing, development and regulatory activities.

The term of the Pfizer Agreement will depend on the status and progress of the collaboration activities of the parties. The Pfizer Agreement will remain in effect until the later of (a) the date on which we enter into our fifth Commercialization Agreement with Pfizer and (b) the date on which Pfizer has fully paid the Funds to us and all such amounts have become available for our use pursuant to the Pfizer Agreement. The Pfizer Agreement may be early terminated by either party for the other party's uncured material breach and Pfizer also has the right to terminate the Pfizer Agreement for convenience upon advance notice to us. Under certain termination scenarios, Pfizer may opt to retain its Options with respect to existing Opted-In Products, in which case its obligation to contribute the Funds with respect to such Opted-In Products will survive termination. Under other termination scenarios, Pfizer will not retain its Options with respect to existing Opted-In Products but may remain obligated to contribute Funds up to an amount necessary to cover certain development costs of such Opted-In Products for a limited period of time. In December 2021, the Pfizer Agreement was assigned to LianBio Development (HK) Limited.

In December 2022, we entered into a commercial agreement with Pfizer (the "Pfizer Commercial Agreement") with respect to sisunatovir as the first Opted-in Product under the Strategic Collaboration Agreement. Pursuant to the Pfizer Commercial Agreement, we assigned and transferred our development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore to Pfizer. We received a $20.0 million upfront payment, which was released as part of previously restricted cash paid by Pfizer to us in 2020 pursuant to the Strategic Collaboration Agreement. In addition, we are eligible to receive up to $135.0 million in potential development and sales milestones contingent on sisunatovir achieving a specified regulatory milestone event prior to the end of October 2035 and specified net sales milestone events. We are further entitled to receive tiered payments in the low single digits on a percentage of net sales of sisunatovir in the territory. Pfizer will lead all development and commercial activities and assume all costs in the territory, and will waive LianBio's milestone payment and royalty payment obligations previously due to ReViral pursuant to the Co-Development and License Agreement dated March 1, 2021 by and between LianBio and ReViral, which was superseded in its entirety by the Pfizer Commercial Agreement.

License Agreement with Nanobiotix

In May 2021, we entered into a license, development and commercialization agreement with Nanobiotix (the "Nanobiotix Agreement"), under which we obtained an exclusive license under certain patents and know-how of Nanobiotix with certain rights to sublicense, to develop and commercialize Nanobiotix's proprietary product NBTXR3 in the territory of Mainland China, Macau, Hong Kong, Thailand, Taiwan, South Korea and Singapore, in the licensed field of use of a product activated by RT in oncology. Under the Nanobiotix Agreement, both parties agreed not to develop, manufacture or commercialize competing products in the licensed territory, subject to customary exceptions.

We are obligated to use commercially reasonable efforts to develop, in accordance with a development and regulatory plan, and commercialize the licensed products in the field and in the licensed territory. We will participate in a global Phase 3 registrational study in H&N cancer for the licensed product and four additional registrational studies across indications and therapeutic combinations. We are obligated to use commercially reasonable efforts to enroll a certain percentage of study patients in the territory in such studies.

We agreed to purchase all licensed products for development and commercialization purposes from Nanobiotix. The parties agreed to execute, within a certain period following the execution of the Nanobiotix Agreement, a separate supply agreement for supply of licensed products in the licensed territory and we have subsequently entered into the clinical supply agreement with Nanobiotix. Under certain specified circumstances, we may request the appointment of a third-party contractor to be mutually agreeable to both LianBio and Nanobiotix for manufacturing licensed products for use in development and commercialization purposes in the territory.

Under the terms of the Nanobiotix Agreement, we paid to Nanobiotix an upfront payment of $20.0 million. If we achieve specified development and sales milestones events, we may be required to make further milestone payments up to $65.0 million in development milestones and up to $155.0 million in commercial milestones to Nanobiotix. In addition, if we successfully develop and commercialize the licensed products, we will pay Nanobiotix tiered royalties of 10-13% of net sales of the licensed products until the latest of the last-to-expire valid claim of a Nanobiotix patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or a the tenth anniversary of the first commercial sale of the licensed product, in each case on a licensed product-by-licensed product and country-by-country basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement will be from a PCT application filed in 2021. The PCT application will have a twenty-year statutory expiration date in 2041 in each of the licensed territories, provided such PCT application would be extended or filed to each licensed territory through national phase and be allowed therein. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. Therefore the term of the Nanobiotix License will depend on the patent coverage we and our partners may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory.

The Nanobiotix Agreement will remain in effect until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or insolvency. If we have a right to terminate for Nanobiotix's material breach, we may elect, instead, to have the agreement continue with a specified reduction to all milestone and royalty payments owed by us. We may also terminate the Nanobiotix Agreement upon a specified notice period if Nanobiotix undergoes a change of control and, under that circumstance, we agree to complete our development activities in support of any ongoing global trial in accordance with the then-current global development plan. Nanobiotix may also terminate the agreement if we challenge any of the licensed patents or if we are acquired by a third party with a competing product and fail to meet certain commercialization benchmarks thereafter. Upon termination of the Nanobiotix Agreement with respect to one or more countries in the territory, we agree to grant to Nanobiotix a fully-paid, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, under any and all party-inventions and patents claiming such party-inventions controlled by us or our affiliates that are necessary or reasonably useful for Nanobiotix to develop, manufacture, and commercialize the licensed product in the terminated territory.

License Agreement with Tarsus

In March 2021, we entered into a development and license agreement with Tarsus (the "Tarsus Agreement"), under which we obtained an exclusive license under certain patents and know-how of Tarsus to develop, commercialize, make and have made (under certain conditions), use, offer for sale, sell and import Tarsus's proprietary product, TP-03, in the licensed territory of Mainland China, Hong Kong, Macau and Taiwan in the licensed field of treatment of Demodex blepharitis and Meibomian Gland Disease in humans. We also obtained a non-exclusive license, under certain conditions, to make and have made the licensed products outside the territory for exploitation in the field and in the territory. Under the Tarsus Agreement, we agreed not to exploit any competing product in the licensed territory.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. We agreed to achieve certain development milestones by specified deadlines that may be extended by paying an extension fee, creditable against subsequent development milestone payments if achieved.

Under the terms of the Tarsus Agreement, we paid to Tarsus an upfront payment of $15.0 million and a second payment of $10.0 million, as well as an additional $30.0 million upon the occurrence of specified milestone events which occurred during 2021. We also issued three warrants (collectively, the "Tarsus Warrants") to Tarsus exercisable for 125,000 ordinary shares in Lian Ophthalmology, our wholly owned subsidiary, representing 12.5% of the fully diluted equity of Lian Ophthalmology at fair market value as of the date of the transaction. The first of the Tarsus Warrants (the "first tranche") became exercisable for 41,666 ordinary shares of Lian Ophthalmology at an exercise price of $109 per share in June 2021 as a result of the achievement of a specified milestone event. Tarsus also had an option to convert the ordinary shares of Lian Ophthalmology underlying the first tranche into 78,373 of our ordinary shares. The second and third of the Tarsus Warrants (the "second tranche" and the "third tranche," respectively) were to become exercisable upon the achievement of certain milestone events for 41,667 ordinary shares of Lian Ophthalmology, at an exercise price of $109 per share. Tarsus also had an option, subject to the achievement of the same milestone events, to convert each of the second tranche and the third tranche into warrants exercisable for 78,373 of our ordinary shares, at an exercise price of $0.000017100448, in each case in accordance with the terms and conditions of the Option Agreement dated as of October 18, 2021 by and among the Company, Lian Ophthalmology and Tarsus (the "Tarsus Option Agreement"). On October 18, 2021, Tarsus exercised its options to convert the Tarsus Warrants under the Tarsus Option Agreement and we subsequently issued to Tarsus 78,373 of our ordinary shares and two warrants to purchase an aggregate of 156,746 of our ordinary shares at an exercise price of $0.000017100448 per share. Concurrently therewith, the Tarsus Warrants were irrevocably terminated. The two outstanding warrants expire on October 17, 2031.

In addition, if we achieve specified development and commercialization milestones, we may be required to pay milestone payments of up to $75.0 million (including the $30.0 million milestone payments referenced above) and $100.0 million, respectively, to Tarsus. In addition, if we successfully develop and commercialize the licensed products, we will pay Tarsus tiered royalties at percentage rates ranging from the low- to high-teens on the net sales of the licensed products until the latest of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or a the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement in Taiwan will have a twenty-year statutory expiration date in 2029, and in each of the other licensed territories the last-to-expire patent is a PCT application and will have a twenty-year statutory expiration date in 2040, provided that such PCT application would enter each of such other licensed territories and be allowed therein. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. We also agreed to enter into separate supply agreements pursuant to which we will purchase licensed products exclusively from Tarsus. However, we also have the right to have a third party manufacture the licensed products for the licensed territory in certain circumstances, including if Tarsus fails to supply certain amounts of licensed product.

The term of the Tarsus Agreement will depend on the patent coverage we and our partners may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The Tarsus Agreement will remain in effect until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or bankruptcy. Tarsus may also terminate the agreement if we challenge any of the licensed patents. We have the right to terminate the Tarsus Agreement for convenience upon advance notice to Tarsus.

Upon termination of the Tarsus Agreement, we must assign and transfer to Tarsus certain product materials related to the licensed products that were created or generated under the agreement.

License Agreement with Landos

In May 2021, we entered into a license and collaboration agreement with Landos (the "Landos Agreement"), under which we obtained an exclusive license with the right to sublicense to affiliates and specified third parties under certain patents and know-how of Landos to develop, manufacture, commercialize and otherwise, make and have made, use, offer for sale, sell, have sold, and import Landos's proprietary compounds, omilancor (formerly known as BT-11) and NX-13, in the licensed regions of Mainland China, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand and Vietnam. We also obtained an exclusive right of negotiation to obtain an exclusive license under applicable patents and know-how of Landos to exploit certain additional products with the same mechanism of action as any licensed compound that are being developed by Landos for use outside the licensed territory. Under the Landos Agreement, both parties agreed not to develop, manufacture, or commercialize competing products in the licensed territory, subject to customary exceptions.

In February 2023, we entered into an amendment to the Landos Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor to NImmune. As a result, the Landos Agreement will relate only to NX-13, and we have entered into a direct license agreement with NImmune setting forth the terms of our continued development and commercialization of omilancor in the above-mentioned licensed regions, as further detailed below.

We granted to Landos a non-exclusive license under any inventions and discoveries that we invent relating to the licensed product, for use in the development, manufacture, commercialization, and exploitation of the compound and licensed product anywhere in the world outside of the territory.

We are obligated to use commercially reasonable efforts to develop, seek regulatory approval for and, following receipt of marketing authorization, commercialize the licensed product in the field and in the licensed territory. Should we decide to participate in a global Phase 3 clinical trial for the licensed product, then we are obligated to use commercially reasonable efforts to enroll a certain percentage of study patients in the territory.

We agreed to purchase all licensed product for development and commercialization purposes from Landos. The parties agreed to execute, within a certain number of months following the execution of the Landos Agreement, a separate clinical supply agreement, and within a certain number of months prior to the first commercial sale, a separate commercial supply agreement, for supply of licensed product in the licensed territory. Under certain specified circumstances, we may assume responsibility for manufacturing the licensed product for use in development and commercialization purposes in the territory.

Under the terms of the Landos Agreement, we paid to Landos an upfront payment of $18.0 million. If we achieve specified development and sales milestones events, we may be required to make further milestone payments under the amended Landos Agreement of up to $40.0 million and $105.0 million, respectively, to Landos. In addition, if we successfully develop and commercialize the licensed product, we will pay Landos tiered royalties at percentage rates ranging from the low- to the mid-teens on the net sales of the licensed product until the latest of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a region-by region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement is a PCT application and will have a twenty-year statutory expiration date in 2039 in each licensed region, provided such PCT application will be extended to each licensed region and be allowed therein. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. The term of the Landos Agreement will depend on the patent coverage we and our partners may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The Landos Agreement will remain in effect until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or insolvency. Landos may also terminate the agreement if we challenge any of the licensed patents. We have the right to terminate the agreement for convenience upon advance notice to Landos.

Upon termination of the Landos Agreement with respect to one or more regions, we agree to grant to Landos a worldwide, irrevocable, perpetual, transferable, exclusive license to certain product inventions and patent rights relating to the licensed product as it exists as of the time of termination, for use in the terminated territory. If the Landos Agreement is terminated after the first commercial sale of the licensed product, then we will assign and transfer, or exclusively license, to Landos any trademarks relating to the licensed product for use in the terminated territory. In addition, upon early termination of the agreement and at the request of Landos, we agreed to assign and transfer to Landos all regulatory filings and approvals and market authorizations for the licensed product for use in the terminated territory. If we terminate the agreement for Landos's material breach, then Landos agrees to pay us for the licenses granted to Landos in the terminated territory, at an amount to be negotiated at the time of termination.

License Agreement with NImmune

In February 2023, we entered into a license and collaboration agreement with NImmune, under which we obtained an exclusive license with the right to sublicense to affiliates and specified third parties under certain patents and know-how of NImmune to develop, manufacture, commercialize and otherwise, make and have made, use, offer for sale, sell, have sold, and import NImmune's proprietary compound, omilancor, in the licensed regions of Mainland China, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand and Vietnam. We also obtained an exclusive right of negotiation to obtain an exclusive license under applicable patents and know-how of NImmune to exploit additional products with the same mechanism of action as the licensed compound that may be developed by NImmune for use outside the licensed territory. Under the NImmune Agreement, both parties have agreed not to develop, manufacture, or commercialize competing products in the licensed territory, subject to customary exceptions.

We granted to NImmune a non-exclusive license under any inventions and discoveries that we invent relating to the licensed product, for use in the development, manufacture, commercialization, and exploitation of the compound and licensed product anywhere in the world outside of the territory.

We are obligated to use commercially reasonable efforts to develop, seek regulatory approval for and, following receipt of marketing authorization, commercialize the licensed product in the field and in the licensed territory. Should we decide to participate in a global Phase 3 clinical trial for a licensed product, then we are obligated to use commercially reasonable efforts to enroll a percentage of study patients to be agreed in the territory.

We agreed to purchase all licensed product for development and commercialization purposes from NImmune. The parties agreed to execute, within a certain number of months following the execution of the NImmune Agreement, a separate clinical supply agreement, and within a certain number of months prior to the first commercial sale, a separate commercial supply agreement, for supply of licensed product in the licensed territory. Under certain specified circumstances, we may assume responsibility for manufacturing licensed product for use in development and commercialization purposes in the territory.

Under the terms of the NImmune Agreement, if we achieve specified development and sales milestones events, we may be required to make milestone payments up to $45.0 million and $105.0 million, respectively, to NImmune. In addition, if we successfully develop and commercialize the licensed product, we will pay NImmune tiered royalties at percentage rates ranging from the low- to the mid-teens on the net sales of the licensed product until the latest of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or a the tenth anniversary of the first commercial sale of the licensed product, in each case on a licensed product-by licensed product and region-by region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement is a PCT application and will have a twenty-year statutory expiration date in 2041 in each licensed region, provided such PCT application will be extended to each licensed region and be allowed therein. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. The term of the NImmune Agreement will depend on the patent coverage we and our partners may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The NImmune Agreement will remain in effect until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or insolvency. NImmune may also terminate the agreement if we challenge any of the licensed patents. We have the right to terminate the agreement for convenience upon advance notice to NImmune.

Upon termination of the NImmune Agreement with respect to one or more regions, we agree to grant to NImmune a worldwide, irrevocable, perpetual, transferable, exclusive license to certain product inventions and patent rights relating to the licensed product as it exists as of the time of termination, for use in the terminated territory. If the NImmune Agreement is terminated after the first commercial sale of the licensed product, then we will assign and transfer, or exclusively license, to NImmune any trademarks relating to the licensed product for use in the terminated territory. In addition, upon early termination of the agreement and at the request of NImmune, we agreed to assign and transfer to NImmune all regulatory filings and approvals and market authorizations for the licensed product for use in the terminated territory. If we terminate the agreement for NImmune's material breach, then NImmune agrees to pay us for the licenses granted to NImmune in the terminated territory, at an amount to be negotiated at the time of termination.

License Agreement with Lyra

In May 2021, we entered into a license and collaboration agreement with Lyra (the "Lyra Agreement"), under which we obtained an exclusive, sublicensable license under certain patents and know-how of Lyra to develop and commercialize and otherwise use, offer for sale, sell, have sold and import Lyra's proprietary product, LYR-210, in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Singapore, South Korea and Thailand. Under the agreement, both parties agreed not to commercialize competing products for specified time periods in the field of chronic rhinosinusitis in the licensed territory, subject to customary exceptions. Lyra will retain rights to LYR-210 outside of the licensed territory.

As part of the Lyra Agreement, we will also have the first right to obtain development and commercial rights in the licensed territories to Lyra's LYR-220, an anti-inflammatory, intra-nasal, drug matrix in development for the treatment of CRS patients who have undergone a prior sinus surgery but continue to have persistent disease.

We granted to Lyra a non-exclusive license under any inventions and discoveries that we invent relating to the licensed product, for use in the development, manufacture, commercialization and other exploitation of the licensed product anywhere in the world outside of the territory.

We are obligated to use commercially reasonable efforts to develop, seek regulatory approval for and, following receipt of marketing authorization, commercialize the licensed product in the field and in the licensed territory.

We agreed to purchase all licensed products for development and commercialization purposes from Lyra. The parties agreed to execute, within a certain number of months following the execution of the Lyra Agreement, a separate clinical supply agreement, and within a certain number of months prior to the first commercial sale, a separate commercial supply agreement, for supply of licensed products in the licensed territory. Under certain specified circumstances, we may assume responsibility for manufacturing licensed products for use in development and commercialization purposes in the territory.

Under the terms of the Lyra Agreement, we paid to Lyra an upfront payment of $12.0 million. In February 2022, the Company was notified that Lyra had achieved a certain development milestone, which, pursuant to the license agreement, triggered a $5.0 million payment due in April 2022. If we achieve specified development and sales milestones events, we may be required to make further milestone payments up to $35.0 million and $95.0 million, respectively, to Lyra. In addition, if we successfully develop and commercialize the licensed product, we will pay Lyra tiered royalties from the low- to high-teens on the net sales of the licensed product until the latest of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a region-by region basis. As of the date of this Annual Report on Form 10-K, the last-to-expire patent under the agreement will have a twenty-year statutory expiration date in 2038 in Mainland China, Hong Kong, South Korea, and Singapore, provided the latest application in each of these countries is allowed. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the licensed product during the term of the applicable agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the licensed product in the licensed territory. The term of this license agreement will depend on the patent coverage we and our partners may obtain, as well as any available regulatory exclusivity, in each region within the licensed territory. The Lyra Agreement will remain in effect until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or insolvency. Lyra may also terminate the agreement if we challenge any of the licensed patents or if we cease to conduct material development or commercialization activities for a certain period and such cessation is not due to any certain specified circumstances. We have the right to terminate the agreement for convenience upon advance notice to Lyra.

Upon termination of the Lyra Agreement, we agree to grant to Lyra a worldwide, irrevocable, perpetual, transferable, exclusive license to certain know-how and patent rights relating to the licensed product as it exists as of the time of termination, for use in the terminated territory. In addition, upon early termination of the agreement and at the request of Lyra, we agree to assign and transfer to Lyra all regulatory filings and approvals and market authorizations for the licensed product for use in the terminated territory. If we terminate the agreement for Lyra's material breach, then Lyra agrees to pay us for the licenses granted to Lyra in the terminated territory at a specified royalty rate.

License Agreement with ReViral

In March 2021, we entered into a co-development and license agreement with ReViral (the "ReViral Agreement"), under which we obtained an exclusive license with certain rights to sublicense under certain patents and know-how of ReViral to develop, commercialize and otherwise exploit ReViral's proprietary compound, sisunatovir, in the licensed territory of Mainland China, Macau, Hong Kong, and Singapore, in the licensed field of all uses and indications for the treatment of respiratory syncytial virus in humans.

In December 2022, we entered into the Pfizer Commercial Agreement with respect to sisunatovir. The ReViral Agreement was superseded in its entirety by the Pfizer Commercial Agreement between Pfizer, ReViral and us. Our responsibilities to carry out development and commercialization activities regarding sisunatovir in the licensed territories and make milestone and royalty payments to ReViral pursuant to the ReViral Agreement are all waived pursuant to the Pfizer Commercial Agreement.

Patents and other intellectual property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates and other commercially important products, technologies, invention and know-how, to operate without infringing, misappropriating or otherwise violating the proprietary or intellectual property rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. Generally, we seek initial proprietary and intellectual property protection for our product candidates in the territories of our business by licensing intellectual property rights from other technology originators or third parties. Throughout the development of our product candidates, we may seek additional means, such as obtaining patents and filing patent applications of our own, to obtain additional protection for improvements to pharmaceutical formulations, methods of use and production, new discoveries and inventions, among other things, which would potentially enhance our proprietary position.

We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties. We generally require our employees, consultants and advisors to enter into confidentiality agreements. These agreements provide that all confidential information 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 under specific circumstances. In the case of our employees, the agreements provide that all of the technology which is conceived by the individual during the course of employment is our exclusive intellectual property. Furthermore, as a matter of company policy, all scientific and technical employees have entered into agreements that generally require disclosure and assignment to us of ideas, developments, discoveries and inventions made by them which relate to their employment with us.

As of December 31, 2022, our patent portfolio includes 34 patent families, including issued patents and pending patent applications that we exclusively in-license from external technology originators in a respective field in territories of Greater China. Our rights are generally limited to the licensed territories.

Mavacamten

As of December 31, 2022, our patent portfolio related to mavacamten includes three patent families licensed from MyoKardia. The first patent family is directed to certain small molecules that are allosteric inhibitors of cardiac myosin, including mavacamten. The family includes an issued patent in Mainland China, Singapore and Hong Kong, and pending patent applications in Mainland China, Singapore and Thailand. Protection based on this patent family was not pursued in Taiwan. There are additional issued patents and pending patent applications in this patent family outside the territory of our license. Any patents issuing from this family will have a twenty-year statutory expiration date in 2034, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is directed to mavacamten for use in the treatment of hypertrophic cardiomyopathy, as well as the dosage form. The family includes pending patent applications in Taiwan, Singapore and Mainland China, as well as other jurisdictions outside the territory of our license. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2038, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The third patent family is directed to the administration of mavacamten and the polymorph. The family includes pending patent applications in Mainland China, Singapore, Hong Kong, Thailand and Taiwan. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2040, excluding any patent term extension or patent term adjustment, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines.

Infigratinib

As of December 31, 2022, our patent portfolio related to infigratinib included five patent families, three of which are owned by Novartis and sublicensed to us by QED and two of which are owned by QED and licensed to us. The first patent family is directed to the composition of matter for infigratinib. The family includes issued patents in Mainland China and Hong Kong, as well as other jurisdictions outside the territory of the QED Agreement. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2025, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The second patent family is directed to a variety of salts and crystalline forms of infigratinib. The family includes an issued patent in Hong Kong and pending applications in Mainland China. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2030, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The third patent family is directed to certain formulations of infigratinib. The family includes an issued patent in Hong Kong and a pending application in Mainland China. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2034, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The fourth patent family licensed from QED is directed to treating urothelial carcinoma and CCA, respectively, with infigratinib. This patent family includes pending applications in Mainland China and Hong Kong. Any patents that may issue from this family of patent applications would have an expected statutory expiration in 2040, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The fifth patent family licensed from QED is directed to treating gastric cancer with infigratinib. This patent family includes a priority application in Mainland China. Any patents that may issue from this family of patent application would have an expected statutory expiration no later than 2043, excluding any patent term adjustment and patent term extension, if applicable, that may be available, provided such Chinese priority application will be converted to a non-provisional PCT application, enter each of the licensed territories and be allowed therein.

BBP-398

As of December 31, 2022, we licensed from Navire three families of patent applications, one of which are owned by the University of Texas System and sublicensed to us by Navire and two of which are owned by Navire and licensed to us. One of these patent families is directed to certain small molecules as ptpn11 (SHP2) inhibitors for treating cancer, including BBP-398. The family includes pending applications in Mainland China, Hong Kong, Taiwan, Thailand, Singapore and South Korea. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2039, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The other two patent families are directed to other compounds as SHP2 inhibitors and any patents that may issue from these families of patent applications will have a twenty-year statutory expiration date between 2037-2039, excluding any patent term adjustment or patent term extension, if applicable, that may be available.

TP-03

As of December 31, 2022, we licensed from Tarsus four families of patent applications, two of which are owned by Elanco and sublicensed to us by Tarsus and two of which are owned by Tarsus and licensed to us. The first patent family is directed to the composition of matter for lotilaner (the active ingredient) and is owned by Elanco. The family includes issued patents in Mainland China and Taiwan. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2029, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is directed to treating blepharitis with lotilaner as well as the eye drop formulation. The family includes pending applications in Mainland China and Hong Kong. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2038, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The third patent family is also directed to the eye drop formulation of lotilaner and its use in treating blepharitis, with additional definition of excipient. The family includes pending applications in Mainland China and Hong Kong. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2040, excluding any patent term adjustment and patent term extension, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines. The fourth patent family is owned by Elanco and is directed to the manufacturing process of lotilaner. The family includes a pending PCT application. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2040, excluding any patent term adjustment and patent term extension, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines.

NBTXR3

As of December 31, 2022, we licensed from Nanobiotix nine families of patent applications. The first patent family is directed to the use of NBTXR3 in RT for treating cancer. The family includes issued patents in Mainland China, Macau, Singapore, Hong Kong and South Korea, and one pending application in Hong Kong. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2029, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is directed to the composition of matter for NBTXR3. The family includes issued patents in Mainland China, Hong Kong, Singapore and South Korea, and pending applications in Singapore and Thailand. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2034, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The third patent family is directed to the use of NBTXR3 in immuno-oncology. The family includes pending applications in Mainland China, Hong Kong, South Korea and Taiwan. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2036, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The fourth patent family is directed to the combo use of NBTXR3 with anti-checkpoint inhibitors. The family includes a PCT application. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2041, excluding any patent term adjustment and patent term extension, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines. The fifth patent family is directed to therapeutic combinations of nanoparticles. The family includes pending applications in Mainland China, South Korea, Singapore and Thailand. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2041, excluding any patent term adjustment and patent term extension, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines. The sixth patent family is directed to another type of chemically different nanoparticles as radioenhancers in oncology. The family includes a PCT application. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2041, excluding any patent term adjustment and patent term extension, if applicable, that may be available. We will only have a license to patent applications in this family to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines. The other three patent families are directed to second generation products of NBTXR3 and any patents that may issue from these families of patent applications will have a twenty-year statutory expiration date between 2032-2034, excluding any patent term adjustment or patent term extension, if applicable, that may be available.

Sisunatovir

As of December 31, 2022, we assigned and transferred our development and commercialization rights to sisunatovir (including three families of patent applications) to Pfizer, which were previously licensed from ReViral.

Omilancor

As of December 31, 2022, we licensed from Landos three families of patent applications directed to omilancor. The first patent family is directed to a composition of matter for omilancor. The family includes issued patents in Mainland China, Hong Kong and South Korea. The patents in this family will have a twenty-year statutory expiration date in 2035, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is directed to crystalline forms of omilancor. A PCT application has been filed for this family and will extend to Mainland China, Hong Kong and South Korea. Any patents that may issue from these families of patent applications will have a twenty-year statutory expiration date in 2041, excluding any patent term adjustment or patent term extension, if applicable, that may be available. The third patent family is directed to the administration of omilancor. A PCT application has been filed for this family and will extend to Mainland China, Hong Kong and South Korea. Any patents that may issue from these families of patent applications will have a twenty-year statutory expiration date in 2041, excluding any patent term adjustment or patent term extension, if applicable, that may be available. We will only have a license to patent applications in the second and third families to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines. In February 2023, we entered into an amendment to the Landos Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor to NImmune, and we have entered into a direct license agreement with NImmune setting forth the terms of our continued development and commercialization of omilancor in LianBio territories.

NX-13

As of December 31, 2022, we licensed from Landos one family of patent applications directed to a composition of matter for NX-13. The family includes issued patents in Mainland China and South Korea, and one pending application in Hong Kong. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2039, excluding any patent term extension or patent term adjustment, if applicable, that may be available.

LYR-210

As of December 31, 2022, we licensed from Lyra three families of patent applications. The first patent family is directed to the implant part for LYR-210. The family includes an issued patent in Mainland China, and pending applications in Mainland China and Hong Kong. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2036, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is a follow-up filing to pursue the implant for LYR-210. The family includes pending applications in Mainland China, South Korea, Singapore and Hong Kong. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2038, excluding any patent term adjustment or patent term extension, if applicable, that may be available. The third patent family is directed to an alternative design of the applicator part for LYR-210. The family includes an issued patent in Mainland China and a pending application in Hong Kong. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2036, excluding any patent term adjustment and patent term extension, if applicable, that may be available.

Generally, patents that may issue from regularly filed applications in the many jurisdictions, including the United States and China, are granted a term of 20 years from the earliest effective non-provisional filing date. In certain jurisdictions, individual patent terms may be extended for varying periods depending on the filing date of the patent application or the issuance date of the patent and the legal term of patents in the countries in which they are obtained. For example, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office review period in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. In China, according to the new Patent Law that came into force on June 1, 2021 (the "PRC Patent Law"), the term of the patent for new drugs that have been approved for marketing in China can be compensated at the request of the patentee. The compensation shall not exceed five years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years. Detailed stipulations such as manner for calculating and conditions for requesting compensation are still under discussion. For more information regarding the risks related to our intellectual property, please see "Part I—Item 1A—Risk Factors—Risks Related to our Intellectual Property."

Regulation

Government regulation of pharmaceutical product development and approval

Chinese regulation of pharmaceutical product development and approval

Since China's entry into the World Trade Organization in 2001, the Chinese government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection.

In October 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 Communist Party of China Central Committee jointly issued the Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices (the "Innovation Opinion"), which is a mandatory plan to further reform the review and approval system and to encourage the innovation of drugs and medical devices. Under the Innovation Opinion and other recent reforms, the expedited programs and other advantages encourage drug manufacturers to seek marketing approval in China first and to develop drugs in high priority disease areas, such as oncology or rare disease.

To implement the regulatory reform introduced by the Innovation Opinion, the Standing Committee of the National People's Congress of the People's Republic of China (the "SCNPC") and the NMPA have revised the fundamental laws, regulations and rules governing pharmaceutical products and the pharmaceutical industry, including the amendment of the framework law known as the Drug Administration Law of the People's Republic of China (the "Drug Administration Law"), which became effective on December 1, 2019. The State Administration for Market Regulation (the "SAMR") has promulgated two key implementing regulations for the Drug Administration Law: (i) the amended Administrative Measures for Drug Registration and (ii) the amended Measures on the Supervision and Administration of the Manufacture of Drugs. Both regulations took effect on July 1, 2020.

Regulatory authorities

In China, the NMPA is the authority under the SAMR that monitors and supervises the administration of pharmaceutical products, medical appliances and equipment, and cosmetics. The NMPA was established in March 2018 as part of the institutional reform of the State Council. Predecessors of the NMPA include the former China Food and Drug Administration (the "CFDA") established in March 2013, the State Food and Drug Administration (the "SFDA") established in March 2003, and the State Drug Administration established in August 1998. The primary responsibilities of the NMPA include:

- monitoring and supervising the administration of pharmaceutical products, medical devices and equipment as well as cosmetics in China;
- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical device, and cosmetics industry;
- evaluating, registering and approving chemical drugs, biological products and traditional Chinese medicine (the "TCM");
- approving and issuing permits for the manufacture and export/import of pharmaceutical products; and examining and evaluating the safety of pharmaceutical products, medical devices, and cosmetics and handling significant accidents involving these products.

According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs published in March 2017, which became effective in May 2017, approvals of clinical trial applications should be issued by the CDE in the name of the CFDA.

China's National Health and Family Planning Commission (the "NHFPC") was rebranded as the National Health Commission (the "NHC") in March 2018. The NHC is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The NHC combines the responsibilities of the former NHFPC, the Leading Group Overseeing Medical and Healthcare Reform under the State Council, the China National Working Commission on Aging, partial responsibilities of the Ministry of Industry and Information Technology in relation to tobacco control, and partial responsibilities from the former State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the Ministry of Health (the "MOH"). Following the establishment of the former SFDA in 2003, the MOH was put in charge of the overall administration of the national health in China, excluding the pharmaceutical industry. The NHC performs a variety of tasks in relation to the health industry such as establishing and overseeing the operation of medical institutions, some of which also serve as clinical trial sites, regulating the licensure of hospitals, and producing professional codes of ethics for public medical personnel. The NHC plays a significant role in drug reimbursement.

Drug Administration Law

The Drug Administration Law as promulgated by the SCNPC in 1984, and the Implementing Measures of the Drug Administration Law as promulgated by the State Council in August 2002, established the legal framework for the administration of pharmaceutical products, including the development and manufacturing of new drugs and the medicinal preparations by medical institutions. The Drug Administration Law also regulates the distribution, packaging, labels and advertisements of pharmaceutical products in China.

Certain amendments to the Drug Administration Law took effect on December 1, 2001 and subsequent amendments were made on December 28, 2013, April 24, 2015 and August 26, 2019. These amendments were formulated to strengthen the supervision and administration of pharmaceutical products and to ensure the quality and safety of pharmaceutical products. The current Drug Administration Law applies to entities and individuals engaged in the development, production, distribution, application, supervision and administration of pharmaceutical products. The Drug Administration Law regulates and prescribes a framework for the administration of the law to pharmaceutical manufacturers, pharmaceutical distribution companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products.

According to the Drug Administration Law, no pharmaceutical products may be produced in China without a Pharmaceutical Manufacturing Permit. A local manufacturer of pharmaceutical products must obtain a Pharmaceutical Manufacturing Permit from one of the provincial administrations of medical products in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards.

In August 2019, the SCNPC promulgated the latest Drug Administration Law (the "2019 Amendment"), which became effective in December 2019. The 2019 Amendment brought a series of changes to the drug supervision and administration system, including (i) the formalization of the drug marketing authorization holder system (the "MAH system"); (ii) expedited approval pathway; and (iii) the cancellation of relevant certification in relation to Good Manufacturing Practice and Good Supply Practice. The 2019 Amendment requires the marketing authorization holder to assume responsibilities for the entire product life cycle, including non-clinical studies, clinical trials, manufacturing, marketing, post-marketing studies, monitoring, reporting and handling of adverse reactions of the drug. The 2019 Amendment also stipulates that the state supports the innovation of drugs with clinical value, encourages the development of drugs with new therapeutic mechanisms and multi-targeted, systematic adjustment and intervention of physiological function, and promotes the technological advancement of drugs.

The Implementing Measures of the Drug Administration Law promulgated by the State Council on August 4, 2002 were amended on February 6, 2016 and March 2, 2019 and serve to provide detailed implementation regulations for the Drug Administration Law. On May 9, 2022, the NMPA published a comprehensive draft of an Amendment to the Implementing Measures of the Drug Administration Law for public comments. The draft amendment introduced changes to the regulatory framework and aimed to codify certain regulatory initiatives implemented by the Chinese government since the promulgation of the current Drug Administration Law in 2019. However, the draft amendment has not been finalized.

Administrative measures for drug registration

In July 2007, the former SFDA released the Administrative Measures for Drug Registration which took effect on October 1, 2007 (the "2007 Drug Registration Regulation"). The 2007 Drug Registration Regulation covers (i) definitions of drug marketing authorization applications and regulatory responsibilities of the former SFDA; (ii) general requirements for drug marketing authorization; (iii) drug clinical trials; (iv) application, examination and approval of drugs (such as new drugs, generic drugs, imported drugs and OTC drugs); (v) supplemental applications and marketing authorization renewals of drugs; (vi) re-registration of drugs; (vii) inspections; (viii) marketing authorization standards and specifications; (ix) time limits; (x) re-examination; and (xi) liabilities and other supplementary provisions.

In January 2020, the SAMR released the amended Administrative Measures for Drug Registration, which took effect in July 2020 (the "2020 Drug Registration Regulation"). Compared to the 2007 Drug Registration Regulation, the 2020 Drug Registration Regulation provides detailed procedural and substantive requirements for the key regulatory concepts established by the 2019 Amendment and confirms a number of reform actions that have been taken in the past years, including but not limited to: (i) fully implementing the MAH system and implied approval for the commencement of clinical trials; (ii) implementing associated review of drugs, excipients and packaging materials; and (iii) introducing four expedited approval pathways, namely the breakthrough designation, conditional approvals, prioritized reviews and special reviews and approvals.

Collecting and using patients' human genetic resources ("HGRs") and derived data

In June 1998, the Ministry of Science and Technology (the "MOST") and the former MOH jointly established the Interim Measures for the Administration of Human Genetic Resources in China. In July 2015, the MOST issued the Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which provides that foreign entities that collect and use patients' HGRs in clinical trials shall be required to file for an advance approval with the Human Genetic Resources Administration of China (the "HGRAC") through its online system.

In October 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval process for collecting and using HGRs for the purpose of seeking marketing authorization of drugs in China.

In May 2019, the State Council of the People's Republic of China issued the Regulation on the Administration of Human Genetic Resources (the "HGR Regulation"), which applies to activities that involve collection; biobanking; use of China-sourced HGRs, which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substances (the "China Biospecimens") and derived data (together with the China Biospecimens, the "China-Sourced HGR"); and the provision of such items to foreign parties or entities established or actually controlled by them. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using Chinese patients' biospecimens at clinical study sites without involving the export of such biospecimens outside of China. A notification filing that specifies the type, quantity and usage of the biospecimens, among others, with the HGRAC is required before conducting such clinical trials. The collection, use, and outbound transfer of Chinese patients' biospecimens in international collaboration for basic scientific research involving export of such biospecimens are still subject to the advance approval of the HGRAC.

In October 2020, the SCNPC promulgated the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative fines significantly in cases in which foreign entities are alleged to have collected, preserved or exported Chinese HGRs.

In March 2022, the MOST issued Answers to Frequently Asked Questions Regarding Human Genetic Resources Administration (the "Q&A Series I"). The Q&A Series I provides short answers to 30 frequently asked questions relating to the collection, preservation, utilization, and external provision of China-Sourced HGR. For example, the Q&A Series I clarifies that a notification filing with the HGRAC is required for the purpose of transferring China-Sourced HGR to regulatory authorities in other jurisdictions.

In March 2022, the MOST issued the Draft Implementing Rules of the HGR Regulation (Draft for Comment) (the "Draft Implementing Rules"). The Draft Implementing Rules are intended to provide operational details and clarify questions that have emerged in the past few years. Under the Draft Implementing Rules, clinical studies conducted for the purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of human genetic materials, will be eligible for a notification filing (as opposed to the advance approval) if the human genetic materials are collected by sites, and processed by sites or an onshore third-party lab specified in the clinical trial protocol. The Draft Implementing Rules provide clearer guidance on how to allocate the intellectual property derived from Sino-foreign cooperative research utilizing China-Sourced HGR. The Draft Implementing Rules enumerate situations where a security review is required for external provision of or open access to of human genetic data, such as external provision of or open access to human genetic data about important genetic pedigrees, human genetic data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals.

In April 2022, the MOST issued Answers to Frequently Asked Questions Regarding Human Genetic Resources Administration (Q&A Series II) (the "Q&A Series II"). The Q&A Series II provides formal written replies to 5 frequently asked questions relating to the collection, preservation, utilization, and external provision of China-Sourced HGR. The Q&A Series II specifies that collection and external provision of or open access to the data related to clinical practices, patient demographics, lab tests, medical images, etc. that do not carry genetic attributes will not be regulated as collection and external provision of or open access to human genetic data. The Q&A Series II stipulates that no advance approval for Sino-foreign cooperative research is required for research utilizing China-Sourced HGR, if the foreign entity who provides funding support will not substantially participate in the research and have no access to or ownership of the research data and research results.

Regulations on the clinical trials and marketing authorization of drugs

Four phases of clinical trials

According to the 2020 Drug Registration Regulation, a clinical development program consists of Phases I, II, III and IV clinical trials as well as bioequivalence trials. Based on the characteristics of study drugs and research objectives, the four phases of studies respectively focus on clinical pharmacology, exploratory, confirmatory and post-approval assessment of efficacy and safety.

Approval authority and process for clinical trial applications

According to the 2019 Amendment and the 2020 Drug Registration Regulation, clinical studies on investigational drugs must be approved by the CDE before their commencement.

Upon the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to the CDE for the application of the Clinical Trial Application (the "CTA") to conduct a drug clinical trial. The CDE will organize pharmaceutical, medical and other reviewers to review the application and to decide whether to approve the drug clinical trial within 60 business days of accepting the application. Once the decision is made, the applicant can locate such decision on the CDE's website. If no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. The 2020 Drug Registration Regulation further requires that the applicant shall, prior to conducting a drug clinical trial, register the information of the drug clinical trial protocol, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant shall update registration information continuously and, upon completion, register information about the outcome of the drug clinical trial. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform. Pursuant to the Notice on the Drug Clinical Trial Information Platform promulgated by former SFDA in September 2013, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the CTA in order to obtain the trial's unique registration number and complete registration of certain follow-up information and first-time submission for disclosure of the drug clinical trial information on the platform before the first subject's enrollment in the trial. If the first-time submission for disclosure is not completed within one year after the approval of the CTA, the applicant shall submit an explanation, and if the first-time submission for disclosure is not completed within three years, the approval of the CTA shall automatically expire.

Qualification of clinical trial institutions and compliance with GCP

According to the Innovation Opinion, certification of clinical trial institutions by the former CFDA and the former NHFPC was no longer required. Instead, a clinical trial institution can be engaged by a drug marketing authorization applicant (i.e., a sponsor) to conduct a drug clinical study after it has been duly registered with the online platform designated by the NMPA. On November 29, 2019, pursuant to the 2019 Amendment, the NMPA and the NHC jointly released the Rules for Administration of the Drug Clinical Trial Institutions, which became effective on December 1, 2019. The rules specify requirements for clinical trial institutions and recordable procedures. Pursuant to the rules, a clinical trial institution should comply with the requirements of the Good Practices for Drug Clinical Trials (the "GCP") and be capable of undertaking drug clinical trials. It should also evaluate, or engage a third party to evaluate, its clinical trial proficiency, facilities and expertise before the recordation. According to the Implementing Measures of the Drug Administration Law, a drug marketing authorization applicant should only engage a clinical trial institution that complies with relevant regulations to carry out a drug clinical trial.

The conduct of clinical trials must adhere to the GCP and the protocols approved by the ethics committee. Since 2015, the former CFDA has strengthened the enforcement against widespread data integrity issues associated with clinical trials in China. To ensure authenticity and reliability of the clinical data, the former CFDA mandated drug marketing authorization applicants to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, the former CFDA also regularly launched onsite clinical trial audits over selected applications and rejected those found with data forgery. The GCP audit has been ongoing and has been able to curb the number of unreliable marketing authorization applications.

In April 2020, the NMPA and the NHC released the Amended GCP that took effect on July 1, 2020. The Amended GCP provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the Amended GCP enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

International multi-center clinical trials regulations

On January 30, 2015, the former CFDA promulgated the Tentative Guidelines for International Multi-Center Clinical Trial (the "Multi-Center Clinical Trial Guidelines"), which took effect on March 1, 2015. The Multi-Center Clinical Trial Guidelines aimed to provide guidance for the regulation of application, implementation and administration of International Multi-Center Clinical Trials in China (the "IMCCT"). IMCCT applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the marketing authorization applicant plans to make use of the data derived from the IMCCTs, such IMCCTs shall satisfy, in addition to the requirements set forth in the Drug Administration Law and its implementation regulations, the Administrative Measures for Drug Registration, the GCP and relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;

- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the study drug, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore IMCCT research centers shall be subject to on-site inspections by the Chinese regulatory authorities.

IMCCTs shall follow the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "ICH-GCP") principles and ethics requirements. Marketing authorization applicants shall ensure the truthfulness, reliability and trustworthiness of clinical trials results. The investigators shall have the qualification and capability to perform relevant clinical trials. The ethics committee shall continuously supervise the trials and protect the subjects' interests, benefits and safety. Before the commencement of the IMCCT, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and applicants shall register and disclose the information of all major investigators and study sites on the NMPA's drug clinical trial information platform.

Data derived from IMCCTs can be used for the marketing authorization applications with the NMPA. When using international multi-center clinical trial data to support marketing authorization applications in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with International Conference on Harmonization-Common Technical Document (the "ICH-CTD") content and format requirements. Also, subgroup research results summary and comparative analysis shall be conducted concurrently.

In October 2017, the former CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration to reform the regulatory framework for IMCCT in China, which includes the following key points:

- The IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for preventive biological products. Phase I IMCCT is permissible in China.
- The application for drug marketing authorization can be submitted directly after the completion of the IMCCT.
- With respect to clinical trial and market authorization applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.

Clinical trial waivers and acceptance of foreign clinical trial data

On July 6, 2018, the NMPA issued the Technical Guidance for Accepting Foreign Clinical Trial Data (the "Foreign Clinical Trial Data Guidance") as one of the implementing rules for the Innovation Opinion. According to the Foreign Clinical Trial Data Guidance, sponsors may use the data of foreign clinical trials to support drug marketing authorization in China, provided that sponsors must ensure the authenticity, completeness, accuracy and traceability requirements, and that such data must be obtained in consistency with the relevant requirements under the ICH-GCP. Clinical trial 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 pre-approval clinical trials being conducted in China. Specifically, in 2018, the NMPA and the NHC issued the Procedures for the Review and Approval of Urgently Needed Foreign New Drugs. The procedures are intended to accelerate approvals for drugs that have been approved within the last ten years in the United States, the European Union or Japan and that treat orphan diseases or prevent or treat serious life-threatening illnesses for which there is either no effective therapy in China or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete post-approval trials in China.

Marketing authorization holder system

Under the authorization of the SCNPC in November 2015, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, which provides a detailed pilot plan for the MAH system for drugs in 10 provinces in China. Under the MAH system, domestic drug research and development institutions and individuals in the piloted regions are eligible to be holders of drug marketing authorizations without having to become drug manufacturers. The Pilot Plan was originally set for a 3-year period by the SCNPC and would end in November 2018. Effective as of November 5, 2018, the SCNPC decided to extend the pilot program for another year.

The latest Drug Administration Law purports to roll out the MAH system nationwide. Companies and research and development institutions can be drug marketing authorization holders. The drug marketing authorization holder should be responsible for their products throughout the life cycle, including nonclinical studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the 2019 Amendment. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that (i) pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs, the marketing authorization holder must meet the specified requirements and obtain the Pharmaceutical Manufacturing Permit for MAH holder; and (ii) each of the contract manufacturers has obtained and maintained a valid Pharmaceutical Manufacturing Permit for the specific type of drugs. The marketing authorization holders can also engage pharmaceutical distribution enterprises with a valid Pharmaceutical Distribution Permit for the distribution activities. Upon receiving the marketing authorizations from the NMPA, a drug marketing authorization holder may transfer its drug marketing authorization to a company that has the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality of the drug, and to fulfill the obligations of the drug marketing authorization holder.

In December 2022, the NMPA issued the Provisions on Supervision and Administration of Marketing Authorization Holders Concerning the Implementation of Primary Responsibilities for Drug Quality and Safety. This regulation requires marketing authorization holders to establish and improve the drug quality management system, and assume primary responsibility for the safety, effectiveness, and quality of drugs during the total product life cycle. Marketing authorization holders need to build an information-based traceability system and establish a sound drug recall system, among other things.

Drug marketing authorization

According to the 2020 Drug Registration Regulation, the applicant may submit an application for drug marketing authorization to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination of the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by the Center for Food and Drug Inspection (the "CFDI"). The NMPA then determines whether to approve the application according to the comprehensive technical review by the CDE. We must obtain approval of drug marketing authorizations before our drugs can be manufactured and sold in the China market.

Drug registration classification

According to the 2020 Drug Registration Regulation, drug marketing authorization applications are divided into three different types, namely traditional Chinese medicine, chemical drugs and biological products. Drugs falling into one of three general types are further divided by their characteristic, level of innovation and status of review and administration according to auxiliary regulatory documents to the 2020 Drug Registration Regulation.

In March 2016, the former CFDA issued the Reform Plan for Registration Classification of Chemical Medicine (the "Reform Plan"), which outlined the reclassifications of drug marketing authorization applications under the 2007 Drug Registration Regulation. Under the Reform Plan, Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs that have equivalent quality and efficacy to the originator's drugs that have been marketed abroad but not yet in China fall into Category 3. Generic drugs that have equivalent quality and efficacy to the originator's drugs and have been marketed in China fall into Category 4. Category 5 drugs are chemical drugs which have already been marketed abroad, but are not yet approved in China.

As a support policy and implementing rule of the 2020 Drug Registration Regulation, the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan, and made minor adjustments to the subclasses of Category 5. According to such rule, Category 5.1 are originator drugs and improved drugs with clear clinical advantages while Category 5.2 are generic drugs, all of which shall have been already marketed abroad but not yet approved in China.

Priority review and accelerated review and approval channels

The NMPA and its predecessors have issued a series of regulatory documents aiming to simplify or accelerate the review and approval process for innovative new drugs or drugs in great clinical demand. According to the Special Examination and Approval of Registration of New Drugs promulgated by the former SFDA on January 7, 2009, the former SFDA conducts special examination and approval for new drug marketing authorization applications when:

- the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered;
- the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad;
- the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinical treatment; or
- the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval of Registration of New Drugs provide that the applicant may file for special examination and approval at the CTA stage if the drug candidate falls within the first or second items. The provisions provide that for drug candidates that fall within the third or fourth items, the application for special examination and approval cannot be made until the marketing authorization application stage.

The Circular Concerning Several Policies on Drug Registration Review and Approval issued by the former CFDA on November 11, 2015 further provides the following policies, potentially simplifying and accelerating the approval process of clinical trials: (x) a single approval for all phases of clinical trials for a new drug, replacing the phase-by-phase application and approval procedure; and (y) a fast-track approval pathway for the following applications: (i) marketing authorization of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (ii) marketing authorization of pediatric drugs; (iii) marketing authorization of drugs treating specific or prevalent diseases in elders; (iv) marketing authorization of drugs listed in national major science and technology projects or national key research and development plans; (v) marketing authorization of drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits that are urgently needed clinically; (vi) marketing authorization of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for CTA which are already approved in the United States or the European Union or concurrent drug marketing authorization applications for drugs which have applied to the United States or European Union regulatory authorities and are manufactured in China using the same production line that passed the onsite inspections by the United States or the European Union regulatory authorities; and (viii) CTA for drugs with urgent clinical need and patent expiry within three years, and marketing authorization applications for drugs with urgent clinical need and patent expiry within one year.

The Opinions on Encouraging Priority Review and Approval for Drug Innovations promulgated by the former CFDA on December 21, 2017 provide that a fast-track CTA or marketing authorization pathway will be available to both innovative drugs with distinctive clinical benefits, which have not been sold within or outside China, and drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

The 2020 Drug Registration Regulation has incorporated the previous reform with respect to the accelerated review and approval process for clinical trials and drug marketing authorizations. The 2020 Drug Registration Regulation and the auxiliary regulatory documents currently provide four procedures for fast-track review and approvals of drugs. The NMPA would prioritize the allocation of resources for communication, guidance, review, inspection, examination and approval of applications that are qualified for the application of the four procedures. The four procedures are (i) the review and approval procedures for break-through therapeutic drugs; (ii) the review and approval procedures for drug conditional approval application; (iii) the priority review procedures for drug marketing authorization approval; and (iv) drug special review and approval procedures in case of public health emergency.

Review and approval procedures for break-through therapeutic drugs

In principle, during the drug clinical trials, an applicant may submit the application to the CDE for its drug to be designated as a break-through therapeutic drug if the following general conditions are met:

- The drug candidate must be an innovative new drug or improved new drug;
- The drug candidate must be used for the prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on the quality of life; and
- There is no other effective prevention or treatment method, or there is adequate evidence proving that the drug candidate has obvious clinical advantages over existing treatment methods.

Review and approval procedures for drug conditional approval application

At the clinical trial stage, an applicant may submit the application to the CDE for its drug to be qualified for conditional approval if the following general conditions are met:

- The drug candidate is for treatment of life-threatening illnesses with no effective treatment method or in dire need in case of a public health emergency; and clinical trial data on drug efficacy is available and the clinical value of the drug candidate can be predicated based on such data; or
- For vaccines urgently needed in major public health crisis or other vaccines that are deemed by the NHC to be urgently needed, they may receive conditional approvals if their assessed benefits outweigh the risks.

Priority review procedures for drug marketing authorization approval

Upon the submission of the marketing authorization application for a drug candidate that has obvious clinical value, an applicant may request that the marketing authorization application be qualified for priority review. Drugs that are qualified for priority review include:

- Drugs that are in short supply and urgently needed clinically, or innovative new drugs or improved new drugs for the prevention and treatment of major contagious diseases or rare diseases;
- Drugs for pediatric use with new product specification, dosage form and strength that comply with pediatric physiological characteristics;
- Vaccines and innovative vaccines urgently needed for the prevention and control of diseases;
- Drugs that received break-through therapeutic drug designation;
- Drugs that are qualified for conditional approval; and
- Others qualified for priority review as stipulated by the NMPA.

Drug special review and approval procedures in case of public health emergency

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 an 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.

Administrative protection for new drugs

Under the 2007 Drug Registration Regulation, the Implementing Measures of the Drug Administration Law (effective as of March 2, 2019) and the Reform Plan, the NMPA may provide for an administrative monitoring period of not more than five years for Category 1 new drugs for the purpose of protecting public health. The new drug monitoring period commences from the date of approval, and the NMPA will continually monitor the safety of those new drugs. However, the 2020 Drug Registration Regulation omits the provisions relating to the administrative exclusivity created by the new drug monitoring period. The NMPA has not issued any written guidance regarding whether it will grant administrative exclusivity during the new drug monitoring period to new drugs approved after the 2020 Drug Registration Regulation took effect.

In July 2021, the NMPA and the China National Intellectual Property Administration (the "CNIPA"), jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "Measures on Patent Linkage"). The Measures on Patent Linkage provide an operating mechanism for the NMPA and CNIPA to link generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. The most recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, describes the general principles of Patent Linkage, but lacks operational details. The Measures on Patent Linkage are intended to answer these operational questions.

The Measures on Patent Linkage describe a framework for a patentee to defend their patent exclusivity. Upon discovery of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the CDE's publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. Moreover, for chemical drugs, the NMPA's approval stay is only nine months, and the technical review does not need to stay in this nine-month period. If the patentee or the interested person cannot secure a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires. In Mainland China, no NMPA approval stay is available for biosimilar applications. The NMPA can proceed with the technical review and grant of marketing authorization following its receipt of biosimilar applications. To delay the entry of biosimilars, the patentee/interested person will need to file an infringement claim with the court or the CNIPA within 45 days after the CDE's publication of the biosimilar application and secure a favorable decision before the NMPA's issuance of the marketing authorization. The NMPA will then convert the marketing authorizations into a conditional approval effective after the relevant patents expire.

The Measures on Patent Linkage further provides the conditions and procedures for the certification of non-infringement for generic companies and the marketing exclusivity period that may be granted to the first generic company succeeding the patent challenge and receiving marketing authorization approval.

Data privacy and data protection

The Chinese government continues to strengthen its regulation of network security, data protection, data privacy and personal information (including personal health information). For example, the PRC Civil Code, which was promulgated by the National People's Congress of the People's Republic of China in May 2020 and became effective in January 2021, provides that the personal information of a natural person 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 make public personal information of others.

In November 2016, the SCNPC promulgated the Cyber Security Law, which became effective in June 2017. The Cyber Security Law requires network operators to perform certain functions related to cybersecurity protection and strengthen their network information management and comply with certain requirements when collecting and using personal information. For instance, under the Cyber Security Law, operators of critical information infrastructure generally are required to store within the territory of Mainland China personal information and important data collected or produced in connection with operations conducted within the territory of Mainland China. In addition, when collecting and using personal information, network operators are required to abide by principles of lawfulness, justifiableness and necessity. Network operators that collect and use personal information are required to announce the rules for such collection and use, expressly disclose the purpose, methods and scope of such collection and use, and obtain the consent of the persons whose personal information are to be collected. Network operators are prohibited from collecting personal information that is unrelated to the services they provide, and from collecting or using personal information in violation of applicable laws and regulations and their agreements regarding their collection and use of such personal information. Network operators are also required to process the personal information they store in accordance with the provisions of laws and administrative regulations and their agreements reached with relevant persons. Network operators are prohibited from disclosing, tampering with or destroying personal information that they collect, and may not disclose personal information to others without the prior consent of the person whose personal information has been collected, unless such personal information has been anonymized by processing it in a manner that prevents the related persons from being identified and any information that can be used to re-identify the related persons from being restored. Under the Cyber Security Law, an individual has the right to require a network operator to delete his or her personal information if he or she finds that the collection and use of such information by such network operator violates applicable laws, administrative regulations or his or her agreement with such network operator, and to require a network operator to correct errors in his or her personal information collected and stored by such network operator. Also, under the Cyber Security Law, individuals or organizations are prohibited from acquiring personal information by stealing it or through other illegal ways, and from illegally selling or providing personal information to others.

On September 14, 2022, the Cyberspace Administration of China (the "CAC") published a draft amendment to the Cyber Security Law for public comment. According to the CAC's explanatory note published together with draft amendment, the draft amendment was formulated to align the Cyber Security Law with several new laws that were released after the Cyber Security Law came into effect in June 2017. These new laws include the Administrative Punishment Law of the People's Republic of China, the Data Security Law, and the PIPL, all of which were adopted or amended in 2021. The draft amendment mainly proposes revisions to Chapter VI of the Cyber Security Law on legal responsibility to adjust the types and ranges of administrative penalties for violating the Cyber Security Law and to align them with other laws. Generally, the fines and penalties available to be imposed by Chinese cyberspace regulators have been significantly increased and expanded.

In July 2018, the National Health Commission promulgated the Measures on Health and Medical Big Data (the "Measures"), which sets out guidelines and principles for standards management, security management and services management for the health and medical big data sector. Under the Measures, health and medical big data is defined as health and medical related data created in the course of preventing and treating illness and managing the health of individuals. The Measures require that all health and medical big data be stored in secure servers located in Mainland China, and that relevant cross-border data transfer laws and regulations be followed and a security assessment be conducted in accordance with relevant laws, regulations and requirements when it is necessary to transfer such data outside of Mainland China.

In June 2021, the SCNPC promulgated the Data Security Law, which became effective on September 1, 2021. The Data Security Law establishes a tiered system for data protection in terms of the data's importance and requires that data identified as "important data," which will be identified by governmental authorities through the use of catalogs, be treated with a higher level of protection. Specifically, the Data Security Law requires any processors of important data to appoint a "data security officer" and a "management department" to take charge of data security. In addition, any processors of important data are required to periodically evaluate the risk of its data processing activities and file risk assessment reports with relevant regulatory authorities. The Data Security Law, in addition to reiterating the Cyber Security Law requirements for cross-border transfers of important data collected and produced during operations within the territory of Mainland China of critical information infrastructure operators, also references additional requirements that are yet-to-be formulated regulating the cross-border transfer of important data by all data processors. Additionally, the Data Security Law prohibits any organization or individual located within the territory of Mainland China from providing to a foreign judicial or law enforcement authority any data stored within the territory of Mainland China without the approval of relevant regulatory authorities. Since the Data Security Law is relatively new, uncertainties still exist in its interpretation and implementation.

The current Cybersecurity Review Measures, which were released by the CAC together with 12 other Chinese regulatory authorities on January 4, 2022, came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, are required to conduct a cybersecurity review. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

On August 20, 2021, the National People's Congress promulgated the PIPL, which became effective on November 1, 2021. The PIPL is an omnibus regulation that provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information of individuals conducted within the territory of mainland China and the processing of personal information of individuals located in mainland China conducted outside of mainland China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, individuals located in mainland China. Under the PIPL, the processing of personal information is not permitted unless a legal basis exists. The legal bases for processing personal information under the PIPL include (i) where the consent of the relevant individual is obtained, (ii) where it is necessary to conclude or perform a contract to which the relevant individual is a party or for implementing human resources management in accordance with labor rules and regulations that are formulated in accordance with the law or collective contracts concluded in accordance with the law, (iii) where it is necessary to perform legal duties or obligations, (iv) where it is necessary to respond to a public health emergency or to protect the life and health of persons or their property, (v) where it is for news reporting and supervision of public opinion carried out for the public interest, and the processing is reasonable in scope, (vi) where it is necessary to process the personal information disclosed by the relevant individual or otherwise legally disclosed, and the processing is reasonable in scope, and (vii) under other circumstances prescribed by laws and regulations. The PIPL clarifies and prescribes new notice and consent requirements for personal information processors, including the requirement to obtain separate consent in five circumstances: (i) when disclosing personal information to another personal information processor, (ii) when processing sensitive personal information, (iii) when transferring personal information outside the territory of mainland China, (iv) when publicly disclosing the personal information of an individual, and (v) when using an individual's personal image or identification information collected by image capture or personal identification equipment installed in public places for purposes other than maintaining public security. The PIPL also provides that critical information infrastructure operators and personal information processors who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in mainland China personal information generated or collected in mainland China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. In addition, under the PIPL, personal information processors processing certain quantities of personal information in accordance with relevant laws and regulations and need to transfer such information out of Mainland China are required to pass a security assessment organized by Chinese cyberspace regulators, and all other personal information processors that are not required to pass the security assessment and need to transfer out of Mainland China personal information shall either: (i) undergo certification by specialized certification agencies in accordance with relevant regulations, (ii) conclude a standard contract designated by China cyberspace regulators with the overseas recipient of the personal information, or (iii) satisfy other conditions contemplated by laws, administrative regulations or Chinese cyberspace regulators. In addition to the above, personal information processors that need to transfer out of Mainland China personal information shall conduct a privacy impact assessment. The PIPL also enumerates a number of data subject rights, including the right of notice, access, correction, deletion, and portability. Additionally, the PIPL prohibits any personal information processor from providing to a foreign judicial or law enforcement authority any data stored within the territory of mainland China without the approval of relevant regulatory authorities. Lastly, the PIPL provides for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities.

On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft Data Security Management Regulations"). The Draft Data Security Management Regulations proposed that data processors, defined as individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion, are subject to cybersecurity review if either they process personal information of more than one million individuals and aim to list on foreign stock markets, or their data processing activities impact or may impact national security. The Draft Data Security Management Regulations also propose requiring data processors seeking to list on foreign stock markets to annually assess their data security and submit the assessment reports to relevant competent authorities. The timing of the release of the final version of the Draft Data Security Management Regulations and its effective date is uncertain.

On January 13, 2022, the draft Guidelines for Identification of Important Data (the "Guidelines") were released for public comment, which sets out six principals for identifying important data: (i) data must be assessed based on its security impact from the perspectives of state security, economy, social stability, public health and safety, etc., data which is only important to organizations internally shall not be regarded as important data; (ii) data classification is important in identifying the area(s) of focus for protection, when classifying data and specifying security protection priorities, in order to ensure the free flow of non-important data while important data should be subject to additional requirements; (iii) existing local regulations and industry practice must be considered to ensure the additional measures work seamlessly with them, (iv) risks should be assessed in a holistic matter including the data's confidentiality, completeness, availability, authenticity, and accuracy, etc.; (v) both the quality and quantity of data must be considered; and (vi) the assessment must be conducted and reviewed on a regular basis because the uses of the data, the way that the data is shared and the importance of data may change over time. The Guidelines, when finalized, are intended to be used by Chinese industry sector regulators to comply with a directive under the Data Security Law to formulate catalogs of important data that apply to organizations operating within the respective sectors.

Data privacy and data protection (cross-border data transfer)

On September 1, 2022, the Security Assessment Measures issued by the CAC came into effect. The Security Assessment Measures set out a security assessment framework for transfers out of Mainland China as well as ground rules for security assessment filings for data transfers out of Mainland China stipulated in the Cyber Security Law and the PIPL.

A security assessment is required for any data transfer out of Mainland China is under any of the following circumstances: (i) transfer of important data by data processors; (ii) transfer of personal information by critical information infrastructure operators and data processors that process personal information of more than one million individuals; (iii) transfer of personal information by data processors that have transferred either personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. According to the CAC, a cross-border data transfer includes (x) an outbound transfer and overseas storage of data collected and generated during a data processor's operation in Mainland China; and (y) a remote access or use of data collected and generated by a data processor stored within Mainland China by overseas institutions, organizations, and individuals.

Data processors are required to submit an application filing and other required materials to apply for a security assessment. During a security assessment, the CAC will primarily focus on risks to national security, public interests, and the legitimate rights and interests of individuals or organizations resulting from the transfer of data out of Mainland China. The data transfer will not be allowed if the CAC does not approve the security assessment filing. Once the CAC approves the security assessment filing, the approval will remain valid for two years and may be renewed. An application for security assessment needs to be re-submitted if there is a change in the data transfer that may affect the security of the transferred data, such as changes in the purpose, method, scope, and type of the transferred data and changes in the purpose and method of the processing of the transferred data by overseas recipients.

The Security Assessment Measures apply to relevant data transfers out of Mainland China conducted prior to September 1, 2022. If a data processor fails to complete its security assessment for any relevant data transfer prior to the effective date of the Security Assessment Measures, it needs to rectify the failure within six months after the effective date of the Security Assessment Measures.

On August 31, 2022, the CAC promulgated the first edition of the Guide to Applications for Security Assessment of Outbound Data Transfers (the "Security Assessment Guide"). The Security Assessment Guide provides practical guidance to the implementation of the Security Assessment Measures.

The Security Assessment Guide reiterates the timeline and procedures for applications for security assessment of outbound data transfers under the Security Assessment Measures. The Security Assessment Guide specifies the dossier requirements for applications for security assessment and provides templates for some required documents. Additionally, the Security Assessment Guide clarifies that the application of security assessment filings are to be submitted to provincial branches of the CAC, who will forward it to the CAC for further review and assessment.

The Security Assessment Guide also reaffirms CAC's position that a cross-border data transfer out of Mainland China includes where a data processor transfers or stores overseas the data collected or generated in its operations in Mainland China, and where a data processor allows an overseas entity, organization, or individual to access, retrieve, download, or export data the data processor collects or generates and stores in Mainland China.

On November 4, 2022, the CAC and SAMR jointly issued the Notification on the Implementation of Personal Information Protection Certification, which implements, among other things, the personal information protection certification ("PIPC") mechanism to satisfy the requirements of the PIPL for the cross-border transfer out of Mainland China of personal information. In parallel with that notification, on June 24, 2022, the National Information Security Standardization Technical Committee issued the first version of the Guidance on Network Security Standardized Practice – Specification for Certification of Personal Information Cross-Border Processing Activities (the "Certification Specification"), and on December 16, 2022, the National Information Security Standardization Technical Committee issued an updated version of the Certification Specification. The Certification Specification serves as an industry standard and provides the general principles and detailed requirements for personal information processors engaging in the cross-border transfer out of Mainland China of personal information to meet in order to obtain a PIPC from qualified certification institutions with respect to such data transfers. Personal information processors that obtain a PIPC may rely on a PIPC to comply with PIPL requirements for cross-border data transfers of personal information out of Mainland China that do not need to undergo a security assessment.

Under the Certification Specification, personal information processors seeking to obtain a PIPC need to (i) demonstrate adherence to general personal information protection principles; (ii) put in place a data transfer agreement meeting certain requirements with overseas recipients of the transferred personal information located outside of Mainland China; (iii) implement certain technical and organizational measures directed at personal information protection, including with respect to the cross-border data transfer processing activities; (iv) agree with the overseas recipients' the same rules for cross-border processing of personal information regarding multiple aspects and jointly observe such rules; (v) conducted personal information protection impact assessments and periodic audits of, among other things, the personal information processor's and the overseas recipients' personal information protection measures, internal controls, protection of data subject rights, and the impact of the legal and network security environment in destination countries and regions; and (vi) meet, bear, and be subject to, and require the overseas recipients to meet, bear, and be subject to certain legal responsibilities and liabilities and supervision by qualified certification institutions and Chinese cyber regulators with respect to their cross-border data transfer processing activities and to data subjects.

On February 24, 2023, the CAC issued the Measures for the Standard Contract for Cross-Border Transfer of Personal Information (the "Measures for the PRC Standard Contract"), which will come into effect on June 1, 2023, introducing a standard contract template for the cross-border transfer of personal information outside of Mainland China (the "PRC Standard Contract"). The PRC Standard Contract clarifies terms and conditions to be agreed on between personal information processors as a data exporter and an overseas recipient as a data importer with respect to cross-border data transfers of personal information out of Mainland China. When the Measures for the PRC Standard Contract come into effect, a personal information processor may enter into the PRC Standard Contract and provide it along with other required materials to relevant governmental authorities for filing to ensure the legality of a cross-border transfer out of Mainland China if the following conditions are satisfied: the personal information processor (i) is not a CIIO; (ii) processes personal information of fewer than 1 million individuals; (iii) has provided personal information of fewer than 100,000 individuals overseas in aggregate since January 1 of the preceding year; and (iv) has provided sensitive personal information of fewer than 10,000 individuals overseas in aggregate since January 1 of the preceding year.

The PRC Standard Contract imposes certain obligations on the parties of such cross-border data transfers to protect the interests of data subjects, including, for example, (i) data exporters are required to use reasonable efforts to ensure data importers have adequate technical and organizational measures to ensure secure processing and have relevant capabilities to fulfill their obligations relating to the data transfer, and (ii) the parties of such cross-border transfer are required to ensure that the rights and interests of data subjects are well recognized in practice (and data subjects' inquiries are promptly responded to), as such data subjects are considered third-party beneficiaries of the PRC Standard Contract.

Additional regulations, guidelines, and measures relating to data privacy and data protection are expected to be adopted, including more guidance from industry sector regulators on the catalogs of important data, which may contain additional requirements for transferring personal health information out of Mainland China.

Since our subsidiaries located in Mainland China operate computer networks as part of their normal operations, we are required to comply with the requirements of Mainland China's cyber security, data protection, and privacy laws and regulations. In addition, in the ordinary course of our business, we collect and store personal information, including personal information about our clinical trial subjects, customers, and employees in Mainland China. We may need to share such personal information with our subsidiaries, licensors, partners, or contractors located outside Mainland China. Mainland China's network and data protection regime is constantly evolving, and we continue to face uncertainties as to whether our efforts to comply with these requirements will be sufficient. Although we develop and maintain compliance protocols and controls designed to maintain compliance with these requirements, development, implementation, improvement, and maintenance of these protocols and controls is costly and requires significant effort, resources, and time. In addition, in certain cases, our CROs, licensors, licensees, partners, and contractors are also required to comply with these laws, and our agreements with them require them to comply with these requirements, but there is always a risk that they may not fully comply with them.

Good pharmacovigilance practice

The latest Drug Administration Law provides that the State shall establish a pharmacovigilance system for monitoring, identifying, assessing and controlling adverse drug reactions and other harmful reactions associated with the use of drugs. As a supporting document in this regard, the Good Pharmacovigilance Practice ("GVP"), which was promulgated by the NMPA and became effective as of December 1, 2021, outlines the key requirements for pharmacovigilance activities to be carried out by drug marketing authorization holders and/or drug clinical trial sponsors. The GVP clarifies that pharmacovigilance activities, including collection, identification, evaluation and control of adverse drug reactions, shall take place in the total life cycle of drugs, from the clinical development stage through the post-approval stage. The GVP calls for effective and differentiated pharmacovigilance activities for different types of drugs, such as innovative drugs, traditional Chinese medicines and ethnic medicines.

Good laboratories practice certification for nonclinical research

To improve the quality of nonclinical research, the former SFDA promulgated the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory in 2003 (the "GLP 2003"). The GLP 2003 was then abolished and replaced by the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, providing that the former SFDA (now the NMPA) is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, the former SFDA (now the NMPA) decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution's organizational administration, personnel, laboratory equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all requirements are met, a GLP certification will be issued by the former SFDA (now the NMPA) and published on the government website.

An online information platform has been launched by the NMPA in December 2022. GLP certified institutions, provincial medical products administrations and the Center for Food and Drug Inspection of NMPA must maintain information related to GLP institutions on the platform, including, among others, GLP certification status, results of GLP inspections, investigations, and penalty of violations.

In January 2023, the NMPA issued a revised version of the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, which will come into effect on July 1, 2023. Under the new rule, a GLP certification issued by the NMPA will be valid for five years. GLP certified institutions shall submit a GLP annual report to the provincial medical products administration, covering, among other items, the institution's basic information, QMS operation status, research progress.

Animal testing permits

According to Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission in November 1988, as amended by the State Council in January 2011, July 2013 and March 2017, and Administrative Measures on the Certificate for Animal Experimentation (Tentative) promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experiments on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;

- the environment and facilities for the animals' living and propagating must meet state requirements;
- the animals' feed must meet state requirements;
- the animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- the management systems must be effective and efficient; and
- the applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

Drug technology transfer regulations and marketing authorization transfer

On August 19, 2009, the former SFDA promulgated the Administrative Regulations for Registration of Drug Technology Transfer to standardize the registration process of drug technology transfer, which includes application for, and evaluation, examination, approval and monitoring of, drug technology transfer. Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the provisions in the technology transfer regulations. Drug technology transfer includes new drug technology transfer and drug production technology transfer.

Conditions for the application for new drug technology transfer

Applications for new drug technology transfer may be submitted prior to the expiration date of the monitoring period of the new drugs with respect to:

- drugs with new drug certificates only; or
- drugs with new drug certificates and drug approval numbers.

For drug products with new drug certificates only and not yet in the monitoring period, or drug substances with new drug certificates, applications for new drug technology transfer should be submitted prior to the respective expiration date of the monitoring periods.

Conditions for the application of drug production technology transfer

Applications for drug production technology transfer may be submitted if:

- the transferor holds new drug certificates or both new drug certificates and drug approval numbers, and the monitoring period has expired or there is no monitoring period; or
- with respect to drugs without new drug certificates, both the transferor and the transferee are legally qualified drug manufacturing enterprises, one of which holds over 50% of the equity interests in the other, or both of which are majority-owned subsidiaries of the same drug manufacturing enterprise.

With respect to imported drugs with imported drug licenses, the original applicants for the imported drug licenses may transfer these drug production technologies to domestic drug manufacturing enterprises.

Application for, and examination and approval of, drug technology transfer

Applications for drug technology transfer should be submitted to the provincial administration of medical products where the transferee is located. If the transferor and the transferee are located in different provinces, the provincial administration of medical products where the transferor is located should provide examination opinions. The provincial administration of medical products where the transferee is located is responsible for examining application materials for technology transfer and organizing inspections on the production facilities of the transferee. Drug control institutes are responsible for testing three batches of drug samples.

The CDE should further review the application materials, provide technical evaluation opinions and form a comprehensive evaluation opinion based on the site inspection reports and the testing results of the samples. The NMPA should determine whether to approve the application according to the comprehensive technical review opinions of the CDE. An approval letter of supplemental application and a drug approval number will be issued to qualified applications. The CDE may require the conduct of clinical studies. For rejected applications, a notification letter of the examination opinions will be issued with the reasons for rejection.

Conditions for the application for marketing authorization transfer

As previously discussed under "Part I—Item 1A—Risk Factors—Risks Related to our In-Licensing Business Model and Dependence on Third Parties," the Drug Administration Law and the 2020 Drug Registration Regulation allow for the transfer of marketing authorization under the MAH system. If the manufacturing location of an imported drug is relocated to China through drug manufacturing technology transfer, the transferee in China can choose to file a supplemental application pursuant to the Administrative Regulations for Technology Transfer Registration of Drugs with the provincial medical product administration which contains technical data showing consistency of quality and manufacturing processes during the two-year grace period from January 13, 2021. Alternatively, the transferee in China can file a marketing authorization application with the CDE referencing technical data in the original import drug approval application dossier pursuant to the NMPA's Administrative Measures for Post-approval Changes to Drugs (Tentative).

Permits and licenses for drug manufacturing operations

Pharmaceutical manufacturing permit and GMP requirements

According to the Drug Administration Law and the Implementing Measures of the Drug Administration Law, to manufacture pharmaceutical products in China, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the relevant provincial medical products administration where the enterprise is located. Among other things, such a permit must set forth the scope of production and effective period. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards.

According to the Implementing Measures of the Drug Administration Law and Measures on the Supervision and Administration of the Manufacture of Drugs, promulgated in August 2004 and amended in November 2017 and January 2020, each Pharmaceutical Manufacturing Permit issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Manufacturing Permit is subject to review by the relevant regulatory authorities on an annual basis. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

The Good Manufacturing Practice was promulgated in March 1988 and was amended in June 1999 and January 2011. The Good Manufacturing Practice comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

Pharmaceutical distribution permit and GSP requirements

To distribute pharmaceutical products in China, including wholesale and retail distribution, a pharmaceutical distribution enterprise must first obtain a Pharmaceutical Distribution Permit.

Pursuant to the Administrative Measures of the Pharmaceutical Distribution Permit promulgated by the former CFDA in February 2004 and subsequently amended in November 2017, each Pharmaceutical Distribution Permit issued to a pharmaceutical distribution enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Distribution Permit is subject to periodic review and inspection by the relevant regulatory authorities. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

The Good Supply Practice for Drugs was promulgated in April 2000 and was amended in November 2012, May 2015 and July 2016. The Good Supply Practice for Drugs is the basic rules for drug operation and quality control, setting forth the requirements for pharmaceutical distribution enterprises throughout the process of procurement, storage, sales and transportation.

U.S. regulation of pharmaceutical product development and approval

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions. These sanctions could include, among other actions, FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters and other types of enforcement-related letters, product recalls, product seizures, relabeling or repackaging, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice or other governmental entities. Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an investigational new drug application ("IND") which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an independent institutional review board ("IRB") or independent ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices ("GCPs") and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug candidate for its proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within sixty days of its receipt of an NDA to file the NDA for review and review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredients ("API") and finished drug product are produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMPs");
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA; and
- payment of user fees and FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Pre-clinical studies

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including GLPs and the U.S. Department of Agriculture's Animal Welfare Act. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long-term pre-clinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

Clinical studies

If the FDA accepts the IND, the drug can then be studied in human clinical trials to determine if the drug is safe or effective. The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of clinical trials, and GCPs are intended to assure that the data and reported results are accurate, and that the rights, safety, and well-being of study participants are protected. GCPs also include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by the IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase 1, Phase 2 and Phase 3 clinical trials.

- ***Phase 1:*** The drug is initially introduced into a small number of healthy volunteers or patients with the target disease or condition who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- ***Phase 2:*** The drug is administered to a limited patient population with the specified disease or condition to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.
- ***Phase 3:*** The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the preclinical studies and clinical trials must be submitted at least annually to the FDA, and more frequently if SAEs occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time during the initial 30-day period or while clinical trials are ongoing under the IND, on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on the clinical trials database maintained by the National Institutes of Health.

NDA submission and FDA review process

The results of pre-clinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each NDA must be accompanied by an application user fee.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of an NDA and respond to the applicant within 10 months from the filing date for a standard NDA and within six months from the filing date for a priority NDA.

The FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMPs to assure and preserve the drug's identity, strength, quality and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may re-analyze clinical trial data and may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient populations or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of a drug or biological product outweigh its risks. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Post-marketing requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements, which include regulations regarding promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMPs. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

Other U.S. regulatory matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, the activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent "fraud and abuse" in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, exclusion from participation in government healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Rest of the world regulation of pharmaceutical product development and approval

For other countries outside of China and the United States, such as countries in Europe, Latin America or other parts of Asia, 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 applicable GCP requirements and the applicable regulatory requirements and ethical principles.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage and reimbursement

Chinese coverage and reimbursement

Historically, most Chinese healthcare costs had been borne by patients out-of-pocket, which had limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the National Healthcare Security Administration (the "NHSA"), as of December 2021, approximately 1.36 billion residents in China were enrolled in the Basic Medical Insurance scheme, representing a coverage rate of above 95% of the total population.

Reimbursement under the national medical insurance program

The Basic Medical Insurance scheme 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 on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Basic Medical Insurance scheme and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions for the Pilot of Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance.

Pursuant to the Chinese Social Insurance Law promulgated by the SCNPC in October 2010 and subsequently amended in December 2018, all employees are required to enroll in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees as required by the state.

The Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance was promulgated by NHSA in July 2020 and came into effect in September 2020. According to which, expenses of drugs listed in the Basic Medical Insurance Catalog, typically known in the industry as the National Reimbursable Drug List ("NRDL"),will be paid in full or part from the basic medical insurance fund in accordance with applicable provisions, and the drugs with the same generic names as those specified in the Basic Medical Insurance Catalog will be automatically regulated by the Basic Medical Insurance Catalog and shall also be eligible for the reimbursement by the basic medical insurance fund. These measures further clarify that the Basic Medical Insurance Catalog shall be promulgated by the NHSA and adjusted on an annual basis. Provinces shall have the right to add eligible ethnic drugs, preparations of medical institutions, and traditional Chinese medicine decoction pieces into the provincial medical insurance-based payment scope, which shall be implemented after being filed with the NHSA for record.

The Chinese Ministry of Human Resources and Social Security, together with other government authorities, have the power to determine the medicines included in the NRDL. In January 2023, the NHSA and the Chinese Ministry of Human Resources and Social Security released the National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (the "2022 NRDL"), and 111 new drugs were admitted to the 2022 NRDL. Previous updates to the NRDL occurred in 2021, 2020, 2019, 2017 and 2009. Admission to the NRDL depends on a number of factors, including on-market experience, scale of patient adoption, physician endorsement, cost effectiveness and budget impact. Since 2019, provincial governments were not allowed to create provincial reimbursable drug lists by adding or removing chemical and biological drugs from the NRDL.

Medicines included in the NRDL are divided into two classes, Class A and Class B. Patients purchasing medicines included in the NRDL are entitled to reimbursement of the entire amount or a certain percentage of the purchase price. The percentage of reimbursement for Class B medicines differs from region to region in China.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the Basic Medical Insurance scheme in a calendar year is capped at the amount in such participant's individual account under such program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

National list of essential drugs

On August 18, 2009, the former MOH and eight other ministries and commissions in China issued the Provisional Measures on the Administration of the National List of Essential Drugs (the "NEDL") and the Guidelines on the Implementation of the NEDL System. The provisional measures aimed to promote essential medicines sold to consumers at fair prices in China and ensured that the general public in China has equal access to the drugs contained in the NEDL. The Provisional Measures on the Administration of the National List of Essential Drugs was then amended in February 2015. The former MOH promulgated the NEDL (Catalog for the Basic Healthcare Institutions) on August 18, 2009, a revised NEDL on March 13, 2013 and another revised NEDL on September 30, 2018, which became effective on November 1, 2018. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The drugs listed in NEDL shall be purchased by centralized tender process and shall be subject to the price control by the National Development and Reform Commission (the "NDRC"). Drugs listed in the NEDL will be given priority to being listed in the NRDL.

Commercial insurance

On October 25, 2016, the State Council and the Communist Party of China Central Committee jointly issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around Basic Medical Insurance, with other forms of insurance supplementing the Basic Medical Insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Price controls

Instead of direct price controls which were historically used in China but abolished in June 2015, the government regulates prices mainly by establishing price negotiations, consolidated procurement mechanism, and revising medical insurance reimbursement standards as discussed below.

NRDL price negotiations

The Chinese government has initiated several rounds of price negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply and oncology drugs since 2016. The average percentage of price reduction has been around 50%. Once the government agreed with the drug manufacturers on the supply prices, the drugs would be automatically listed in the NRDL and qualified for public hospital purchase.

There were NRDL price negotiations in 2018, 2019, 2020, 2021 and 2022. In 2022, 111 new drugs were added to the 2022 NRDL, the average price reduction of the 108 drugs participating in price negotiations is 60.1%.

Centralized procurement and tenders

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aims to regulate the purchasing process of pharmaceutical products by medical institutions. The former MOH and other relevant government authorities have promulgated a series of regulations in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000 and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, non-for-profit medical institutions established by county or higher-level government are required to implement centralized tender procurement of drugs.

The former MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the former MOH, the former SFDA and other four national departments jointly promulgated the Notice of the Financial Planning Department of Ministry of Health on Issue of the Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions. According to the notice, non-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalog of drugs subject to centralized procurement. Except for drugs in the NEDL (the procurement of which shall comply with the relevant rules on NEDL), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and TCMs, in principle, all drugs used by non-for-profit medical institutions medical institutions shall be subject to centralized procurement. On July 7, 2010, the former MOH and six other ministries and commissions jointly promulgated the Notice on Printing and Distributing the Working Regulations of Medical Institutions for Centralized Procurement of Drugs to further regulate the centralized procurement of drugs and clarify the code of conduct of the parties in centralized drug procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs promulgated in January 2017 aim to deepen the reform of medical health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralized Procurement and Use of the Drug Organized by the State promulgated in January 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and model of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralized tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. 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, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

"4+7" Volume-based drug procurement and tenders

In June 2018, the State Council decided to launch a new round of drug pricing and procurement reform. This reform is implemented mainly by the NHSA, a new government authority established in 2018 as part of the institutional restructuring with a mandate of pricing and procurement of drugs and medical disposables. The NHC supports the reform by introducing policy that encourages purchasing and prescribing of the selected drug, and managing the supplier's behavior. The NMPA is responsible for the quality assurance of the drug.

On November 15, 2018, the Joint Procurement Office, the procurement alliance formed by representatives of procurement agencies in 11 pilot cities established to oversee the bidding and procurement process, published the Paper on Drug Centralized Procurement in "4+7" Regions, launching the national pilot scheme for centralized volume-based drug procurement and tenders. According to the papers, the initial procurement of 31 generic drugs was implemented in 4 municipalities, namely Beijing, Shanghai, Tianjin and Chongqing, and 7 cities, namely Shenyang, Guangzhou, Shenzhen, Xi'an, Dalian, Chengdu, and Xiamen. This pilot program is thus also referred to as the "4+7" procurement scheme. On January 1, 2019, the General Office of the State Council published a circular on National Pilot Program for Centralized Procurement and Use of the Drug Organized by the State, which provides detailed implementing measures for the nation-wide centralized drug procurement and tender scheme.

The "4+7" pilot program puts special emphasis on procurement volume guarantee. Public hospitals in pilot regions are encouraged to form a group procurement organization to increase the negotiation leverage. The committed volume will be shared by all qualified bid-winners, and public hospitals should prioritize their use of drugs purchased through the volume-based procurement in order to realize the volume commitment. Under this program, a company is provided with a substantial volume guarantee. The selected drugs must pass the generic drug consistency evaluation on quality and effectiveness. The reform policy is aimed to lower drug costs for patients, reduce transaction costs for enterprises, regulate drug use of hospitals, and improve the centralized drug procurement and pricing system. The centralized volume-based procurement is open to all approved enterprises that manufacture drugs on the government-set procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs are considered, and their quality consistency with the originator drugs will be the main criteria for evaluation. Production capacity and stability of the supplier are also considered.

On December 17, 2018, the preliminary results of the "4+7" centralized volume-based procurement were announced: 25 out of 31 generic drugs were selected, of which there are 3 originator drugs and 22 generics. As of December 2019, many provinces have published regional implementation measures, expanding the pilot program. On January 21, 2020, the results of the second round of the national centralized volume-based procurement and tender program were published: the average price reduction reached more than 50%, and the highest reduction has reached 90%. The results of the third, the fourth, the fifth, the sixth (specially for insulin) and the seventh round of the national centralized volume-based procurement and tender program published on August 24, 2020, February 8, 2021, June 28, 2021, November 30, 2021 and July 12, 2022, respectively, show similar levels of reduction in average price reduction of about 50%, with the highest reduction reaching about 93%, 96%, 98%, 74% and 98%, respectively.

Two-invoice system

In addition to the centralized tender process, the Chinese government also rolled out a "two-invoice system." Under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms issued by the General Office of the State Council in April 2016, the two-invoice system will be fully implemented in China. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (Tentative), which came into effect in December 2016, the two-invoice system means, in principle, there cannot be more than two invoices issued for drug products supplied by manufacturers to public hospitals. To meet this requirement, many drug manufacturers have reduced the tiers of distributors, or converted drug distributors into contracted service organizations. This excludes the sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to its exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary (or between its wholly owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. The reduction in distribution tiers resulted in a decrease in distribution mark-ups, hence the supply prices to public hospitals would also be reduced. Compliance with the two-invoice system is a prerequisite for pharmaceutical companies to participate in the tender and procurement processes of public hospitals, which currently provide most of Chinese healthcare services. Manufacturers and distributors that fail to implement the two-invoice system may lose their qualifications to participate in the tender and procurement process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals. The two-invoice system has been implemented in all provinces, each with its own regional implementation rules.

Medical insurance reimbursement standards

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents, issued by the State Council on January 3, 2016, call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified Basic Medical Insurance system. This unified Basic Medical Insurance system will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangement who participate in the Basic Medical Insurance for urban employees.

The General Office of the State Council further announced a master plan for the medical insurance reimbursement reform in June 2017. The main objectives are to implement a diversified reimbursement mechanism including Diagnosis Related Groups ("DRGs"), per-capita caps, and per-bed-day caps. Local administration of healthcare security will introduce a total budget control for their jurisdictions and decide the amount of reimbursement to public hospitals based on hospitals' performance and the spending targets of individual Basic Medical Insurance funds. In June 2019, the NHSA, the Ministry of Finance, the NHC and the National Administration of Traditional Chinese Medicine jointly issued the Notice on the National List of Pilot Cities for the DRG Payment Mechanism, identifying 30 cities as pilot cities for the DRG payment pilot program, proposing to further the medical insurance reimbursement reform.

To further standardize payment in the Basic Medical Insurance schemes, in October 2019, the NHSA issued two key technical documents for a pilot project that introduces DRGs, the Technical Guideline of the Classification and Payment for China Healthcare Security Diagnosis Related Groups (CHS-DRG) and the CHS-DRG Classification Plan. According to the classification plan, patients will be sorted into 26 major diagnostic categories and 376 adjacent diagnosis-related groups. DRG-based settlement is currently only applicable to expenses of inpatient care incurred by the insureds at designated hospitals participating in the DRG payment pilot programs and payable by regional medical insurance fund under the Basic Medical Insurance schemes. DRG-based payments are made directly to the participating medical institutions, while the covered benefits enjoyed by the insureds, under the current public insurance schemes, are not affected by such settlement. In June 2020, the NHSA issued a more detailed CHS-DRG Classification Plan, further diving the 376 diagnosis-related groups into 618 basic reimbursement unit. The 30 municipalities participating in the DRG pilot project were required to submit technical assessment report to the local branch of NHSA before August 31, 2020. Upon receiving NHSA's approval, the participating municipalities may commence conducting simulation runs of the pilot project. After the simulation runs, the DRG-based settlement system is expected to be launched gradually from 2022 to 2024. In February 2020, the Communist Party of China Central Committee and the State Council jointly promulgated the Opinions on Deepening the Reform of the Healthcare Security System, which suggests that a multi-compound medical insurance payment method based on payment by disease shall be implemented. In October 2020, the NHSA issued the Notice on Issuance of the Pilot Work Plan for Total Budget by Regional Points Method and Diagnosis-Intervention Packet Payment to introduced and further implement the Diagnosis-Intervention Packet ("DIP") payment. DIP and DRG are the same in essence and principle, and therefore DIP can be considered as a variant of DRG. In November 2020, the NHSA issued two key technical documents for the DIP payment pilot project, the China Healthcare Security Technical Specification of Diagnosis-Intervention Packet (DIP) and the DIP Classification Catalog (Version 1.0). In July 2021, the NHSA issued the Medical Insurance Handling Management Regulations (Trial) for Diagnosis-Intervention Packet (DIP) Payment to provide detailed guidance for implementing medical insurance payment based on DIP. In the List of Pilot Cities for DRG/DIP Payment published by the NHSA on December 17, 2021, 18 cities were identified as pilot cities for the DRG payment pilot program, 12 cities were identified as pilot cities for the DIP payment pilot program, and 2 cities were identified as pilot cities for both the DRG payment pilot program and the DIP payment pilot program. In order to accelerate the reform of DRG / DIP payment, the NHSA has formulated and made public a Three-Year Action Plan for DRG / DIP payment reform on November 19, 2021, which makes it clear that by the end of 2024, DRG / DIP payment reform will be carried out in all overall planning areas across the country. By the end of 2025, DRG / DIP payment will cover all qualified medical institutions providing inpatient services.

Healthcare system reform

In the past decade, the Chinese government promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the Communist Party of China Central Committee and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. The State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System on December 27, 2016. The General Office of the State Council issued a Notice on the Issuance of the 14th Five-year Medical-Security Plan on September 29, 2021. The General Office of the State Counsel issued a Notice on the Main Tasks for Strengthening the Reform of Healthcare System for each year of 2017, 2018, 2019, 2021, and 2022.

Highlights of these healthcare reform policies and regulations include the following:

One of the main objectives of the reform was to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. During the 14th five-year period (2021-2025), Basic Medical Insurance coverage will remain above 95% of the country's population every year.

Another main objective of reform was to improve the healthcare system, through the reform and development of a graded diagnosis and treatment system, modern hospital management, Basic Medical Insurance, drug supply support and comprehensive supervision.

The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education were to be provided to urban and rural residents. In the meantime, the reforms also encouraged innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to prove definite efficacy and positive risk-benefit ratio.

The key tasks of the reform in the 13th five-year period were as follows: (i) to deepen the reform of public hospitals, (ii) to accelerate the development of a graded diagnosis and treatment system, (iii) to consolidate and improve the universal medical insurance system, (iv) to guarantee drug supply, (v) to establish and improve a comprehensive supervision system, (vi) to cultivate talented health-care practitioners, (vii) to stabilize and perfect the basic public health service equalization system, (viii) to advance the construction of health information technology, (ix) to accelerate the development of the health services industry generally, and (x) to strengthen organization and implementation.

On December 28, 2019, the SCNPC promulgated the Law of the People's Republic of China on Promotion of Basic Medical and Health Care, which came into effect in June 2020. Such law established the legal framework for the administration of basic medical and health services for citizens in China, including the administration of basic medical care services, medical care institutions, medical staff, guarantee of drug supply, health promotion and guarantee of medical funds.

On February 25, 2020, the Communist Party of China Central Committee and the State Council jointly promulgated the Opinions on Deepening the Reform of the Healthcare Security System, which envisages that a higher-level healthcare system should be established by 2030, which centers on basic medical insurance, is underpinned by medical aid and pursues the joint development of supplementary medical insurance, commercial health insurance, charitable donations and medial mutual assistance. To this end, such opinions map out tasks in several respects, including making the mechanism of medical insurance benefits more impartial and appropriate, improving the robust and sustainable operating mechanism for funds raised, establishing more effective and efficient healthcare payment mechanism, and enhancing the supervision and administration on medical security fund and etc.

According to the 14th Five-year Medical-Security Plan, China should enhance the medical insurance system through collaborative governance, optimizing medical insurance payments and the drug pricing mechanism, while strengthening the medical fund supervision system. Efforts should also be made to build up a strong supporting system with a solid legal basis and better digital services. More efforts are needed too to enhance the basic medical security system, improve the mechanism that provides insurance and aid for the treatment of major and serious diseases, and boost the synergy between health insurance and medical assistance.

U.S. coverage and reimbursement

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs are covered and adequately reimbursed by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. These third-party payors are increasingly limiting coverage of medical drugs, reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. Federal and state governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. If our drug candidates are approved, limitations on coverage or reimbursement as well as price controls and cost-containment measures could have a material adverse effect on our sales, results of operations and financial condition.

Health care reform initiatives in the United States have resulted in significant changes to the coverage, reimbursement and delivery of health care, including drugs. Health care reform efforts are likely to continue and such efforts have included, and may include in the future, attempts to repeal or modify prior healthcare reform.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2030 (except May 1, 2020 to March 31, 2022) unless additional Congressional action is taken. If we obtain approval to market a drug candidate in the United States, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Other healthcare laws

Other Chinese healthcare laws

Advertising of pharmaceutical products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes promulgated by the SAMR in December 2019 and effective in March 2020, an enterprise seeking to advertise its pharmaceutical products must apply for an advertisement approval number. The advertisement approval number is issued by the relevant local administrative authority. The validity term of the advertisement approval number for drugs shall be consistent with the shortest validity term of the pharmaceutical product marketing authorization, filing certificate or Pharmaceutical Manufacturing Permit. If no valid term is prescribed in the pharmaceutical product marketing authorization, filing certificate or Pharmaceutical Manufacturing Permit, the valid term of the advertisement approval number shall be two years. The content of an approved advertisement may not be altered without prior approval.

Insert sheet and labels of pharmaceutical products

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the former SFDA (now the NMPA). A drug insert sheet should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindication, precautions, storage, production date, batch number, expiry date and drug manufacturer.

Packaging of pharmaceutical products

According to the Measures for the Administration of Pharmaceutical Packaging effective on September 1, 1988, pharmaceutical packaging must comply with national and industry standards. If no national or industry standards are available, the enterprise can formulate its own standards and implement after obtaining the approval of administration of medical products and bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its own packaging standards. Drugs that have not developed and received approval for packing standards must not be sold or traded in China (except for drugs for the military).

Measures for the supervision and administration of online drug sales

On August 3, 2022, the SAMR announced the Measures for the Supervision and Administration of Online Drug Sales (the "Measures"), which came into effect on December 1, 2022. The Measures set out a comprehensive regulatory framework for the online sale of drugs, including the online sale of prescription drugs and the regulation of trading platforms that engage in the online sale of drugs.

The Measures include six chapters and 42 articles. The main sections include: (i) the obligations, qualifications, and responsibilities of online drug sellers; (ii) the responsibilities of trading platforms for online drug sales; (iii) the supervision and management of online sales of prescription drugs; (iv) the division of responsibilities of drug regulators at all levels in the supervision of online drug sales; and (v) the legal liability for illegal online drug sales. Notably, both drug marketing authorization holders and drug distributors can qualify as online drug sellers. Online sale of prescription drugs is permitted, but drug retailers and providers of trading platforms for the online sale of prescription drugs must abide by the regulatory requirements specified in the Measures.

Other U.S. healthcare laws

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- federal false claims laws, including the False Claim Act and the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the FDCA, which among other things, strictly regulates drug and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians and teaching hospitals (and other healthcare professionals starting in 2021) to the federal government for re-disclosure to the public; and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state 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 federal laws, thus complicating compliance efforts.

If and when we become subject to such laws, efforts to ensure that our activities comply with applicable healthcare laws may involve substantial costs. Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we could be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business.

Other significant Chinese regulation affecting our business activities in China

Chinese regulation of foreign investment

The establishment, operation and management of corporate entities in China are governed by the PRC Company Law, which was adopted by the SCNPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies and foreign-invested companies limited by shares. Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail. In December 2021, the SCNPC issued the first draft amendment to the PRC Company Law for comment. The first draft amendment to the PRC Company Law has made roughly 70 substantive changes on the basis of the 13 chapters and 218 articles of the current PRC Company Law (rev. 2018). The amendment would (i) refine special provisions on state-funded companies; (ii) improve the company establishment and exit system; (iii) optimize corporate structure and corporate governance; (iv) optimize the capital structure; (v) tighten the responsibilities of controlling shareholders and management personnel; and (vi) strengthen corporate social responsibility. In December 2022, the SCNPC issued the second draft amendment to the PRC Company Law for comment. On the basis of the changes made in the previous draft, the second draft amended PRC Company Law has introduced numerous new provisions to further strengthen shareholder's capital contribution responsibility, reinforce liabilities of directors and senior management by holding them jointly liable for their willful misconduct or gross negligence, optimize corporate structure and enhance corporate governance of listed companies, among other things. Listed companies are required to disclose information on shareholders and actual controllers in accordance with applicable laws. Shareholders are obliged to make capital contributions in advance at the request of a company or its creditor where the company is unable to pay its debts when they become due.

Investment activities in China by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the latest Special Administrative Measures (Negative List) for Foreign Investment Access (2021) (the "Negative List"), which was promulgated by the Ministry of Commerce of the People's Republic of China (the "MOFCOM") and the NDRC on December 27, 2021 and took effect on January 1, 2022. The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

The Foreign Investment Law was promulgated by the NPC in March 2019 and become effective in January 2020. After the Foreign Investment Law came into force, the Law of the People's Republic of China on Wholly Foreign-Owned Enterprises, the Law of the People's Republic of China on Sino-foreign Equity Joint Ventures and the Law of the People's Republic of China on Sino-foreign Contractual Joint Ventures have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: (i) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; (ii) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; (iii) investing by foreign investors in new projects in China alone or jointly with other investors; and (iv) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law, which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law came into effect, the Regulation on Implementing the Law on Sino-Foreign Equity Joint Ventures, Provisional Regulations on the Duration of Sino- Foreign Equity Joint Ventures, the Regulations on Implementing the Law on Wholly Foreign-Owned Enterprises and the Regulations on Implementing the Law on Sino-Foreign Cooperative Joint Ventures have been repealed simultaneously.

In December 2019, the MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information, which came into effect in January 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Invested Enterprises has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities pursuant to these measures.

Chinese regulation of commercial bribery

Pursuant to specific provisions in the Anti-Unfair Competition Law of the People's Republic of China promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019 (the "PRC Anti-Unfair Competition Law"), commercial bribery is prohibited. Under the current effective PRC Anti-Unfair Competition Law, a business operator shall not resort to bribery, by offering money or goods or by any other means, to any of the following entities or individuals, in order to seek a transaction opportunity or competitive advantage: (i) any employee of the counterparty in a transaction; (ii) any entity or individual entrusted by the counterparty in a transaction to handle relevant affairs; or (iii) any other entity or individual that is to take advantage of powers or influence to influence a transaction. Administrative liability is directly imposed on the bribe maker, however, both the bribe maker and the bribe recipient are subject to civil and criminal liability.

In November 2022, the SAMR issued for public comments a draft revision to the PRC Anti-Unfair Competition Law. Under the draft revised law, offering benefits directly to the transaction counterparty might also be considered a commercial bribe, and the scope of commercial bribery has been expanded to include making a bribe with the help of a third party. Both the bribe maker and the bribe recipient are subject to administrative liability prescribed by the draft revised law.

Further, pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its 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 became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for the establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant Chinese government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third-party promoters, and it will not be subject to penalties or sanctions by relevant Chinese government authorities as a result of failure to monitor their operating activities.

Chinese regulation of product liability

In addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in China. Under current Chinese law, manufacturers and vendors of defective products in China may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the People's Republic of China (the "PRC Civil Law"), promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the People's Republic of China (the "PRC Civil Code"), which was promulgated in May 2020 and became effective on January 1, 2021, amalgamates and replaces a series of specialized laws in civil law area, including the PRC Civil Law. The rules on product liability in the PRC Civil Code remain consistent with the rules in the PRC Civil Law.

On February 22, 1993, the Product Quality Law of the People's Republic of China (the "Product Quality Law") was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised on July 8, 2000, August 27, 2009 and December 29, 2018 respectively. Pursuant to the revised Product Quality Law, manufacturers who produce defective products and distributors who sell defective products may be subject to civil or criminal liability and revocation of their business licenses.

The Law of the People's Republic of China on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Chinese tort law

Under the Tort Law of the People's Republic of China (the "Tort Law"), which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as the issuance of a warning, the recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages. The PRC Civil Code amalgamated and replaced the Tort Law effective January 1, 2021. The rules on tort in the PRC Civil Code are generally consistent with the Tort Law.

Chinese regulation of intellectual property rights

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

Patents

Pursuant to the PRC Patent Law, most recently amended in December 2008 and October 2020, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten and fifteen years, respectively, from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Inventiveness means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the CNIPA. Normally, the CNIPA publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date of application.

Article 19 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China. The PRC Patent Law also sets up the framework and adds the provisions for patent linkage and patent term extension.

Patent term extension and adjustment

The PRC Patent Law, which was most recently amended by the SCNPC on October 17, 2020, and became effective on June 1, 2021, for the first time, provides for patent term extension and adjustments for certain patents. Under the PRC Patent Law, patent term extensions can be obtained for regulatory delays in the review and approval of new drugs but are limited to no more than five years and the total post-marketing patent term of the new drug cannot exceed 14 years. The PRC Patent Law also provides for patent term adjustments where there is an unreasonable delay caused during patent examination. A patentee may apply for a patent term adjustment where the patent is granted at least four years after the filing date, and at least three years after substantive examination was requested. It remains to be seen how the patent term extensions and adjustments under the PRC Patent Law will be implemented. The Chinese government published draft amendments to the Implementing Regulations of the Patent Law on November 27, 2020, which provides further details on what is an unreasonably delay in respect of patent term adjustments and proposes certain limitations on the types of patents eligible for patent term extensions, details of how amount of the extension would be determined and applicability to drug products covered by the relevant patent. For example, there is a risk that the patent term extension will only apply where approval in Mainland China by the NMPA is the first approval anywhere in the world.

Patent linkage

The PRC Patent Law describes the general principles of linking generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. In July 2021, the NMPA and the China National Intellectual Property Administration ("CNIPA"), jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) ("Measures on Patent Linkage"), providing an operating mechanism for Patent Linkage. Upon notification of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the CDE's publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. For chemical drugs, the NMPA would initiate a nine-month approval stay period upon notification. If the patentee or the interested person cannot secure a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires.

Patent enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

Medical patent compulsory license

According to the PRC Patent Law, for the purpose of public health, the CNIPA may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which China has acceded.

Exemptions for unlicensed manufacture, use, sale or import of patented products

The PRC Patent Law provides five exceptions permitting the unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;
- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or

- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, users or imports patented drugs or patented medical equipment for the above mentioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

Trade secrets

According to the PRC Anti-Unfair Competition Law, the term "trade secrets" refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of above mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others trade secrets, the third party may be deemed to have committed a misappropriation of the others' trade secrets.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Trademarks and domain names

Trademarks. According to the Trademark Law of the People's Republic of China, promulgated by the SCNPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules (collectively, the "Trademark Law"), the Trademark Office of China National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout China. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration. As of December 31, 2022, we had four trademark applications pending in Mainland China, nine trademarks registered in Mainland China, five trademarks registered in Hong Kong, three trademarks registered in Singapore, one trademark application pending in Singapore, one trademark application pending in the United States, four trademarks registered in Taiwan, four trademarks registered in Macau, six trademark applications pending in Macau, two trademark applications pending in South Korea, one trademark application pending in Thailand, two trademark applications pending in Cambodia, two trademarks registered in Indonesia and two trademarks registered in the Philippines.

Domain Names. Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective from November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of Chinese internet domain names. We have registered www.lianbiopharma.com and www.lianbio.com.

PRC Anti-Monopoly Law

On June 24, 2022, the SCNPC published amendments to the PRC Anti-Monopoly Law (the "amended AML"), which came into effect on August 1, 2022. The amended AML formally implements China's latest anti-monopoly policies by, among other things, improving regulatory rules for anti-competitive agreements, expressly addressing monopoly issues in the platform economy, and substantially increasing the penalties for violating the law.

The improvements of the regulatory rules for anti-competitive agreements made by the amended AML mainly includes: (i) expressly stipulating that an agreement which fixes or limits resale prices, that is, a vertical anti-competitive agreement, is not prohibited if relevant business operators can prove that such agreement does not have the effect of eliminating or restricting competition; (ii) formally provides the "safe harbor" regime which stipulates that a vertical anti-competitive agreement is not prohibited, if the parties' market share in the relevant market is lower than the market share percentage set by the anti-monopoly enforcement agency and other conditions established by the anti-monopoly enforcement agency are met; (iii) codifies that business operators shall not organize other business operators to reach a monopoly agreement or provide substantial assistance for other business operators to reach a monopoly agreement.

The amended AML formally extends the anti-monopoly regulatory regime to the platform economy by outlining the general principal that business operators shall not engage in monopolistic activities, such as by taking advantage of data and algorithms, technology, capital advantage, and platform rules. The amended AML also specifically prohibits business operators from abusing market dominance, such as by using data and algorithms, technology, and platform rules.

Penalties for violation of the AML have been substantially increased by the amended AML. For example, according to the amended AML, if a company completes a concentration of business in violation of the AML that will have or is likely to have the effect of eliminating or restricting competition, in addition to other remedial measures, a fine of up to 10% of the last year's sales revenue may be imposed. If the concentration of business in violation of the AML completed by the company does not have the effect of eliminating or restricting competition, a fine of up to RMB 5 million may be imposed. In the case that the aforementioned violation has particularly serious circumstances, bad impact, or consequences, the fine imposed may be further increased to between two and five times the aforementioned fine amount.

Chinese regulation of labor protection

Under the Labor Law of the People's Republic of China, effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the Employment Contract Law of the People's Republic of China, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, 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 as requested by the Labor Contract Law of the People's Republic of China.

Pursuant to the Work Safety Law of the People's Republic of China effective on November 1, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Good Manufacturing Practice effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable Chinese laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011 and was amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds, which became effective on January 22, 1999 and was amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees, which became effective on January 1, 1995, and the Regulations on Work-related Injury Insurance, which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Regulations relating to foreign exchange registration of offshore investment by Chinese residents

In July 2014, the State Administration of Foreign Exchange (the "SAFE") issued SAFE Circular 37 and its implementation guidelines. Pursuant to SAFE Circular 37 and its implementation guidelines, residents of China (including Chinese institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle ("SPV") directly established or indirectly controlled by Chinese residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such Chinese residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a Chinese resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the Chinese individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or Chinese residents to penalties under Chinese foreign exchange administration regulations.

Regulations relating to employee stock incentive plan

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 (the "Stock Option Rules"). In accordance with the Stock Option Rules and relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our share 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 China who exercise stock options, or whose restricted shares vest, will be subject to Chinese individual income tax ("IIT"). The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee stock options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their stock options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities.

Regulations relating to dividend distribution

Pursuant to the PRC Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law of the People's Republic of China, foreign investors may freely remit into or out of China, in renminbi or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of China.

In January 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote the Reform of Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Regulations relating to foreign exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises ("SAFE Circular 142") regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into renminbi by restricting how the converted renminbi may be used. SAFE Circular 142 provides that the renminbi capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the renminbi capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such renminbi capital may not be changed without SAFE's approval, and such renminbi capital may not in any case be used to repay renminbi loans if the proceeds of such loans have not been used. In March 2015, SAFE issued the Circular of the State Administration of Foreign Exchange on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises ("SAFE Circular 19"), which took effective and replaced SAFE Circular 142 on June 1, 2015. Although SAFE Circular 19 allows for the use of renminbi converted from the foreign currency-denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted renminbi for purposes beyond the business scope, for entrusted loans or for inter-company renminbi loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account ("SAFE Circular 16"), effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using renminbi capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue renminbi entrusted loans to a prohibition against using such capital to issue loans to unassociated enterprises. Violations of SAFE Circular 19 or SAFE Circular 16 could result in administrative penalties.

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment was promulgated by SAFE in November 2012 and amended in May 2015, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in China shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment ("SAFE Circular 13"), which took effect on June 1, 2015 and was amended in December 2019. SAFE Circular 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

Other Chinese national -and provincial- level laws and regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

Chinese regulations on securities offering and listing outside of China

On February 17, 2023, the CSRC promulgated a new set of regulations consists of the Trial Measures and five supporting guidelines which will come into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

The Trial Measures and supporting guidelines apply to overseas offerings by domestic companies of equity shares, depository receipts, convertible corporate bonds, or other equity-like securities, and overseas listing of the securities for trading. Both direct and indirect overseas securities offering and listing by domestic companies would be regulated, of which the former refers to securities offering and listing in an overseas market made by a joint-stock company incorporated domestically, and the latter refers to securities offering and listing in an overseas market made in the name of an offshore entity, while based on the underlying equity, assets, earnings or other similar rights of a domestic company which operates its main business domestically. According to the Trial Measures, if an issuer meets the following conditions, the offering and listing shall be determined as an indirect overseas offering and listing by a domestic company: (i) the total assets, net assets, revenues or gross profits of the domestic companies of the issuer in the most recent financial year account for more than 50% of the corresponding figure in the issuer's audited consolidated financial statements over the same period; (ii) the majority of the senior management in charge of business operation and management of the issuer are Chinese citizens or habitually reside in China, or its main places of business operation are located in China or main parts of business activities are conducted in China.

Under the Trial Measures and supporting guidelines, a filing-based regulatory system would be implemented covering both direct and indirect overseas offering and listing. For an indirect initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to submit the filing documents to the CSRC within three working days after such application of overseas offering and listing is submitted. The CSRC would, within 20 working days if filing documents are complete and in compliance with the stipulated requirements, complete the filing and publish the filing information on the CSRC's official website. While for confidential filings of overseas offering and listing application documents, the designated filing entity may apply for an extension of the publication of such filing. The issuer shall report to the CSRC within three working days after the overseas offering and listing application documents become public. In addition, subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after the offering is completed.

Meanwhile, overseas offering and listing would be prohibited under certain circumstances, including but not limited to that (i) the offering and listing are expressly forbidden by the Chinese laws, regulations and relevant rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws or (iii) there are material disputes with regard to the ownership of the equity held by the domestic company's controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the domestic company shall postpone or terminate the intended overseas offering and listing, and report to the CSRC and competent authorities under the State Council in a timely manner.

If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they may be warned and fined up to RMB10 million. The controlling shareholders, and actual controllers of such domestic companies that organize or instruct the aforementioned violations may be fined up to RMB10 million and directly liable persons-in-charge and other directly liable persons may be each fined up to RMB 5 million..

Auxiliary rules for the regulations on supervision and administration of medical devices

On February 9, 2021, the State Council published new Regulations on Supervision and Administration of Medical Devices, or Order 739, which became effective on June 1, 2021. This top-level medical device administrative regulation contains a number of important changes, the practical effects of which will be implemented in corresponding auxiliary regulations and rules. Recently, a series of regulations have been amended accordingly to support the implementation of Order 739 in terms of the production, distribution and clinical trials of medical devices.

- Measures for the Supervision and Administration of the Production of Medical Devices

On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Production of Medical Devices, or Order 53, promulgated by the SAMR, became effective. All medical device manufacturing activities within China should comply with Order 53. Order 53 clarifies the responsibilities and obligations of medical device registrants/record-filing applicants and their entrusted manufacturers where applicable. Order 53 also establishes a medical device reporting system with an aim to improve administration of medical device production. The reporting system consists of several types of reports, including annual self-inspection report, production product variety report, production conditions change report, re-production report and recall and disposal report. The medical device registrants/ record-filing applicants and/or the medical device manufacturers need to submit corresponding reports to the local relevant Medical Product Administrations in accordance with Order 53.

- Measures for the Supervision and Administration of the Distribution of Medical Devices

On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Distribution of Medical Devices, or Order 54, promulgated by SAMR, came into effect. All medical device distribution activities within China should comply with Order 54. Under Order 54, explicit regulatory requirements were introduced to distributors of medical devices. For example, Order 54 requires medical device distributors to establish a quality management system and adopt quality control measures covering the total process of distribution and submit annual self-inspection reports to local relevant medical product administrations.

- Good Practices for Medical Device Clinical Trials

On May 1, 2022, a revised version of the Good Practices for Medical Device Clinical Trials, or 2022 Medical Device GCP, jointly released by the NMPA and the National Health Commission, came into effect. All medical device clinical trials that have not passed ethics review by May 1, 2022 must be conducted in compliance with the 2022 Medical Device GCP, if they were conducted for the purpose of applying for medical device registrations. The 2022 Medical Device GCP specifies responsibilities of each party participating in a medical device clinical trial, in particular the responsibilities of the sponsor. The 2022 Medical Device GCP no longer requires clinical trials of medical devices to be conducted in two or more clinical trial institutions. This will make it easier for medical device companies to conduct medical device registration studies.

Other Chinese national- and provincial-level laws and regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, and fire hazard control in all material aspects. We believe that we are currently in compliance with these laws and regulations in material aspects; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

Manufacturing

We plan to rely on our licensing partners and third-party contract manufacturing organizations with which they contract to manufacture our drug product supply for our planned clinical trials. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, we expect to work with our licensors' third-party suppliers to ensure sufficient capacity to meet our manufacturing requirements. In addition, we may rely on other third parties to perform additional steps in the manufacturing process, including storage of our product candidates.

We have entered into clinical supply agreements with our licensing partners with respect to certain of our product candidates, and expect to enter into additional clinical supply agreements related to other product candidates. We believe that these clinical supply agreements will be sufficient to accommodate our planned clinical trials of our current product candidates. We currently do not have any commercial supply contracts for our product candidates and we are in discussions with, or plan to have discussions with, our licensing partners to enter into such commercial supply contracts. We may need to obtain additional manufacturing arrangements to meet our future clinical and commercial needs, which would require significant capital investment.

Employees and human capital resources

As of December 31, 2022, we had 163 full-time employees. Of these full-time employees, 61 employees are engaged in research and development activities and 102 are engaged in general and administrative activities. As of December 31, 2022, 17 employees were employed in the United States and 146 employees were employed in Greater China and South East Asia. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We operate in a highly competitive environment for human capital, particularly as we seek to attract and retain talent with solid experience in the biotechnology and pharmaceutical sectors. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. To help promote alignment between our employees and our shareholders, all employees are currently eligible to participate in our equity programs through the receipt of new hire and annual equity grants. We believe that in addition to incentivizing growth that leads to shareholder value, broad eligibility for our equity programs helps promote employee retention.

Available information

Our website address is www.lianbio.com, and our investor relations website is located at investors.lianbio.com. Information on our website is not incorporated by reference herein. We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site (http://www.sec.gov) containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

Investing in our American Depositary Shares ("ADSs") involves a high degree of risk. Investors should carefully consider the risks described below, together with all other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our ADSs. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Doing Business in China and Our International Operations

Changes in the economic, political, legal and social conditions and policies of the Chinese government or in relations between China and the United States (or other countries) may materially and adversely affect our business, financial condition, results of operations, access to capital, and the market price of our ADSs.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, the Chinese government has implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities ("VIEs"). In light of such developments, the U.S. Securities and Exchange Commission (the "SEC") has imposed enhanced disclosure requirements on China-based companies. Although we do not have a VIE structure, due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, the Chinese government may intervene with our operations and our business in China and the United States, and the market price of our ADSs may also be adversely affected.

The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs, and the Chinese government has indicated an intent to increase the government's oversight and control over offerings conducted overseas and foreign investment in China-based issuers, which could significantly limit or completely hinder our ability to offer ADSs to our investors, and could cause the value of our ADSs to significantly decline or become worthless.

The Chinese government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further its regulatory, political and societal goals. The Chinese government published new policies in 2021 that significantly affect certain industries, such as the education industry and internet platform economics, 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 Chinese authorities to continue to operate our business, which may adversely affect our business, financial condition and results of operations. Furthermore, statements made by the Chinese government have indicated an intent to increase the government's oversight and control over offerings of securities of companies with significant operations in China that are to be conducted in foreign markets, as well as foreign investment in China-based issuers like us. Any such action, if taken by the Chinese government, could significantly limit or completely hinder our ability to continue to offer ADSs to our investors, and could cause the value of our ADSs to significantly decline or become worthless.

Changes in relations between the United States and China, as well as relations with other countries, and/or changes in U.S. and Chinese regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ADSs.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We have business operations in both the United States and China and conduct clinical activities in China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our product candidates, the hiring of scientists and other research and development personnel, the demand for our product candidates, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ADSs or prevent us from selling our product candidates in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with significant China-based operations, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which Chairman Gensler stated that he asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with VIE structures. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations in China. However, it is possible that this Annual Report on Form 10-K and the Company's other filings with the SEC may be subject to enhanced review by the SEC, and that this additional scrutiny could affect our ability to effectively raise capital in the United States.

In response to the SEC's July 30, 2021 statement, the China Securities Regulatory Commission (the "CSRC") announced on August 1, 2021, that "[i]t is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China-based companies listed in the United States so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," the CSRC emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated, if the U.S. or Chinese governments take retaliatory actions due to trade or geopolitical tensions between the two countries, or if the Chinese government exerts more oversight and control over securities offerings that are conducted in the United States, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ADSs.

Uncertainties in the China legal system could materially and adversely affect us.

In 1979, the Chinese 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 investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. The China legal system is based on written statutes and unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. Since these laws and regulations are relatively new and the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the China legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities market and promote the high-quality development of capital markets, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us.

Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), the regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, materially and adversely impacting our operating results.

China has implemented extensive data protection, privacy and information security rules and is considering a number of additional proposals relating to these subject areas. Based on our understanding of these laws, regulations and policies, some of which were only recently enacted, and the government regulators' interpretation of those legal requirements as applied to biopharmaceutical companies like us, we believe we are compliant with all of our material legal obligations. Nevertheless, we face significant uncertainties and risks which, as explained below, may materially and adversely affect our operations.

General risks surrounding the types of data we process and types of processing activities in which we engage

We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or anonymized health data for clinical trials in compliance with local regulations. This data could be deemed by government regulators to be "personal information," "important data," or "core data." Under the Cyber Security Law of the People's Republic of China (the "Cyber Security Law") and the Data Security Law, data categorized as core data or important data, the latter of which will be determined by governmental authorities in the form of catalogs which have not been published, is to be processed and handled with a higher level of protection, but what data constitutes core data or important data is currently not clearly defined except for certain industry sections. Therefore, in order to comply with the statutory requirements, we will need to determine whether we possess core data or important data, monitor the important data catalogs that are expected to be published by local governments and industry regulators, perform risk assessments and comply with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of core data or important data.

With China's growing emphasis on its sovereignty over data derived from China, the outbound transmission of de-identified or anonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, Data Security Law, the PIPL, the HGR Regulations and various implementing regulations and standards. Due to operational needs, we may from time to time transfer and store personal data and information outside of China in the future. Therefore, we will need to comply with the increasingly strict regulations over cross-border data transfers and monitor any new rules or regulations published by local governments and industry regulators.

Cybersecurity

The Cyber Security Law, which became effective in 2017, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt an MLPS, under which network operators are required to perform obligations of security protection to ensure that their networks are free from interference, disruption or unauthorized access, and prevent network data on their networks from being disclosed, stolen or tampered. Under the MLPS, entities' operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong, from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We are obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents.

Establishing and maintaining such systems and complying with such requirements takes substantial time, effort, and cost, and we may not be able to establish and maintain such systems or comply with such requirements as fully as needed for compliance with our legal obligations. Despite our investment, such systems and compliance efforts may not adequately protect us or enable us to appropriately respond to or mitigate all data compliance risks or data security and network security risks or incidents we face.

Cybersecurity review

Following the Draft Data Security Management Regulations, the Cybersecurity Review Measures, which came into effect on February 15, 2022, confirmed that critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, are required to conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

Pursuant to the Draft Data Security Management Regulations, data processors seeking to list on foreign stock markets shall assess their data security themselves or through data security service organizations annually, and submit the assessment reports to relevant competent authorities.

We have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator" or "online platform operator" or requiring us to go through cybersecurity review procedures by the CAC pursuant to the Cybersecurity Review Measures. Based on our understanding of the Cybersecurity Review Measures and the Draft Data Security Management Regulations, if enacted as currently proposed, we do not expect ourselves to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over Mainland China's national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information of more than one million users or individuals. However, there remains uncertainty as to how the Cybersecurity Review Measures and the Draft Data Security Management Regulations, if enacted as currently proposed, will be interpreted or implemented and whether Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Cybersecurity Review Measures and the proposed Draft Data Security Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Cybersecurity Review Measures, the Draft Data Security Management Regulations, if enacted, or other laws and regulations related to privacy, data protection and information security.

It is also unclear at the present time how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. Mainland China's regulators may impose penalties for non-compliance ranging from fines to suspension of operations, and this could lead to us delisting from the U.S. stock market. Currently, we have not been involved in any investigations on cybersecurity review initiated by the CAC or related governmental regulatory authorities, and we have not received any inquiry, notice, warning, or sanction in such respect.

Cross-border data transfer requirements (security assessment; certification; standard contract)

China continues to strengthen its regulation of cross-border transfers out of Mainland China of data, including important data and personal information.

The requirement for some data processors to store personal information or important data in China, unless certain legally recognized protective measures are undertaken, was first introduced in 2017 under the Cyber Security Law, but is now solidified through the publication of the PIPL and the Security Assessment Measures. The PIPL requires that personal information processors processing certain quantities of personal information in accordance with relevant laws and regulations and need to transfer such information out of Mainland China to pass a security assessment organized by Chinese cyberspace regulators, and all other personal information processors that are not required to pass the security assessment and need to transfer out of Mainland China personal information to either: (i) undergo certification by specialized certification agencies in accordance with relevant regulations, (ii) conclude a standard contract designated by China cyberspace regulators with the overseas recipient of the personal information, or (iii) satisfy other conditions contemplated by laws, administrative regulations or Chinese cyberspace regulators. In addition to the above, personal information processors that need to transfer out of Mainland China personal information shall conduct a privacy impact assessment.

Notably, the PIPL provides for significant fines for serious violations of up to RMB 50 million, or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or pseudonymized health data for clinical trials in compliance with local regulations. This data could be deemed as personal data or important data. We may transfer and store personal data and information that whistleblowers provide through our whistleblower hotline to, in, and using centralized databases and systems located in the United States, Mainland China, and Hong Kong. In addition, we have engaged a third-party data processor to process the personal data and information that such whistleblowers provide, on our behalf. Such personal data and information will be stored in one or more databases located on servers hosted and operated by the third party, in the United States.

To implement the security assessment mechanisms for cross-border transfers out of China of data under the Cyber Security Law, the Data Security Law, and the PIPL, the CAC promulgated the Security Assessment Measures, which took effect on September 1, 2022, and published the Security Assessment Guide on August 31, 2022. Under the Security Assessment Measures, a mandatory security assessment is required for data transfers out of Mainland China under any of the following circumstances: (i) transfer of important data by data processors; (ii) transfer of personal information by critical information infrastructure operators and data processors that process personal information of more than one million individuals; (iii) transfer of personal information by data processors that have transferred either personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. The Security Assessment Measures have retroactive effect for relevant cross-border data transfers out of Mainland China conducted prior to September 1, 2022, and data processors are required to undergo mandatory security assessment for such prior relevant cross-border data transfers by February 28, 2023. We do not believe, based on our understanding of the Security Assessment Measures that our transfers of data out of Mainland China currently or in the past require us to undergo a mandatory security assessment under the Security Assessment Measures, but we may in the foreseeable future conduct cross-border data transfers of data that require us to undergo a mandatory security assessment under the Security Assessment Measures for such transfers.

To implement the standard contract mechanism for cross-border transfers out of China of personal information under the PIPL, on February 24, 2023, the CAC published the PRC Standard Contract, which will come into effect on June 1, 2023. Once this comes into effect, personal information processors may conclude a PRC Standard Contract with overseas recipients of personal information to comply with PIPL requirements for cross-border transfers out of Mainland China of personal information that do not need to undergo a security assessment.

To implement the personal information protection certification mechanism for cross-border transfers out of China of personal information under the PIPL, on November 4, 2022, the CAC and SAMR jointly issued the Notification on the Implementation of Personal Information Protection Certification. In parallel, on December 16, 2022, the National Information Security Standardization Technical Committee released an updated version of the Certification Specification which provides the general principles and detailed requirements for personal information processors engaging in the cross-border transfer out of Mainland China of personal information to meet in order to obtain a personal information protection certification from qualified certification institutions for cross-border transfers out of China of personal information governed by the PIPL.

Transferring data to foreign law enforcement agencies or judicial authorities

The Data Security Law and PIPL prohibit entities in Mainland China from transferring data (including personal information) stored in Mainland China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. We may need to pass a government security review or obtain government approval in order to share data (including personal information) stored in Mainland China with judicial and law enforcement authorities outside of Mainland China. Therefore, if judicial and law enforcement authorities outside Mainland China require us to provide data stored in Mainland China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impacts on our operations in and outside of Mainland China. Recently, the CAC has taken action against several Chinese internet companies listed on U.S. securities exchanges for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law of the People's Republic of China (the "National Security Law"), the Cyber Security Law and the Cybersecurity Review Measures, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests."

Industry and local regulations

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in Mainland China. For example, the HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR outside of China. Chinese parties are required to seek an advance approval for the collection and biobanking of all China-Sourced HGR. Approval for any export or cross-border transfer of China-Sourced HGR in the form of biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the Human Genetic Resources Administration of China (the "HGRAC") for record purposes and to obtain a notification filing number in order to transfer the data. The HGR Regulation also requires that foreign parties or entities established or actually controlled by them ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

To further tighten the control of China-Sourced HGR, the SCNPC issued the Eleventh Amendment to the Criminal Law of the People's Republic of China on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR and the illegal transfer of China-sourced biospecimens outside of Mainland China. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to seven years and/or a criminal fine. In October 2020, the SCNPC adopted the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law will establish an integrated system to regulate biosecurity-related activities in Mainland China, including, among others, the security regulation of HGR and biological resources. The Biosecurity Law for the first time expressly declared that Mainland 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 China-Sourced HGR by foreign parties or entities established or actually controlled by them in Mainland China. Though the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by Mainland China's highest legislative authority, it gives Mainland China's primary regulator of HGR, the Ministry of Science and Technology, or MOST, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in Mainland China and elsewhere are often uncertain and in flux.

So far, the HGRAC has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant human genetic materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any clinical trial applications until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in Mainland China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multinational pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAC approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of 6 to 12 months, respectively.

Uncertainties about our compliance with the changing legal landscape despite our best efforts

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with the Cyber Security Law, the Data Security Law, the PIPL and other related laws and regulations could significantly increase the cost to us of providing our products, require significant changes to our operations or even prevent us from providing certain products in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, products or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law, the PIPL and/or related laws and regulations. Any failure on our part to comply with such laws or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition and results of operations. If the Chinese parties fail to comply with data protection, data privacy and cybersecurity laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, we may lose our confidential information and be subject to litigation and government enforcement actions. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, delays in sharing or an inability to share or receive clinical trial data with or from our collaborators, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in Mainland China. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the PIPL, the Cyber Security Law, the Cybersecurity Review Measures and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital in the U.S. market in the future.

The national security legal regime imposes stricter data localization requirements on personal information and human health-related data and requires us to undergo cybersecurity or other security review and assessments, obtain government approval or certification, implement technical and organizational measures for data privacy and protection, conduct privacy impact assessments, or put in place certain contractual protections before transferring personal information and human health-related data out of Mainland China. As a result, personal information, important data and health and medical data that we or our customers, vendors, clinical trial sites, pharmaceutical partners and other third parties collect, generate or process in Mainland China may be subject to such data localization requirements and heightened regulatory oversight and controls. We may need to maintain local data centers in Mainland China, enter into standard contracts with the overseas recipients of any personal information processed by us, conduct privacy impact assessments, undergo security assessments, or obtain the requisite approvals from the Chinese government for the transmission outside of Mainland China of such controlled information and data, which could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside Mainland China. We expect that the evolving regulatory interpretation and enforcement of the national security legal regime will lead to increased operational and compliance costs and will require us to continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss of use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of Mainland China, be unable to comply with our contractual requirements, suffer reputational harm, or be subject to penalties, including administrative, civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. If any of these were to occur, it could materially adversely affect our ability to operate our business and our financial results.

The approval of, or filing or other procedures with, the CSRC or other Chinese regulatory authorities may be required in connection with issuing our equity securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures. We are also required to obtain business licenses from Chinese authorities in connection with our general business activities currently conducted in China.

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council of the People's Republic of China (the "State Council") jointly promulgated the Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law, pursuant to which Chinese regulators are required to accelerate rulemaking related to the overseas issuance and listing of securities, and update the existing laws and regulations related to data security, cross-border data flow, and management of confidential information. Numerous regulations, guidelines and other measures have been or are expected to be adopted under the umbrella of or in addition to the Cyber Security Law and Data Security Law. As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

Furthermore, On February 17, 2023, the CSRC promulgated a new set of regulations consists of the Trial Measures and five supporting guidelines which will come into effect on March 31, 2023, to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

As of the date of this Annual Report on Form 10-K, we have not received any inquiry, notice, warning or sanction regarding obtaining approval, completing filing or other procedures in connection with previous offerings of our equity securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. Based on our understanding of the newly issued Trial Measures and the supporting guidelines after they come into effect on March 31, 2023, we will not at once be required to submit an application to the CSRC for previous offerings of our equity securities to foreign investors. However, if we intend to make any subsequent securities offerings in the same overseas market, we may be required to submit filings with the CSRC within three working days after any such subsequent securities offering is completed. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. If it is determined in the future that the approval of, filing or other procedure with the CSRC or any other regulatory authority is required with respect to previous offerings of our equity securities to foreign investors, or if we are required to complete relevant procedures for future offerings of our equity securities to foreign investors, it is uncertain whether we will be able and how long it will take for us to obtain the approval or complete the filing or other procedure or obtain a waiver for such procedures, despite our best efforts. If we, for any reason, are unable to obtain or complete, or experience significant delays in obtaining or completing, the requisite relevant approvals, filing or other procedures, we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in mainland China, limit our ability to pay dividends outside of mainland China, limit our operations in mainland China, delay or restrict the repatriation of the proceeds from our public offerings into mainland China or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs. Any uncertainties and/or negative publicity regarding the aforementioned approval(s), filing or other procedure(s), the interpretation and implementation of existing laws and regulations, or any further laws, regulations or interpretations that may be released and enacted in the future could have a material adverse effect on the trading price of the ADSs.

To operate our general business activities currently conducted in China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the SAMR. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied.

Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.

In December 2012, the SEC instituted administrative proceedings under Rule 102(e)(1)(iii) of the SEC's Rules of Practice against China-based accounting firms alleging that these firms had violated U.S. securities laws and the SEC's rules and regulations thereunder by failing to provide to the SEC the firms' audit work papers with respect to certain China-based companies under the SEC's investigation. On January 22, 2014, the administrative law judge (the "ALJ") presiding over the matter rendered an initial decision that each of the firms had violated the SEC's rules of practice by failing to produce audit workpapers to the SEC. The initial decision censured each of the firms and barred them from practicing before the SEC for a period of six months. On February 12, 2014, certain of these China-based accounting firms appealed the ALJ's initial decision to the SEC. On February 6, 2015, the four China-based accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC in response to future document requests by the SEC made through the CSRC. If China-based accounting firms fail to comply with the documentation production procedures in the settlement agreement or if there is a failure of the process between the SEC and the CSRC, the SEC could restart the proceedings against the firms.

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major Chinese operations may find it difficult or impossible to retain auditors in respect of their operations in China, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our ADSs may be adversely affected.

If the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements would substantially reduce or effectively terminate the trading of our ADSs in the United States.

Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our product candidates.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labelling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In order to commercialize our product candidates and manufacture and distribute pharmaceutical products in China, the third-party manufacturers, distributors or service providers with which we or our partners contract, as applicable, will be required to:

- obtain a pharmaceutical manufacturing permit for each production facility or active ingredient registration approval from the National Medical Products Administration of China (the "NMPA") and its relevant branches for the manufacture of our products;
- obtain a pharmaceutical distribution permit from the NMPA and its relevant branches for the distribution of our products; and
- renew the pharmaceutical manufacturing permits and the pharmaceutical distribution permits every five years, among other requirements.

If our partners' third-party manufacturers, distributors or service providers are unable to obtain or renew such permits or any other permits or licenses required for our operations, they will not be able to manufacture or distribute our product candidates and we will not be able to engage in the commercialization and distribution of our product candidates and our business may be adversely affected.

The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

Although the audit report included in this Annual Report on Form 10-K is prepared by U.S. auditors who are currently inspected by the Public Company Accounting Oversight Board (the "PCAOB"), there is no guarantee that future audit reports will be prepared by auditors that are completely inspected by the PCAOB and, as such, our investors may in the future be deprived of such inspections, which could result in limitations or restrictions to our ability to access the U.S. capital markets. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act (the "HFCA Act") or the Consolidated Appropriations Act, 2023 (the "CAA") if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely or the SEC identifies us as a Commission-Identified Issuer (as defined below), and as a result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities.

As an auditor of companies that are registered with the SEC and publicly traded in the United States and a firm registered with the PCAOB, our auditor is required under the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Although we have substantial operations within China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our U.S. auditor is currently inspected by the PCAOB.

Inspections of other auditors conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating auditors' audits and their quality control procedures. As a result, to the extent that any components of our auditor's work papers are or become located in China, such work papers will not be subject to inspection by the PCAOB. As a result, investors would be deprived of such PCAOB inspections, which could result in limitations or restrictions to our access of the U.S. capital markets.

Furthermore, in recent years, U.S. regulatory authorities have continued to express their concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular under Chinese law, the United States enacted the HFCA Act in December 2020. The HFCA Act includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction. Under the HFCA Act, to the extent that the PCAOB has been unable to inspect an issuer's auditor for three consecutive years, the SEC shall prohibit its securities registered in the United States from being traded on any national securities exchange or over-the-counter markets in the United States.

Furthermore, on June 22, 2021, the U.S. Senate passed the AHFCA Act, which, if enacted, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years (as opposed to the three years stipulated under the HFCA Act). On December 29, 2022, the President signed the CAA into law. The CAA contained, among other things, an identical provision to the proposed AHFCA Act, which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two. Our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for two consecutive years, and this ultimately could result in our ADSs being delisted.

On September 22, 2021, the PCAOB adopted PCAOB Rule 6100, Board Determinations Under the Holding Foreign Companies Accountable Act, implementing the HFCA Act, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCA Act, whether the Board is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. On November 5, 2021, the SEC announced that it had approved Rule 6100.

On December 2, 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCA Act. The rules apply to registrants that the SEC identifies as having filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that PCAOB is unable to inspect or investigate completely because of a position taken by an authority in foreign jurisdictions ("Commission-Identified Issuers"). On December 16, 2021, the PCAOB issued a Determination Report, which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in Mainland China and Hong Kong because of positions taken by Chinese authorities in those jurisdictions. The PCAOB made these determinations pursuant to PCAOB Rule 6100. The SEC began to identify Commission-Identified Issuers for fiscal years beginning after December 18, 2020. A Commission-Identified Issuer will be required to comply with the submission and disclosure requirements in the annual report for each year in which it was identified. If a registrant is identified as a Commission-Identified Issuer based on its annual report for the fiscal year ended December 31, 2021, the registrant will be required to comply with the submission or disclosure requirements in its annual report filing covering the fiscal year ended December 31, 2022. If we are identified as a Commission-Identified Issuer, the SEC could prohibit the trading of our securities on national exchanges. The final HFCA Act amendments became effective on January 10, 2022, and the SEC has begun to identify and list Commission-Identified Issuers on its website.

Although a portion of the total audit hours for our December 31, 2022 audit were provided by the local China member firm, our principal auditor is headquartered in the United States and is an independent registered public accounting firm that has been inspected by the PCAOB on a regular basis. The PCAOB currently has access to inspect the working papers of our auditor. Our principal auditor is not headquartered in Mainland China or Hong Kong and was not identified in the Determination Report as a firm subject to the PCAOB's determination.

Several China-based companies, including certain companies with business models similar to our own, have been identified as Commission-Identified Issuers under the HFCA Act. If our operations change in a way that requires us to retain an independent registered public accounting firm that the PCAOB is unable to inspect or investigate completely, we may also be identified as a Commission-Identified Issuer under the HFCA Act and subject to de-listing on Nasdaq.

Additionally, in October 2021, Nasdaq adopted additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer (a "Restrictive Market"). Under the new rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by the Nasdaq to be a Restrictive Market. China will likely be determined to be a Restrictive Market and, as a result, the Nasdaq may impose on us additional continued listing criteria or deny continued listing of our securities on the Nasdaq, and we cannot assure you whether Nasdaq or regulatory authorities would apply additional and more stringent criteria to us after considering the effectiveness of our auditor's audit procedures and quality control procedures, adequacy of personnel and training, or sufficiency of resources, geographic reach or experience as it relates to our audit.

On August 26, 2022, the CSRC, the Ministry of Finance of the PRC (the "MOF"), and the PCAOB signed a Statement of Protocol (the "Protocol"), governing inspections and investigations of audit firms based in Mainland China and Hong Kong, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in Mainland China and Hong Kong. Pursuant to the fact sheet with respect to the Protocol disclosed by the SEC, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. On December 15, 2022, the PCAOB Board determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in Mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB Board will consider the need to issue a new determination. In the event it is later determined that the PCAOB is unable to inspect or investigate completely our auditor, then such lack of inspection could cause trading in our securities to be prohibited under the HFCA Act, and ultimately result in a determination by a securities exchange to delist our securities.

While there has been dialogue among the CSRC, the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in China, including the Statement of Protocol, there can be no assurance that we will be able to comply with requirements imposed by U.S. regulators or Nasdaq. In December 2022, the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB-registered public accounting firms in mainland China. Until a new determination is reached by the PCAOB, the SEC has determined that there are no issuers currently at risk of having their securities subject to a trading prohibition under the HFCA Act. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, if the PCAOB were to issue a new determination regarding limitations on its ability to inspect or investigate our independent auditor and we were to fail to meet the audit requirements of the HFCA Act for two consecutive years, we may be prohibited from listing our securities on a national securities exchange and be delisted from the Nasdaq. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The market price of our ADSs could be adversely affected as a result of anticipated negative impacts of these executive or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these executive or legislative actions are implemented and regardless of our actual operating performance.

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, including the effects of Russia's invasion of Ukraine.

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

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the renminbi;
- changes in a specific country's or region's political or economic environment, especially with respect to a particular country's treatment of or stance towards other countries;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad,
- including, for example, the variable tax treatment in different jurisdictions of options granted under our equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- business interruptions resulting from geopolitical actions, including war, such as the ongoing war between Russia and Ukraine, and terrorism, health epidemics and pandemics, such as the COVID-19 pandemic or natural disasters including earthquakes, typhoons, floods and fires.

For example, our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ADSs may be adversely affected by the geopolitical factors arising in connection with Russia's invasion of Ukraine. Although we do not conduct business in either Russia or Ukraine, our global operations expose us to geopolitical risks, including, in this instance, with respect to how the United States and China choose to respond to the war between Ukraine and Russia. For instance, in connection with this war, the United States and other nations have raised the possibility of secondary sanctions on China, Chinese banks and Chinese businesses that do business with Russia or its allies. We do not currently conduct business in Russia or with Russian counterparties, but we may be impacted by sanctions if third parties with which we do business, such as business partners, suppliers, intermediaries, services providers or banks, are subject to such sanctions or if broader sanctions are imposed. Our business and operations may also be adversely impacted by any actions taken by China in response to the war or any related sanctions or threatened sanctions. If this war continues or expands, or if it leads to continued political or economic instability or terrorist activity, or if it gives rise to further government actions such as sanctions or increased economic or political tensions, in particular between the United States and China, our business and financial results may be adversely impacted and the value of our ADSs may significantly decline. In addition, although we do not currently conduct any clinical trials in Russia or Ukraine, we or our partners may experience disruptions with respect to clinical trials and operations as a result of the war and its related effects, which could materially adversely impact our or their ability to conduct business, including clinical trials, in the manner and on the timelines presently planned.

If we fail to comply with Chinese environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, fire safety and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous waste products. We are therefore subject to Chinese laws and regulations concerning the discharge of wastewater, gaseous waste and solid waste during our processes, including those relating to product development. We engage competent third-party contractors for the transfer and disposal of these materials and wastes. Despite our efforts to comply fully with environmental and safety regulations, any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, the shutdown of our facilities and/or the incurrence of obligations to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge 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, administrative or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and public liability insurance to cover costs and expenses that may be incurred if third parties are injured on our property, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government may take steps towards the adoption of more stringent environmental regulations, and, due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, our contract research organizations ("CROs") may incur substantial capital expenditures to install, replace, upgrade or supplement their manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations and our business may be materially adversely affected.

China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

A majority of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China, as well as by China's economic, political and social conditions in relation to the rest of the world. China's economy differs from the economies of other countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. In recent years, the Chinese government has implemented measures emphasizing market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises. However, a significant portion of productive assets in China are still owned by the Chinese government. The Chinese government continues to play a significant role in regulating industrial development. The government also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policies, restricting the inflow and outflow of foreign capital and providing preferential treatment to particular industries or companies.

The Chinese government also has significant authority to exert influence on the ability of a China-based company, such as our company, to conduct its business. For example, our financial condition and results of operations may be adversely affected by government control over or perceived government interference in capital investments or changes in tax, cyber and data security, capital investments, cross-border transaction and other regulations that are currently applicable or may in the future be applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

As the Chinese economy has become increasingly linked with the global economy, China is affected in various respects by downturns and recessions of major economies around the world. The various economic and policy measures enacted by the Chinese government to forestall economic downturns or bolster China's economic growth could materially affect our business. Any adverse change in the economic conditions in China, policies of the Chinese government or laws and regulations in China could have a material adverse effect on the overall economic growth of China and, in turn, our business.

Uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies in China could materially and adversely affect us.

We conduct our business primarily through our subsidiaries in China. Chinese laws and regulations govern our operations in China. Our subsidiaries are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our economic activities in China. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not always be aware of any potential violation of these policies and rules. Such unpredictability regarding our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations. Furthermore, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and we may not receive the level of legal protection we would otherwise benefit from in more developed legal systems. These uncertainties could materially and adversely affect our business and results of operations.

On January 1, 2020, the Foreign Investment Law of the People's Republic of China ("Foreign Investment Law") took effect. The Foreign Investment Law imposes information reporting requirements on foreign investors and the applicable foreign invested entities. Non-compliance with the reporting requirements will result in corrective orders and fines between RMB 100,000 and RMB 500,000. The Foreign Investment Law imposes the duties of keeping trade secrets of foreign investors and foreign-invested entities confidential on the administrative authorities to protect intellectual property rights of foreign investors and foreign-invested entities. No administrative authorities or their staff members may compel technology transfer by administrative means or illegally reveal or provide trade secrets of foreign-invested entities to third parties.

Additionally, the NMPA's recent reform of the drug review and approval process may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our product candidates in a timely manner.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for preclinical studies or clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. Conversely, for example, China's recently-passed Anti-Foreign Sanctions Law may introduce counter, retaliatory measures against U.S. sanctions, which may cause some confusion and uncertainty over the regulatory sanctions landscape between the U.S. and China. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Restrictions on currency exchange may limit our ability to receive and use effectively financing in foreign currencies.

Our Chinese subsidiaries' ability to obtain currency exchange is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the SAFE. In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the SAMR or its local branch, reporting of foreign investment information with the Ministry of Commerce of the People's Republic of China (the "MOFCOM") or its local branch or registration with other governmental authorities in China.

In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we cannot assure investors that we will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to adhere to such requirements or obtain such approval, our ability to fund our Chinese operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

Chinese regulations relating to the establishment of offshore special purpose companies by residents in China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In 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"). SAFE Circular 37 requires residents of China to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by residents of China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by China residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of China do not complete their registration with the local SAFE branches, the Chinese subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross-border foreign exchange activities, and the offshore parent company may be restricted in its ability to contribute additional capital into its Chinese subsidiaries. Moreover, failure to comply with the SAFE registration and amendment requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions.

Certain residents of China may hold direct or indirect interests in our company, and we will request residents of China who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our shareholders or beneficial owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross-border investment activities or those of our China subsidiaries and limitations on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to our investors and other holders could be materially and adversely affected.

Chinese regulations establish complex procedures for some acquisitions of China-based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

Chinese regulations and rules concerning mergers and acquisitions including the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (the "M&A Rules") and other regulations and rules with respect to mergers and acquisitions establish additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a Chinese 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 Chinese time-honored brand. Moreover, according to the Anti-Monopoly Law of the People's Republic of China promulgated on August 30, 2007 and amended on August 1, 2022, and the Provisions on Thresholds for Reporting of Concentrations of Undertakings issued by the State Council in August 2008 and amended in September 2018, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the applicable threshold is crossed and such concentration shall not be implemented without the clearance of prior reporting. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise "national security" concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises "national defense and security" or "national security" concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. As such our ability to expand our business or maintain or expand our market share through future acquisitions would be materially and adversely affected.

Our business may benefit from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies may have an adverse effect on our results of operations.

In the past, local governments in Mainland China have granted certain financial incentives from time to time to Chinese entities as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of any government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to amend or terminate the relevant financial incentive policies or to reduce or eliminate incentives at any time. In addition, some government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to do so we may be deprived of the relevant incentives. We have received certain financial grants from the Science and Technology Commission of Shanghai Municipality. We cannot assure you of the continued availability of any government incentives we do receive, nor the availability of any new government incentives. Any reduction or elimination of such incentives may have an adverse effect on our results of operations.

If we are classified as a China resident enterprise for China income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders.

The Enterprise Income Tax Law of the People's Republic of China (the "EIT Law") which was promulgated in March 2007, became effective in January 2008, and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008 and as amended in April 2019, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, personnel, accounts and assets of enterprises." Under the EIT Law, an enterprise incorporated outside of China whose "de facto management bodies" are located in China may be considered a "resident enterprise" and will be subject to a uniform 25% enterprise income tax ("EIT") rate on its global income. The Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as Chinese Tax Resident Enterprises on the Basis of De Facto Management Bodies ("SAT Circular 82") issued by the State Taxation Administration of the People's Republic of China (the "SAT") on April 22, 2009, and as amended in November 2013 and December 2017 further specifies certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in China and therefore be considered a China resident enterprise. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in China. Although SAT Circular 82 only applies to foreign enterprises that are majority-owned and controlled by Chinese enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the Chinese tax authorities as the reference for determining whether the enterprises are Chinese tax residents, regardless of whether they are majority-owned and controlled by Chinese enterprises.

We believe that neither we nor any of our subsidiaries outside of China is a China resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by the Chinese tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body." If the Chinese tax authorities determine that we or any of our subsidiaries outside of China is a Chinese resident enterprise for EIT purposes, that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly owned subsidiaries in China, a 25% EIT on its global income may increase our tax burden.

In addition, if we are classified as a China resident enterprise for Chinese tax purposes, we may be required to withhold tax at a rate of 10% from dividends we pay to our shareholders, including the holders of our ADSs, that are non-resident enterprises. Further, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% Chinese withholding tax on gains realized on the sale or other disposition of ADSs or ordinary shares if such income is treated as sourced from within China. Furthermore, gains derived by our non-Chinese individual shareholders from the sale of our ordinary shares and ADSs may be subject to a 20% Chinese withholding tax. It is unclear whether our non-China-based individual shareholders (including our ADS holders) would be subject to any Chinese tax (including withholding tax) on dividends received by such non-Chinese individual shareholders in the event we are determined to be a China resident enterprise. If any Chinese tax were to apply to such dividends, it would generally apply at a rate of 20%. Chinese tax liability may vary under applicable tax treaties. However, it is unclear whether our non-China shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that we are treated as a China resident enterprise.

We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. If any of our Chinese subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us.

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

Renminbi is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use any future renminbi revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our Chinese subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our Chinese subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in renminbi to fund our business activities outside of China or pay dividends in foreign currencies to holders of our ordinary shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

In response to the persistent capital outflow in China and renminbi's depreciation against the U.S. dollar in the fourth quarter of 2016, the People's Bank of China ("PBOC") and the SAFE promulgated a series of capital controls in early 2017, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

The Chinese government may continue to strengthen its capital controls, and more restrictions and substantial vetting processes may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our Chinese subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends or otherwise fund and conduct our business.

We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises.

The indirect transfer of equity interests in China resident enterprises by a non-China resident enterprise ("Indirect Transfer") is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises ("SAT Circular 7") sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding Chinese assets directly or indirectly in the course of a group's overseas restructuring, and the factors to be considered in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the Chinese taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the Chinese taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-Chinese tax payable on the gain derived from the indirect transfer of the Chinese taxable assets is lower than the potential Chinese income tax on the direct transfer of such assets. A transaction that does not satisfy all four tests in the immediate preceding sentence may nevertheless be deemed to lack a bona fide commercial purpose if the taxpayer cannot justify such purpose from a totality approach, taking into account the transferred group's value, income, asset composition, the history and substance in the structure, the non-Chinese tax implications, any tax treaty benefit and the availability of alternative transactions. Nevertheless, a non-resident enterprise's selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 if the shares and ADSs were purchased on the public market as well and will not be subject to Chinese tax pursuant to SAT Circular 7.

However, as there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by investors that are non-Chinese resident enterprises, or the sale or purchase of shares in other non-Chinese resident companies or other taxable assets by us. For example, the Chinese tax authorities may consider that our most recent offering involves an indirect change of shareholding in our Chinese subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Although we believe no SAT Circular 7 reporting was required for our initial public offering on the basis that the initial public offering had commercial purposes and was not conducted for tax avoidance, Chinese tax authorities may pursue us to report under SAT Circular 7 and request that we and our Chinese subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non-resident enterprises should not be subject to tax under SAT Circular 7, for any future offerings of our equity interests or other transactions, which may have an adverse effect on our and their financial condition and day-to-day operations.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the "Stock Option Rules"). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our share incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our Chinese individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under Chinese law.

We are required to obtain certain permissions from Chinese authorities to transfer certain data.

We are required to obtain approval from the CAC when the transfers out of Mainland China of certain data that is determined to be important data or personal data falls into any of the scenarios requiring a security assessment by CAC specified in the Security Assessment Measures. The cross-border transfer out of Mainland China of data requiring such a security assessment will not be allowed if the CAC does not approve the security assessment filing. In addition, the disclosure, sharing or exporting to foreign parties or entities established or actually controlled by them by a Chinese-owned entity of any data derived from human organs, tissues or cells of Chinese individuals that contain human genetic materials requires a project-level approval by or a separate notification filing to the HGRAC. The HGRAC also requires submission of a copy of the data to be exported. If our Chinese subsidiaries intend to receive certain clinical or personal data from Chinese-owned entities or transfer certain clinical or personal data out of Mainland China, they need to first evaluate whether a security assessment by CAC or a clearance from the HGRAC will be triggered by such data transfer, pass the necessary security assessment, and make the necessary notification filings or obtain the necessary project-level approvals for such data transfer.

If our Chinese subsidiaries do not receive or maintain approvals for such data transfers or inadvertently conclude that security assessments, approvals, or notification filings needed for such data transfers are not required, or if there are changes in applicable laws (including regulations) or interpretations of laws and our Chinese subsidiaries are required but unable to pass security assessments, obtain approvals, or make notification filings in the future, then such Chinese subsidiaries may be unable to effectuate such data transfers and this could adversely affect the operations of our Chinese subsidiaries, including limiting or prohibiting the ability of our Chinese subsidiaries to operate, and our relationships with our licensing and other collaboration partners.

Risks Related to our Financial Position, Need for Additional Capital, and Limited Operating History

We have incurred significant losses since our incorporation, have not generated any revenue from product sales to date and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements and through our initial public offering in November 2021. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our incorporation in July 2019. For the years ended December 31, 2022 and 2021, our net losses were $110.3 million and $196.3 million, respectively.

We expect to continue to incur losses in the foreseeable future, and we expect these losses to increase as we:

- continue our development and conduct preclinical studies and clinical trials of our product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- commercialize any of our product candidates for which we may obtain marketing approval;
- acquire or in-license other intellectual property, product candidates and technologies;
- hire additional clinical, operational, financial, business development, alliance management, quality control and scientific personnel;
- establish a sales, marketing and commercialization infrastructure for any products that obtain regulatory approval;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend intellectual property-related claims; and
- incur additional legal, accounting and other expenses associated with operating as a U.S.-listed public company.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining marketing approval for these product candidates and marketing and selling those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our development efforts, expand our business or continue our operations. A decline in the value of our ADSs could cause our investors to lose all or part of their investment.

Our business model is designed to continue to in-license additional product candidates for development. We will likely need substantial additional funding for our current and future product development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

Our operations have consumed substantial amounts of cash since our incorporation. The net cash used in our operating activities was $99.2 million and $164.0 million for the years ended December 31, 2022 and 2021, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our current clinical-stage product candidates and seek regulatory approval for these and other future product candidates. Our business model is designed to continue to in-license additional product candidates for development, and we expect to make significant upfront payments, milestone payments and/or royalty payments to our current and any future licensing partners as we continue to advance the development and commercialization of our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We have also incurred and will continue to incur expenses as we create additional infrastructure to support our operations as a U.S. public company. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our development programs, future in-licensing of product candidates or any future commercialization efforts.

We believe our cash, cash equivalents, marketable securities and restricted cash as of December 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements through at least December 31, 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the extent to which we acquire or in-license other product candidates and technologies;
- the number and development requirements of the product candidates we pursue;
- the initiation, type, number, scope, progress, expansions, results, costs and timing of the preclinical studies and clinical trials of our product candidates, including those we may choose to pursue in the future;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory approval;
- the cash received, if any, from commercial sales of any product candidates for which we receive regulatory approval;
- our ability to achieve sufficient market acceptance, adequate coverage, and adequate market share and revenue for any approved products;
- the amount of revenue we receive pursuant to our in-license arrangements;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;

- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers, preclinical and clinical development personnel and commercial personnel; and
- the costs of operating as a U.S.-listed public company.

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

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. We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of holders of our ordinary shares or ADSs will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of holders of our ordinary shares or ADSs. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in our undertaking certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our ADSs to decline. Additionally, to finance any acquisitions, licensing arrangement or strategic alliance, we may choose to issue our ordinary shares as consideration, which could dilute the ownership of our shareholders. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

We have a very limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced our operations in July 2019. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and product candidates, acquiring or in-licensing product and technology rights and conducting development activities for our product candidates. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials or obtained regulatory approval for, or demonstrated an ability to commercialize, any of our product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history and/or approved products on the market.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate, may make it difficult to evaluate our current business and prospects for future performance. Our short history makes any assessment of our future performance or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. In addition, as a new business, we may be more likely to encounter unforeseen expenses, difficulties, complications and delays due to limited experience. If we do not address these risks and difficulties successfully, our business will suffer.

Financial and capital markets volatility may adversely affect access to capital for life sciences companies, including us.

Financial and capital markets are experiencing significant volatility and the volatility is adversely affecting access to capital and credit for many life sciences companies, and that risk is currently exacerbated for companies like ours with significant operations in China by factors such as the geopolitical tensions between the U.S. and China, the ongoing war between Russia and Ukraine, the uncertainty about the duration, scope, and effect of any COVID-19 restrictions and uncertainty whether other banks and/or financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting Silicon Valley Bank, New York Signature Bank and the banking system and financial markets. In the event that these continued adverse market conditions may affect us, we may be unable to obtain adequate capital or credit market financing, obtain that capital or credit on favorable terms, or access such capital or credit in manners most favorable to us.

Risks Related to our Business and Industry

Risks related to our development and commercialization of our product candidates

All of our product candidates are still in development in our licensed territories. If we are unable to advance our product candidates through preclinical and clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially adversely affected.

All of our product candidates are still in development in our licensed territories. Our ability to generate revenue from our product candidates is dependent on the receipt of regulatory approval and successful commercialization of such products, which may never occur. Each of our product candidates will require additional clinical development, regulatory approval in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our and our partners' financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment in, and completion of, preclinical studies and clinical trials;
- obtaining positive results in our preclinical and clinical trials demonstrating efficacy, safety and, where applicable, durability of effect of our product candidates;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;
- successful completion of all safety and efficacy studies, including studies that may be conducted outside of China, required to obtain regulatory approval in China and other jurisdictions for our product candidates;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- negotiating and executing supply agreements with our partners for clinical supply and commercial manufacturing of our product candidates;
- the ability of third-party manufacturers to establish and adapt their commercial manufacturing capabilities to the specifications for our product candidates for clinical supply and commercial manufacturing;
- obtaining and maintaining patent, trade secret and other intellectual property protection;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with available therapies and alternative drugs;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following regulatory approval in China and other jurisdictions.

The success of our business is dependent upon our ability to develop and commercialize our clinical-stage product candidates, including, among others, mavacamten for the treatment of obstructive and non-obstructive hypertrophic cardiomyopathy ("oHCM" and "nHCM," respectively), TP-03 for the potential treatment of Demodex blepharitis and Meibomian Gland Disease and NBTXR3 for the potential treatment of head and neck ("H&N") cancer and other solid tumors. With respect to certain of our product candidates, including NBTXR3 and mavacamten, we plan to join our partners' planned and ongoing Phase 3 global clinical trials in certain indications by enrolling patients in China and potentially other Asian markets to both expedite our partners' global development programs and enable us to seek regulatory approval in China. As a result, our business is substantially dependent on our and our partners' ability to complete the development of, obtain regulatory approval for, and successfully commercialize these and our other product candidates in a timely manner. If, for example, our partners, or partners' sublicensees or acquirers, change their Phase 3 clinical trial strategies for our partnered products, including changing Phase 3 clinical trial strategies for a product candidate or indication for which we had anticipated joining their Phase 3 global clinical trial, or deprioritizing our partnered programs, or, if we do not succeed in independently developing, obtaining regulatory approval for, or commercializing our product candidates, we could experience significant delays in our ability to successfully commercialize product candidates, or be unable to commercialize product candidates at all.

We cannot commercialize product candidates in China without first obtaining regulatory approval from the NMPA. Similarly, we cannot commercialize product candidates in other jurisdictions outside of China without obtaining regulatory approval from comparable foreign regulatory authorities. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly, both inside and outside of China, and approval may not be granted. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Even if our product candidates were to successfully obtain approval from the U.S. Food and Drug Administration (the "FDA") and comparable foreign regulatory authorities, we would still need to seek approval in China and any other jurisdictions where we plan to market the product. For example, we will conduct clinical trials of each of our product candidates in patients in China prior to seeking regulatory approval in China. Even if our product candidates have successfully completed clinical trials outside of China, there is no assurance that clinical trials conducted with Chinese patients will be successful. Any safety issues, product recalls or other incidents related to products approved and marketed in other jurisdictions may impact approval of those products by the NMPA. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations imposed on certain product candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future.

We are heavily dependent on the successful development and commercialization of our late-stage product candidates, including mavacamten, TP-03 and NBTXR3.

Our business and future success depends heavily on our ability to develop and commercialize our late-stage product candidates, including mavacamten, TP-03 and NBTXR3, and to satisfy the necessary regulatory requirements for their marketing and sale. If our clinical trials relating to these product candidates reveal safety and/or efficacy issues, we and our licensing partners may need to invest additional time and resources in research and development to attempt to remedy the issues identified. The development of the related product candidate could subsequently be impacted, which could potentially have a significant negative impact on our business prospects, financial condition and anticipated growth.

We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must limit our development programs to specific product candidates that we identify for specific indications. Our business model is designed for us to continue to in-license additional product candidates for development. Our current financial and managerial resources may not be sufficient to successfully license or develop such product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, 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.

If safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with our product candidates, we may be unable to market such product candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain product candidates, including NBTXR3 and BBP-398, for use in combination with other cancer therapies. However, we have not developed or obtained regulatory approval for, and we do not manufacture or sell, any cancer therapies we plan to use or may use in combination with NBTXR3 or BBP-398. We may also seek to develop additional product candidates for use in combination with other therapeutics in the future.

Even if one or more of our product candidates, including NBTXR3 or BBP-398, were to receive regulatory approval for use in combination with cancer therapies, as applicable, or another therapeutic, we would continue to be subject to the risk that the NMPA or another regulatory authority could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in NBTXR3 or BBP-398 or one of our other products being removed from the market or being less successful commercially. Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved cancer therapy or therapeutic for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies and therapeutics face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for SAEs, delays in clinical trials, and lack of NMPA or other regulatory approval. If the NMPA or another regulatory authority revokes its approval of any cancer therapies or another therapeutic we may use in combination with NBTXR3 or BBP-398 or any of our other product candidates, we will not be able to market our product candidates in combination with such revoked cancer therapy or therapeutic.

We face substantial competition, which may result in our competitors discovering, developing or commercializing drugs before or more successfully than we do, or developing therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, including from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. For example, there are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the fields of cardiovascular disease, oncology, ophthalmic disease, respiratory disease and inflammatory disease. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to that of our product candidates. Potential competitors also include academic institutions, government authorities and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

An important part of our corporate strategy is to build a diversified product pipeline by acquiring or in-licensing and developing, or partnering to license and develop, product candidates that we believe are highly differentiated and have significant commercial potential. The acquisition or licensing of product candidates is very competitive and more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages over us, as may other emerging companies that take similar or different approaches to product acquisitions. We are aware of certain companies, including Zai Lab Limited (“Zai Lab”) and BeiGene, Ltd. (“BeiGene”), that have business models that may compete directly with our own.

In addition, we face competition with respect to the indications for which we are pursuing our product candidates. For instance, there are a number of companies developing or marketing treatments globally and in China for hypertrophic cardiomyopathy (“HCM”), inflammatory bowel disease (“IBD”), respiratory syncytial virus (“RSV”), cholangiocarcinoma (“CCA”), non-small cell lung carcinoma (“NSCLC”) and gastric cancer, including many major pharmaceutical and biotechnology companies. For example, Cytokinetics, Inc., and its partner Ji Xing Pharmaceuticals are developing aficamten, a cardiac myosin inhibitor in development for the treatment for HCM and there are also several programs in development targeting SHP2, including clinical programs run by Novartis AG, Revolution Medicines, Inc., Relay Therapeutics, Inc. and its partner Genentech, Inc. and Jacobio Pharmaceuticals Co. Ltd. and its partner AbbVie Inc.

Many of our competitors have significantly greater financial resources and expertise in conducting preclinical studies and clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration programs for clinical trials, as well as in acquiring or in-licensing technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain NMPA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours or acquire significant market share by being listed in the National Reimbursable Drug List (the "NRDL") before ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products.

Nonclinical and clinical development involves a lengthy and expensive process with an uncertain outcome.

There is a risk of failure for each of our product candidates. It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we, including through the efforts of our partners, must conduct preclinical studies and must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. The outcomes of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results of such clinical trial. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Future preclinical studies and clinical trials of our product candidates may not be successful.

Commencement of clinical trials is subject to finalization of the trial design based on ongoing discussions with the NMPA and/or other applicable regulatory authorities in the jurisdictions in which the clinical trials are being conducted, which could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not anticipate. Successful completion of our clinical trials is a prerequisite to submitting a marketing authorization application to the NMPA and/or other regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of our product candidates. Even if we are able to obtain marketing approval for any future product candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those product candidates. We do not know whether the clinical trials for our product candidates will begin or be completed on schedule, if at all.

We, including through the efforts of our partners, may incur additional costs or experience delays in completing preclinical studies or clinical trials, or ultimately be unable to complete the development and commercialization of our product candidates.

We, including through the efforts of our partners, may experience delays in completing preclinical studies or clinical trials, and numerous unforeseen events could arise during, or as a result of, any future preclinical studies or clinical trials, which could delay or prevent us from receiving regulatory approval. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time or will be completed on schedule, if at all. We may experience numerous adverse or unforeseen events during, or as a result of, our or our partners' preclinical studies and clinical trials that could delay or terminate our clinical trials, or delay or prevent us from receiving marketing approval or commercialize our product candidates, including:

- Our partners may experience delays, including with respect to the timing of their studies, pre-clinical studies, clinical trials, or regulatory reviews, which may influence the timing of our planned clinical development strategy;
- we may receive feedback from the NMPA or other relevant regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials, impeding our ability to commence a clinical trial;
- we may experience delays in receiving, or may fail to receive, approval or written acknowledgment of the recordation filings we or our collaborating clinical trial sites submitted to the HGRAC or comparable regulatory authorities;
- regulators or institutional review boards ("IRBs") or independent ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in obtaining required IRB approval at a prospective clinical trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or clinical trials may fail to show safety or efficacy or otherwise produce negative or inconclusive results, or we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon product development programs;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- clinical trial sites, investigators, CROs or third-party contractors used in our or our partners' preclinical studies and our and our partners' clinical trials may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply, fail to meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators or engage new CROs or third-party contractors;
- the treatment conventions and approaches of individual physicians or hospitals and clinics may differ both locally and among our licensed territories, and may contribute to failures to comply with regulatory standards or maintain quality controls or deviations from clinical trial protocols, which would impact clinical trial operations and impact our ability to generate data consistent with that generated in our partners' global clinical trials;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our partners, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us;
- the supply or quality of our product candidates or other materials necessary to conduct preclinical studies and clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other potential therapies in the same product portfolios as our product candidates that raise safety or efficacy concerns about our product candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols; inspection of the trial sites, laboratories or other participants of the clinical trial operations by the NMPA, HGRAC or other regulatory authorities that results in the imposition of a clinical hold; unforeseen safety issues or adverse events ("AEs"); failure to demonstrate a benefit from using a drug; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Further, the NMPA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Many of the factors or potential disruptions that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the lapse, revocation or denial of regulatory approval of our product candidates or the abandonment by us of such development programs.

If we are required to conduct additional clinical trials or testing of our product candidates, if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- be unable to continue the clinical trial or carry out commercialization activities of a product candidate due to lapsed or revoked regulatory approval;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of certain products;
- be subject to restrictions on the distribution and/or commercialization of products; and/or
- have the product removed from the market after obtaining regulatory approval.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could allow our competitors to bring products to market before we do or could result in the delay of our ability to successfully commercialize our product candidates until after the patents relevant to a particular product candidate have expired, harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials will depend in part on the speed at which we and our partners can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA or similar regulatory authorities. In particular, our clinical trials include some patients with specific genetic mutations or markers that may make them ideal candidates for treatment. These genetic mutations or markers, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genetic mutations or markers. For example, we are studying infigratinib in gastric cancer patients with FGFR2 gene amplifications, which limits the total size of the addressable patient population available and may cause delays in clinical development. The inability to enroll a sufficient number of patients with the applicable genetic mutation or marker or that meet other applicable criteria for our clinical trials has resulted in and could result in further significant delays and could require us to abandon one or more clinical trials altogether. In addition, our or our partners' ability to enroll patients has been and may be further delayed by the COVID-19 pandemic.

In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, there are ongoing clinical trials, or we expect clinical trials to be initiated, in China of investigational therapeutic candidates for the treatment of gastric cancer, HCM, non-small cell lung cancer and other indications that we are pursuing, or may in the future pursue.

Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- the availability of an appropriate genomic screening test;
- the regulatory approval required for conducting genomic screening tests;
- the perceived risks and benefits of the product candidate under study, including 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;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability and efficacy of competing therapies and clinical trials;
- the ability to monitor patients adequately during and after treatment;
- natural disasters or public health epidemics and pandemics, such as the COVID-19 pandemic; and
- the proximity and availability of clinical trial sites for prospective patients.

If patients are unwilling to participate in our clinical trials for any reason, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential product candidates may be delayed. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our ADSs to decline and limit our ability to obtain additional financing.

Interim, topline and preliminary data from preclinical studies or clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our or our partners' preclinical studies and our or our partners' clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim, topline or preliminary data by us, our partners or by our competitors could result in volatility in the price of our ADSs.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is derived from information that is typically extensive, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain regulatory approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Results from previous or ongoing studies are not necessarily predictive of our or our partners' future clinical trial results, and initial or interim results may not continue or be confirmed upon completion of the trial. There is limited data concerning long-term safety and efficacy following treatment with our product candidates. These data, or other positive data, may not continue or occur for these patients or for any future patients in our or our partners' ongoing or future clinical trials, and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials. There can be no assurance that any of these trials will ultimately be successful or support further clinical advancement or marketing approval of our product candidates.

Undesirable side effects and AEs could delay or prevent the regulatory approval of our product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects and AEs that occur in our clinical trials could cause us to interrupt, delay or halt clinical trials or could cause regulatory authorities or IRBs to interrupt, delay or halt our clinical trials, and could also result in a more restrictive label or the delay or denial of regulatory approval by the NMPA or other regulatory authorities. In particular, as is the case with other oncology drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology product candidates. For example, the known AEs for infigratinib include temporary increases in the mineral phosphorus (also called phosphate) in the blood, temporary changes in kidney function, which are most frequently seen at the same time as the changes in phosphorus blood levels, and eye-related side effects (most frequently dry eye and blurry vision). Adverse events that have been observed in clinical trials of other SHP2 inhibitors include hematologic abnormalities and potential changes in regulation of serum electrolytes, particularly calcium and phosphorus. The results of our product candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects, including undesirable side effects related to off-target toxicity. In addition, if any of our product candidates are tested or used in combination with other drugs, these combinations may have additional side effects, which could be more severe than those caused by either therapy alone. Any patient deaths or severe side effects caused by our product candidates, or by therapies or therapeutic candidates of other companies that are thought to have similarities with our product candidates, or the use of our product candidates in combination with other drugs could result in the delay, suspension or termination of our clinical trials by us, an ethics committee, the NMPA or other regulatory authorities. The NMPA or comparable regulatory authorities could order us to cease further development of or deny or revoke approval of our product candidates for any or all targeted indications. The drug-related side effects or AEs could adversely affect patient recruitment or the enrolled patients' ability or willingness to complete the trial, or could result in potential product liability claims or contract disputes. Any of these occurrences may harm our business, financial condition and prospects significantly. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, or if we fail to achieve market acceptance of any product candidate, the commercial prospects of such product candidates will be harmed and our ability to generate revenue from any of these product candidates would be delayed or eliminated.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive regulatory approval and we, our partners or others identify undesirable side effects or AEs related to our product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- the NMPA or other comparable regulatory authorities may revoke or limit their approval of such product candidates;
- our clinical trials may be placed on hold;
- the NMPA or other comparable regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication or the revision of package insert;

- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of our product candidates;
- the NMPA or other comparable regulatory authorities may require a Risk Mitigation Plan ("RMP") or comparable report or plan (or analogous requirement) to mitigate risks, which 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;
- we may be subject to regulatory investigations and government enforcement actions, including being subject to fines, injunctions or the imposition of criminal or civil penalties;
- we may decide to remove such product candidates from the marketplace;
- the product candidates may become less competitive;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenue.

If we are unable to obtain NMPA approval for our product candidates to be eligible for accelerated review or approval pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if our product candidates were to be qualified for accelerated review or approval, it may not lead to a faster development, review or approval process.

The 2020 Drug Registration Regulation and the auxiliary regulatory documents currently provide four procedures for fast-track review and approvals of drugs. The four procedures are (i) the review and approval procedures for break-through therapeutic drugs; (ii) the review and approval procedures for drug conditional approval application; (iii) the priority review procedures for drug marketing authorization approval; and (iv) drug special review and approval procedures in case of a public health emergency. The NMPA would prioritize the allocation of resources for communication, guidance, review, inspection, examination and approval of applications that are qualified for the application of the four procedures.

Although we have previously applied and may in the future apply for fast-track review and approval of certain of our product candidates as a break-through therapy, for priority review, or for conditional approval, we may not be able to submit the application for break-through therapy designation or obtain the NMPA's approval for break-through therapy designation or priority review or obtain the NMPA's conditional approval for any of our product candidates in a timely manner, or at all. For example, in February of 2022 the NMPA granted breakthrough therapy designation in China for mavacamten for the treatment of patients with oHCM. However, even if granted, break-through therapy designation or priority review may not lead to faster development or accelerate the regulatory review or approval process. Moreover, such designation does not increase the likelihood that our product candidates will receive regulatory approval. If break-through therapy designation or priority review is not granted, our timeline for the development, regulatory approval and commercialization of our product candidates may be adversely affected and associated costs may increase. We may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future if our product candidates fail to be qualified for any accelerated review and approval pathway, we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions or any approval contains significant limitations.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Additionally, if we, through third parties, engage in the scale-up of manufacturing, we may encounter unexpected issues relating to the manufacturing process or the quality, purity and stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of preclinical studies and clinical trials. Such changes may also require additional testing, notification or approval by the NMPA or other comparable regulatory authorities, including additional pharmacokinetics ("PK") or pharmacodynamics trials. This could delay completion of preclinical studies and clinical trials; require us to conduct bridging clinical trials or studies, or to repeat one or more clinical trials; increase study or clinical trial costs; or delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analyses, and use such estimates in making decisions regarding our product development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus during preclinical studies or clinical trials. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects. Further, even if we obtain approval for a product candidate, the NMPA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development.

Risks related to our business operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of the members of our development team, as well as the other principal members of our management team, including Yizhe Wang, Ph.D., our Chief Executive Officer and Yi Larson, our Chief Financial Officer. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time with one month's prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, sales and marketing and other qualified personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers 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 drugs as part of a cross-border company in our key geographies. Competition to hire from this limited 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, our management team is required to devote significant time to new compliance initiatives from our status as a U.S. public company, which may require us to recruit more management personnel. Failure to succeed in our preclinical studies or clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

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

As we advance our development and commercialization plans and operate as a public company, we expect to need additional managerial, operational, financial and other personnel. We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of product development, regulatory affairs and business and commercial development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and could have a materially adverse effect on our business.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market, distribute and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the NMPA or comparable regulatory authorities in other jurisdictions, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales, distribution and marketing operations. Without an internal commercial organization or the support of a third party to perform sales, distribution and marketing functions, we may be unable to compete successfully against these more established companies.

Product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability exposure related to the use of our product candidates in clinical trials or any product candidates we may decide to commercialize in the future. If we cannot successfully defend against claims that the use of such product candidates in our clinical trials or any products, including any of our product candidates which receive regulatory approval in the future, caused injuries, we could incur substantial liabilities and our relationship with our partner clinical trial sites may be adversely affected. Regardless of merit or eventual outcome, liability claims may result in:

- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants or clinical trial sites or investigators and inability to continue clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- the inability to commercialize any product candidates that we may develop;
- initiation of investigations by regulators;
- loss of revenue;
- a diversion of management's time and our resources; and
- a decline in the price of our ADSs.

In addition, our licensing partners are subject to similar product liability risks in the jurisdictions in which they operate. Any of these events could prevent us, our current partners or our potential future partners from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

The Good Clinical Practices ("GCP") generally requires the study sponsor to purchase insurance for clinical trials. Except for the China GCP, existing Chinese laws and regulations do not require us to have, nor do we currently maintain, liability insurance to cover product liability claims. We do not have business liability or, in particular, product liability insurance for each of our product candidates. Any litigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with our collaborators.

Our internal information technology systems, or those used by our CROs, our licensors' contract manufacturing organizations ("CMOs") or our other collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization programs.

Despite the implementation of security measures, our internal information technology systems and those of our CROs, our licensors' CMOs and our other collaborators, contractors and consultants are vulnerable to damage from internal or external events, such as computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, which compromise the confidentiality, integrity and availability of the systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development, gaining regulatory approval for our product candidates and commercialization efforts and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather conditions), medical epidemics and pandemics, such as the COVID-19 pandemic, terrorist attacks, war or geopolitical events, such as the ongoing war between Russia and Ukraine, or other similar events. Such events could cause loss of data, damage to systems and data and leave us unable to utilize key business systems or access important data needed to operate our business, including our development activities or gaining regulatory approval for our product candidates. Our CROs, our licensors' CMOs and our other collaborators, contractors and consultants have and in the future may face similar risks, and service disruptions or security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. 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. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we and our third-party vendors have on occasion experienced, and will continue to experience, threats to our or their data and systems, including malicious codes and viruses, phishing, business email compromise attacks, ransomware or other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data security and data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We develop and maintain systems and controls designed to prevent these events from occurring, and we are establishing processes to identify and mitigate threats. The development and maintenance of these systems, controls and processes is costly and will require ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our CROs, our licensors' CMOs and our other collaborators, contractors or consultants, or our and their efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, ransomware, industrial espionage attacks or insider threat attacks that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us.

Risks related to the regulation of our business

Our product candidates are subject to extensive regulation, and we cannot give any assurance that any of our product candidates will receive regulatory approval or be successfully commercialized.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export and post-approval pharmacovigilance compliance, are subject to comprehensive regulation by the NMPA and other regulatory authorities in China, and by comparable authorities in other countries where we may seek to obtain regulatory approval for our product candidates. We are not permitted to market any of our product candidates in China or other jurisdictions unless and until we receive regulatory approval from the NMPA and comparable regulatory authorities.

Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The Technical Guidelines for the Acceptance of Overseas Clinical Trial Data for Drugs published in 2018, for example, outlines the method by which foreign clinical data may be used to support an application. The Center for Drug Evaluation of the NMPA will assess data obtained from an overseas clinical trial to determine whether the data demonstrate the likelihood of ethnic sensitivity (*i.e.*, whether the overseas data includes enough Chinese patients to justify safety and efficacy for Chinese patients). If there is insufficient information or the data suggests ethnic inconsistencies in effectiveness and safety, we may be required to conduct a bridging pharmacokinetics trial in Chinese patients either before or in tandem with initiating a clinical trial in China (for example, we are conducting a PK trial of TP-03 in healthy adults in China), and any such clinical trial may not be able to replicate the efficacy and safety data from global trials. Securing regulatory approval may also require the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. The NMPA may also require a RMP or analogous requirement in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

We cannot provide any assurance that we will ever obtain regulatory approval for any of our product candidates or that any of our product candidates will be successfully commercialized, even if we receive regulatory approval. Our product candidates may not be effective, may be only moderately effective or may prove to have a high and unacceptable severity and prevalence of undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In such an event, our clinical trials could be suspended or terminated and the NMPA or other relevant regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

The process of obtaining regulatory approvals in China and other countries is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. The regulatory process in China is also evolving and subject to change. Changes in regulatory approval policies, standards or procedures during the development period may require us to change our planned clinical trial designs or otherwise spend additional resources and effort to obtain clinical trial or marketing authorization approvals of our product candidates, and changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted marketing authorization application, pre-market approval or equivalent application type, may cause delays in the approval or rejection of an application. In addition, policy changes may result in significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. The NMPA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- failure to satisfy the requirements of the NMPA or comparable regulatory authorities regarding regulatory inspections, including GCP, Good Supply Practices ("GSP") or Good Manufacturing Practice ("GMP"), product conformity inspections and other routine or ad hoc inspections;
- failure to satisfy the requirements of the HGRAC or comparable regulatory authorities, or to obtain the HGRAC's or comparable regulatory authorities' approvals regarding the collection, use or outbound transfer of Chinese HGRs;
- failure of CROs, clinical trial sites or investigators to comply with the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the requirements of China GCP imposed by the NMPA;

- failure of the clinical trial results to meet the level of statistical significance required by the NMPA or comparable regulatory authorities for approval;
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the NMPA or comparable regulatory authorities;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the NMPA or comparable regulatory authorities disagreeing with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in China or elsewhere;
- the NMPA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions or inactions that materially and adversely impact the clinical trials and the regulatory application process.

In addition, even if we were to obtain approval, regulatory authorities may revoke approval, may approve any of our product candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our drugs or indirectly limit our ability to charge or change the price of our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials 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. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining 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, while 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 NMPA grants marketing approval of a product candidate, comparable regulatory authorities in foreign 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, and greater than, those in China, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or 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 receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our product candidates, we may be subject to penalties.

If the NMPA or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any such product candidate will be subject to extensive and ongoing regulatory requirements. These requirements may include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, and continued compliance with Current Good Manufacturing Practices ("cGMPs"), Good Laboratory Practices ("GLPs") and GCPs. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials for the surveillance and monitoring the safety and efficacy of the product candidate.

Once a drug is approved by the NMPA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our product candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market or voluntary or mandatory drug recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring mediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, such as boxed warnings;
- imposition of an RMP, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil, administrative or criminal penalties; and
- revocation of approval of such drug.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may harm our business, financial condition and prospects significantly.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, which could adversely impact our operating results.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate in Greater China and other Asian markets have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law, which became effective in June 2017, created China's first national-level data protection regime for "network operators," which may include all organizations in China that provide services over the internet or another information network.

We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or anonymized health data for clinical trials in compliance with local regulations. This data could be deemed by government regulators to be "personal information" or "important data." With China's growing emphasis on its sovereignty over data derived from China, the outbound transmission of de-identified or anonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, the Data Security Law, the PIPL, and various implementing regulations and standards. We may transfer and store personal data and information that whistleblowers provide through our whistleblower hotline to, in, and using centralized databases and systems located in the United States, Mainland China, and Hong Kong. In addition, we have engaged a third-party data processor to process the personal data and information that such whistleblowers provide, on our behalf. Such personal data and information will be stored in one or more databases located on servers hosted and operated by the third party, in the United States.

Under the Cyber Security Law and the Measures on Standard, Safety and Service of the National Medical Care Big Data (Tentative), the transmission of certain personal information, important data and health and medical care big data outside of China is only permitted upon the completion of a security assessment conducted by or as determined by the Chinese government.

In addition, the SCNPC promulgated the Data Security Law on June 10, 2021, which became effective on September 1, 2021. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities, and introduces a data classification and hierarchical protection system. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the PIPL, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We will be obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems fully as needed to ensure compliance with our legal obligations. Despite our investment in establishing these systems, such systems may not fully guard us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we face. Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of important data, and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in China with judicial and law enforcement authorities outside of China. If judicial and law enforcement authorities outside China require us to provide data stored in China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impact on our operations both in and outside of China.

Furthermore, on December 28, 2021, the CAC, China's top cyberspace regulator, released the final version of the Revised Draft CAC Measures ("the Revised CAC Measures"), which came into effect on February 15, 2022. Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

On September 1, 2022, the Security Assessment Measures issued by the CAC came into effect. Under the Security Assessment Measures, the outbound transfer of data by a data processor would be subject to application of a security assessment under any of the following circumstances: (i) transfer of important data by data processors; (ii) transfer of personal information by critical information infrastructure operators and data processors that process personal information of more than one million individuals; (iii) transfer of personal information by data processors that have transferred either personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. According to statements by the CAC, an outbound transfer of data includes (i) an outbound transfer and overseas storage of data collected and generated during a data processor's operation in mainland China; and (ii) a remote access or use of data collected and generated by a data processor stored within mainland China by overseas institutions, organizations, and individuals.

In November 2021, the CAC further published the Draft Data Security Management Regulations, under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Data Security Management Regulations reiterate that data processors shall be subject to cybersecurity review if they process personal information of more than one million persons and aim to list on foreign stock markets, or the data processing activities influence or may influence national security. The Draft Data Security Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by themselves or through data security service organizations, and submit the assessment reports to relevant competent authorities. As the Draft Data Security Management Regulations was released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty.

The national security legal regime imposes stricter data localization requirements on personal information and human health-related data and requires us to undergo cybersecurity or other security review, obtain government approval or certification, or put in place certain contractual protections before transferring personal information and human health-related data out of China. As a result, personal information, important data and health and medical data that we or our customers, vendors, clinical trial sites, pharmaceutical partners and other third parties collect, generate or process in China may be subject to such data localization requirements and heightened regulatory oversight and controls. To comply with these requirements, maintaining local data centers in China, conducting security assessments or obtaining the requisite approvals from the Chinese government for the transmission outside of China of such controlled information and data could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside China. We expect that the evolving regulatory interpretation and enforcement of the national security legal regime will lead to increased operational and compliance costs and will require us to continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss or use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of Mainland China, be unable to comply with our contractual requirements, suffer reputational harm or be subject to penalties, including administrative, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. If any of these were to occur, it could adversely affect our ability to operate our business and our financial results.

The General Office of the State Council passed the Scientific Data Administrative Measures in March 2018, which provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality and security of scientific data. Scientific data is defined as data generated from basic research, applied research, experiments and developments in the fields of natural sciences, engineering and technology. It also includes the original and derived data by means of surveillance, monitoring, field studies, examination and testing that are used in scientific research activities. All scientific data generated by research entities, including research institutions, higher education institutions and enterprises that is created or managed with government funds, or funded by any source that concerns state secrets, national security, or social and public interests, must be submitted to data centers designated by the Chinese government for consolidation. Disclosure of scientific data will be subject to regulatory scrutiny.

The definition of scientific data is quite broad, but the Chinese government has not issued further guidance to clarify if clinical study data would fall within the definition of scientific data. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data centers, or prevented the cross-border transmission and sharing of clinical study data. While we do not currently plan to utilize government funds when conducting our research and development activities, we may pursue some forms of government funding or support in the future. We plan to closely monitor legal and regulatory developments in this area to see how scientific data is interpreted, and we may be required to comply with additional regulatory requirements for sharing clinical study data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the HGR Regulation promulgated by the State Council, which became effective on July 1, 2019, applies to activities that involve collection; biobanking; use of HGR, which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substances (the "China Biospecimens"); and derived data, in China (together with the China Biospecimens, the "China-Sourced HGR"), and provision of such items to foreign parties. The HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR outside of China. Chinese parties are required to seek an advance approval for the collection of certain HGR and biobanking of all HGR. Approval for any export or cross-border transfer of China Biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the HGRAC for record and obtain a notification filing number in order to transfer. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

If the Chinese parties fail to comply with data protection laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, we may lose our confidential information and be subject to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGRAC has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any clinical trial applications until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multi-national pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAC approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of six to 12 months, respectively.

To further tighten the control of China HGR, the SCNPC issued the Eleventh Amendment to the Criminal Law of the People's Republic of China on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR, the illegal transfer of China-sourced biospecimens outside of China, and the transfer of China-sourced derived data to foreign parties or entities established or actually controlled by them without going through security review and assessment. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to seven years and/or a criminal fine. In October 2020, the SCNPC adopted the Biosecurity of the People's Republic of China ("PRC Biosecurity Law"), which became effective on April 15, 2021. The PRC Biosecurity Law will establish an integrated system to regulate biosecurity-related activities in China, including, among others, the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time 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 China-Sourced HGR by foreign entities in China. Though the PRC Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulator 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 for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In addition, in the United States, at both the federal and state levels, and in territories outside of Mainland China where we have rights to and plan to develop and commercialize our in-licensed product candidates, including Hong Kong, Macau, Singapore, South Korea, Taiwan and Thailand, we are subject to laws and regulations that address privacy, personal information protection and data security. Numerous laws and regulations, including security breach notification laws, health information privacy laws and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

We expect that these data protection and transfer laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under data protection, privacy and security laws in China, the United States and other countries where we plan or conduct business will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, result in the suspension of ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the European Union General Data Protection Regulation, Cyber Security Law and HGR Regulation. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business and results of operations.

Reimbursement may not be immediately available for our product candidates in China or other countries, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceuticals vary widely from country to country. In China, the NHSA and its local counterparts, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, or the NRDL or provincial or local medical insurance catalogs for the national medical insurance program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

Historically, products included in the NRDL were typically generic and essential drugs. Innovative drugs were more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance. Since 2016, the government has started to include more innovative drugs in the NRDL through negotiations with marketing authorization holders of patented drugs, drugs with an exclusive source of supply and oncology drugs. On January 18, 2023, the NHSA published the 2022 NRDL, which included 111 additional drugs, among which 108 drugs were added to the 2022 NRDL via price negotiation with drug companies, resulting in an average price reduction of 60.1%.

We expect that most of our product candidates will be eligible for inclusion in the NRDL for the National Medical Insurance scheme, but such inclusion is not guaranteed. If we were to successfully launch commercial sales of our product candidates, our revenue from such sales will initially be self-paid by patients, which may make our product candidates less accessible. If the NHSA or any of its local counterparts accepts our application for the inclusion of our product candidates in the NRDL or provincial or local medical insurance catalogs, which may increase the demand for our product candidates, our potential revenue from the sales off our product candidates may still decrease as a result of lower prices we may be required to charge for our product candidates that are included in the NRDL or provincial or local medical insurance catalogs.

Moreover, eligibility for reimbursement in China or other countries does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including but not limited to licensing fees and costs incurred in development, distribution and sale. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in China or in other countries where we market our drugs. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Risks Related to our In-Licensing Business Model and Dependence on Third Parties

If we breach our licenses or other intellectual property-related agreements for our product candidates or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.

Our business relies, in large part, on our ability to develop and commercialize product candidates we have licensed and sublicensed from third parties, including mavacamten from MyoKardia Inc. ("MyoKardia," now a wholly owned subsidiary of Bristol-Myers Squibb ("BMS")), TP-03 from Tarsus Pharmaceuticals, Inc. ("Tarsus"), infigratinib from QED Therapeutics, Inc. ("QED"), NBTXR3 from Nanobiotix S.A. ("Nanobiotix"), BBP-398 from Navire Pharma, Inc. ("Navire"), LYR-210 from Lyra Therapeutics, Inc. ("Lyra"), NX-13 from Landos BioPharma, Inc. ("Landos") and omilancor from NImmune Biopharma, Inc. ("NImmune"). Our licenses may not cover all intellectual property rights owned or controlled by our licensors and relevant to our product candidates. If we have not obtained a license to all intellectual property rights owned or controlled by our licensors that are relevant to our product candidates, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors breach such agreements, we may not be able to enforce such agreements against our licensors or their parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing to us the right to develop and commercialize the applicable product candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such product candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations, including development and diligence obligations, providing certain information regarding our activities with respect to such product candidates and/or maintaining the confidentiality of information we receive from our licensors. For example, under our license agreement with MyoKardia, we are required to use commercially reasonable efforts to conduct the clinical, regulatory and other activities necessary to develop and commercialize mavacamten in the licensed territories in accordance with a development plan and a commercial plan, and MyoKardia may terminate the agreement if we fail to achieve certain key milestones. Our other license agreements include similar performance obligations and termination provisions.

If we fail to meet any of our obligations under our license and intellectual property-related agreements, our licensors may have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sublicensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable product candidates and other third parties may be able to market product candidates similar or identical to ours. In such case, we may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. For example, if our agreement with Navire for BBP-398 terminates for any reason, we are required to grant Navire an exclusive license to certain of our intellectual property rights that cover inventions created by us solely or jointly with Navire in our performance of or exercise of our rights under our agreement with Navire or are used or applied as of the date of such termination in our development, manufacture or commercialization of BBP-398. Our license agreements with each of our other licensors contain similar provisions. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our product candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such product candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our ability to generate revenue and achieve profitability from third party licensed product candidates also depends upon our ability to retain exclusivity on the licensed product candidates and related product candidates controlled by the licensor. For example, under our agreement relating to BBP-398, Navire is required to grant us the first right to exclusively negotiate an exclusive license to develop, manufacture and commercialize certain compounds or products that Navire or its affiliates may acquire during the term of the license agreement to develop products or therapies in combination with BBP-398. However, we may fail to reach a definitive agreement during such negotiation period.

In addition, disputes may further arise regarding intellectual property subject to a license agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party and have granted us a sublicense. For example, our licenses from QED, Navire and Tarsus comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses, and our ability to produce and sell our products and product candidates may be materially harmed.

Our licenses from MyoKardia, QED, Navire, Nanobiotix, Lyra, Tarsus, Landos and NImmune are limited to intellectual property rights under the control of such licensors. To the extent any of our licensors loses control over any of the intellectual property rights we license from them for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize our related product candidates. Any of the foregoing would have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or sublicensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we experience disruptions to our business relationships with our licensors, we could lose the ability to continue to source, develop and commercialize our product candidates, including ultimately losing our rights to such product candidates. For example, we have entered into an agreement with MyoKardia for clinical supply of mavacamten and also are working with MyoKardia on the regulatory approval process. If we are unable to secure clinical supply of mavacamten in a timely manner (or at all), we may suffer significant delays in the regulatory approval process, be unable to conduct clinical trials or fail to commercialize mavacamten in a timely manner (or at all). MyoKardia may terminate the agreement if we fail to achieve certain key milestones.

We rely on Perceptive Advisors, LLC ("Perceptive"), our founder and a significant shareholder in our company, as a source for identifying partners from which we may in-license product candidates. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise in sourcing opportunities and our business could be substantially harmed. Perceptive and its affiliates exercise significant influence over us, which may limit the ability of our investors and other holders to influence corporate matters and could delay or prevent a change in corporate control.

We rely in part on our relationship with Perceptive, our founder and a significant shareholder in our company, to implement our business strategy, including sourcing and identifying potential partners from which we may in-license product candidates for development. Perceptive has significant expertise in operational, financial, strategic and other matters key to our business strategy. This expertise has been available to us through the representatives Perceptive has had on our board of directors. As of March 23, 2023, Perceptive and its affiliates beneficially own 53.7% of our ordinary shares, based on the number of shares outstanding as of March 23, 2023. Because entities affiliated with Perceptive control a majority of the voting power of our outstanding ordinary shares, we are a controlled company (within the meaning of the Nasdaq rules). We intend to take advantage of corporate governance exemptions available to controlled companies, including exemptions from:

- the requirement that a majority of the board of directors consist of independent directors;
- the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.

As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all of the Nasdaq corporate governance rules.

In addition, two of our non-employee directors are affiliated with Perceptive. As a result, Perceptive has the ability to substantially influence us, including through our 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. Perceptive and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. In the ordinary course of its business activities, Perceptive's interests may not always coincide with our corporate interests or the interests of minority holders of our ADSs, and it may exercise its voting and other rights in a manner with which other holders may not agree or that may not be in the best interests of our other shareholders. Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our company.

Our business model is designed to in-license additional product candidates for development. If Perceptive divests of its investment in our company or is no longer a significant shareholder, we may lose access to its expertise and would need to rely on other avenues, such as through our strategic collaboration agreements with Pfizer Inc. and BridgeBio Pharma LLC, to source potential licensing partners and product candidates for development. In addition, conflicts of interest could arise in the future between us, on the one hand, and Perceptive and its affiliates and affiliated funds, including its and their current and future portfolio companies, on the other hand, concerning potential business opportunities, including potential licensing parties. Perceptive and its affiliated funds invest in companies that develop and commercialize drugs in global markets. As a result, Perceptive and its affiliates' and affiliated funds' current and future portfolio companies may now or in the future, directly or indirectly, compete with us for partnership and licensing opportunities.

We rely on our licensors and their contracts with third-party manufacturers to produce any product candidates that we are developing in our territories and for which we receive regulatory approval and engage in commercialization. If the manufacturing facilities of these third-party manufacturers are not approved by regulators, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

We currently intend to rely on our licensors and their third-party manufacturers for the manufacture of the clinical and commercial supply of our product candidates. Our licensors will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and they may not be able to do so on favorable terms. Prior to being permitted to sell any drugs produced at these facilities, the facilities will need to be inspected and approved by regulatory authorities. If these facilities are not approved by regulators or are damaged or destroyed, or otherwise subject to disruption, our licensors may require substantial lead time to replace their manufacturing capabilities.

In such event, our licensors would be forced to identify and rely partially or entirely on alternative third-party CMOs for an indefinite period of time. Any new facility needed to replace an existing production facility would need to comply with the necessary regulatory requirements and be tailored to our licensors' production requirements and processes. We also would need regulatory approvals before using any products manufactured at a new facility in clinical trials or selling any products that are ultimately approved. If our licensors' third-party manufacturers experience a shortage in supply, such shortage would have a negative impact on our business. Any disruptions or delays at the facilities of our licensors' third-party manufacturers or their failure to maintain regulatory compliance would impair our ability to develop and commercialize our product candidates, which would adversely affect our business and results of operations. In addition, any interruption of supplies would adversely affect our business and results of operations. For example, the COVID-19 pandemic has had and could continue to have a broad impact on the production and supplies of active ingredients or other raw materials and result in a potential shortage of supply.

Our anticipated reliance on a limited number of third-party manufacturers through our licensing partners exposes us to a number of risks, including the following:

- our licensing partners could be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited;

- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our licensors' third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our licensors' manufacturing procedures and other logistical support requirements appropriately;
- our licensors' future CMOs may not perform as agreed, may not devote sufficient resources to our licensors' and our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- manufacturers may be subject to ongoing periodic unannounced inspection by regulatory authorities to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our licensors' third-party manufacturers in the manufacturing process for our product candidates;
- our licensors' third-party manufacturers could breach or terminate their agreements with our licensors;
- raw materials and components used in the manufacturing process, particularly those for which our licensors have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our licensors' CMOs and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our licensors' CMOs may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over the ability of our licensors' CMOs to maintain adequate quality control, quality assurance and qualified personnel.

We rely on third parties to conduct some of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely on third-party CROs to conduct some of our preclinical studies and clinical trials and to monitor and manage data for certain of our preclinical studies and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the timing, conduct, and completion of our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we relied entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with GLP and the Regulations for the Administration of Affairs Concerning Experimental Animals or the Animal Welfare Act requirements. We and our CROs are required to comply with GCP and GLP regulations and guidelines enforced by the NMPA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure investors that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with International Council for Harmonisation GCP and China GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for which they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or compromised.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with our CROs, our product development efforts could be delayed.

We rely on third-party vendors and CROs for some of our preclinical studies and clinical trials related to our product development efforts. Switching or adding additional CROs involves additional cost and requires management's time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have the ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

We are dependent on third-party manufacturers retained by our licensing partners for the manufacture of our product candidates and for our supply chain. If we or our licensing partners experience problems with any of these third parties, the manufacture of our product candidates or products could be delayed, which could harm our results of operations.

In order to successfully commercialize our product candidates, we currently intend to rely on our licensing partners to identify qualified CMOs for the scaled production of a commercial supply of certain of our product candidates. For a number of our product candidates, we or our licensing partners have not yet identified suppliers to support scaled production. If we or our licensing partners are unable to contract with CMOs for clinical and commercial supply of our product candidates, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. For example, we source our clinical drug supply of mavacamten through a clinical supply agreement and expect to source our commercial drug supply of mavacamten through a commercial supply agreement with MyoKardia, and any disruption or delay in the ability of BMS to manufacture and deliver mavacamten for our clinical trials, or any disruption in our planned supplier relationship with BMS, could harm our business, results of operations, financial condition and prospects. Similarly, we source our clinical drug supply of, and expect to source our commercial drug supply, of TP-03 from Tarsus, and such supply is contingent upon Tarsus’s ability to obtain adequate supply.

Our reliance on third-party manufacturers retained by our licensing partners to manufacture our product candidates entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on such third parties for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by such third parties because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by such third parties, based on their own business priorities, at a time that is costly or damaging to us. In addition, the NMPA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMPs and China GMP standards. Any failure by the third-party manufacturers retained by us or our licensing partners to comply with cGMPs and China GMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or the imposition of civil and criminal penalties.

Any significant disruption in our potential supplier relationships could harm our business. We intend to source key materials from third parties, either directly through our licensors or indirectly through our licensors' agreements with suppliers or their manufacturers who have agreements with suppliers. We anticipate that, in the near term, all key materials will be sourced through third parties, including, for example, our clinical drug supply of mavacamten, which we have sourced under a clinical supply agreement with BMS. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture some of our drugs. Such suppliers may not sell these key materials to us or our licensors' manufacturers at the times we need them or on commercially reasonable terms. We currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If we or our licensors' manufacturers are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

If any manufacturer with which we or our licensors currently or may in the future contract fails to perform its obligations, we or our licensors, as applicable, may be forced to enter into an agreement with a different manufacturer, which we or our licensors may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we or our licensors establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we or our licensors may have difficulty, or there may be contractual restrictions prohibiting us or our licensors from, transferring such skills to a back-up or alternate supplier, or we or our licensors may be unable to transfer such skills at all. In addition, if we or our licensors are required to change manufacturers for any reason, we or our licensors will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. The delays associated with the verification of a new manufacturer could negatively affect our ability to advance clinical trials or otherwise develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which may increase our or our licensors' reliance on such manufacturer or require us or our licensors to obtain a license from such CMO in order to have another manufacturer manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Furthermore, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Because of the complex nature of our compounds, we or our licensors' manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to complete large-scale clinical trials or make commercially successful products. In addition, as our product development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of our current licensors' suppliers may need to increase their scale of production to meet our projected needs for commercial manufacturing. Any failure on the part of our licensors' suppliers to meet our needs for commercial manufacturing could adversely impact our business and result of operations.

We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.

We have licensed and sublicensed patent rights from third parties for our development programs, including mavacamten from MyoKardia, TP-03 from Tarsus, NBTXR3 from Nanobiotix, LYR-210 from Lyra, NX-13 from Landos and omilancor from NImmune. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sublicensors. We cannot be certain that these patents and patent applications have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our product candidates. If our licensors or such third parties fail to prepare, prosecute or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with certain of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. For example, under our license agreement with MyoKardia, MyoKardia has the first right to enforce the licensed patents in our licensed territory, subject to certain exceptions. MyoKardia also maintains the right to enforce such licensed patents in all other territories. Under our license agreement with Tarsus, we have the first right to enforce the licensed patents in our licensed field and territory. However, Tarsus maintains the sole right to enforce such licensed patents in all other territories, or if we do not elect to enforce the licensed patents against an infringement action within a specified timeframe of our notifying Tarsus or being notified by Tarsus of the infringement in our licensed territory. Each of our other license agreements contains similar provisions allocating rights to control the enforcement and defense of the licensed intellectual property.

Even if we are permitted to pursue the enforcement or defense of our licensed and sublicensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates. As a result, we may not be able to prevent competitors from developing and commercializing competitive product candidates in territories included in all of our licenses.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the product candidates that we license from third parties. Moreover, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sublicensors. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

In addition, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights or other rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates covered by these license agreements. If such licenses are terminated, we may be required to seek alternative in-license arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, we may need to modify or cease the development, manufacture and commercialization of one or more of our product candidates, and competitors would have the freedom to seek regulatory approval of and to market products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us, and our ability to successfully develop and commercialize any of our product candidates and technology may be adversely affected.

Our success depends, in part, on our ability to protect our proprietary technology and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights (whether owned or in-licensed), including patent rights. We seek to protect the product candidates and technology that we consider commercially important by filing patent applications in the major pharmaceutical markets, including China and other countries and regions; relying on trade secrets or pharmaceutical regulatory protection; or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and product candidates. If we or our licensors are unable to obtain or maintain intellectual property protection with respect to our product candidates and technology we develop or do not otherwise adequately protect our intellectual property, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our or their research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any patents we may own or in-license will have, or that any of our patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Furthermore, patents have a limited lifespan, and the term of any patents we may own or in-license may be inadequate to protect our competitive position of our product candidates or technology for an adequate amount of time.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of any patent protection we may have. If the patent protection provided by our patents with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patents may be invalidated, and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our development output, such as our employees, corporate collaborators, outside scientific collaborators, CMOs, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, 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 or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the "first-to-file" system under which the first party to file a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology that we invented.

In addition, under the Patent Law of the People's Republic of China (the "PRC Patent Law"), any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration ("CNIPA") for confidentiality examination. Otherwise, in general, if an application is later filed in China, the patent right will not be granted. Moreover, even if patents do grant from any of the applications, the grant of a patent is not conclusive as to its scope, validity or enforceability. This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China. Currently, we do not have any invention patents granted to us by CNIPA and we do not have any invention patents under the application process. However, the CNIPA has granted to our partners 14 invention patents to our various partners related to our in-licensed assets.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates and the relevant patent offices or intellectual property courts may not agree with our interpretation as to whether we have patentable technology. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure investors that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our in-licensed patents may be challenged in the courts or patent offices in China and other countries and regions. We and our licensors may be subject to the submission of third-party opposition to the CNIPA against our pending application, or may become involved in invalidation proceedings or similar proceedings in foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our in-licensed 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 product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or one of our licensors, may have to participate in proceedings on the ownership dispute of our licensor's invention or other features of patentability of our in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, 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 product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the terms of patents are finite. The patents we in-license and the patents that may issue from our licensors' currently pending owned and in-licensed patent applications generally have a 20-year protection period starting from such patents and patent applications' earliest filing date. 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 in-licensed patents and our licensors' owned patents or patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, the compound patent for infigratinib expires in 2025, the compound patent for TP-03 expires in 2029 and the method patent for NBTXR3 expires in 2029, which, in each case, may be prior to or shortly after the time that such product candidates are commercialized.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

Our business relies, in part, on our ability to develop and commercialize product candidates we have licensed from third parties, and we have entered into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. Our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our product candidates, and we may need to obtain additional licenses from our existing licensors and others to allow commercialization of product candidates we may develop. In such case, we may need to obtain additional licenses which may not be available on an exclusive basis, on commercially reasonable terms or at a reasonable cost, if at all. In addition, if our licensors breach the license agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable product candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such product candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such product candidates and/or maintaining the confidentiality of information we receive from our licensors.

If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, have the right to re-obtain the licensed and sublicensed technology and intellectual property. If any of our licensors terminate any of our licenses, we might not be able to develop, manufacture or market any drug or product candidate that is covered by the licenses provided for under these agreements and other third parties may be able to market product candidates similar or identical to ours. In such case, we may have to negotiate new or reinstated agreements with less favorable terms, and may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. We may also face claims for monetary damages or other penalties under these agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our product candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such product candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our market exclusivity in China under the data exclusivity and monitoring surveillance period mechanisms.

In China, theoretically, market exclusivity of an innovative or improved new drug is protected via three mechanisms: patent exclusivity, data exclusivity, and monitoring surveillance period. According to the Implementing Regulations of the PRC Drug Administration Law, the Chinese government protects undisclosed data from drug studies and prevents the approval of an application by another company that uses the undisclosed data of an approved drug. It grants data exclusivity for a period of six years to data included in an NDA applicable to a new chemical entity. In practice, however, the NMPA has not established an effective mechanism to enforce data exclusivity. The NMPA issued a draft regulation on regulatory data protection on April 25, 2018, for public comments, but this draft regulation has yet to be finalized and implemented.

In addition, if an approved drug manufactured in China qualifies as an innovative drug or an improved new drug before December 1, 2019, such drugs will be eligible for a monitoring surveillance period for up to 5 years. During this post-marketing surveillance period, the NMPA will not accept marketing authorization applications filed by another company for the same product. In addition, the NMPA will not approve marketing authorization applications filed by another company to produce, change the dosage form of or import the drug while the innovative or improved new drug is under surveillance for the purpose of protecting public health. Therefore, this monitoring surveillance period provides a de facto exclusivity to locally manufactured innovative drugs or improved new drugs. Since our in-licensed assets are not locally manufactured and were not approved before December 1, 2019, we can only rely on patent exclusivity to protect our market exclusivity in China.

We may not be able to protect our intellectual property in China.

The validity, enforceability and scope of protection available under the relevant intellectual property laws in China are uncertain and still evolving. Implementation and enforcement of Chinese intellectual property-related laws have historically been deficient and ineffective. Accordingly, intellectual property and confidentiality legal regimes in China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

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

Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Moreover, when we have in-licensed intellectual property, the decision as to the jurisdictions in which to seek protection may have already been made by the licensor. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in countries where protection has not been sought and obtained. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong. These products may compete with our products, 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, including China. 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 or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, 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, could put 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in Greater China and the other Asian markets in which we operate, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws by authorities in China, the United States and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, including changing the standards of patentability, and any such changes could have a negative impact on our business. For example, the recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, introduced patent extensions to eligible innovative drug patents, but lacks operational details. According to the PRC Patent Law, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. The adoption of this amendment may enable the patent owner to submit applications for a patent term extension. The actual 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.

Similarly, in the United States, the Leahy-Smith America Invents Act (the "America Invents Act"), which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system as of March 2013, changes to the way issued patents are challenged and changes to the way patent applications are disputed during the examination process. These include allowing third party submission of prior art to the U.S. Patent and Trademark Office (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. As a result of these changes, patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective in March 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. There could be similar changes in the laws of foreign jurisdictions that may affect the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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

In addition to the protection afforded by registered patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how, continuing technological innovation and other proprietary information to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our trade secrets and proprietary technology and processes, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants, CROs and other third parties, and into confidentiality and invention or patent assignment agreements with our consultants and employees. 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. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. 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. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets, including through intellectual property litigations or other proceedings, is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts in China and other jurisdictions inside and outside the United States are less prepared, less willing or unwilling to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. For example, competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts; willfully infringe, misappropriate or otherwise violate our intellectual property rights; design around our intellectual property protecting such technology; or develop their own competitive technologies that fall outside of our intellectual property rights. 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 others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition and results of operations. If we do not apply for patent protection or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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, which would have a material adverse effect on our ability to successfully commercialize any product or technology.

The life of a patent and the protection it affords is limited. For example, in China, if all maintenance fees are timely paid, the natural expiration of an invention patent is 20 years from its application date, if no patent term adjustment or extension is involved. 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 as well as the NMPA and the CNIPA in China, 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. 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.

We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.

Our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license product candidates to grow our product candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as cardiovascular and oncology. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

The recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and took effect in June 2021, describes the general principles of patent term extension and patent linkage. The patent term extension provided by the amended PRC Patent Law is similar to that under the Hatch Waxman Amendments. In July 2021, the NMPA and CNIPA jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "Measures on Patent Linkage"). The Measures on Patent Linkage describe a framework for patentees to defend their patent exclusivity and provides the conditions and procedures for the certification of non-infringement for generic companies and the marketing exclusivity period that may be granted to the first generic company receiving marketing authorization approval and succeeding the patent challenge. As of the date of this Annual Report on Form 10-K, no operational details have been published and taken effect on the patent term extension, and uncertainties remain with respect to how the Chinese government will implement the patent term extension in China. As a result, the patents we have in-licensed or own in China may not be eligible to be extended for any patent term lost during the regulatory review process. In addition, an extension may not be granted because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors could face reduced barriers to marketing competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical data and launch their product earlier than might otherwise be the case. If we are unable to successfully challenge potential patent infringement or obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following or before our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to government patent agencies over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to patent agencies. The government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

As of December 31, 2022, we had four trademark applications pending in Mainland China, nine trademarks registered in Mainland China, five trademarks registered in Hong Kong, three trademarks registered in Singapore, one trademark application pending in Singapore, one trademark application pending in the United States, four trademarks registered in Taiwan, four trademarks registered in Macau, six trademark applications pending in Macau, two trademark applications pending in South Korea, one trademark application pending in Thailand, two trademark applications pending in Cambodia, two trademarks registered in Indonesia and two trademarks registered in the Philippines. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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

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:

- our competitors may be able to make products or product candidates that are similar to product candidates we are developing or may develop but that are not covered by the claims of the patents that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future, which could result in the patents applied for not being issued or being invalidated after issuing;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to file patent applications covering certain inventions, which could result in the patents applied for not being issued or being invalidated after issuing;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights; it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we receive regulatory approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- 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 or sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may discover certain technologies containing such trade secrets or know-how through independent research and development and/or 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.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. We or our licensors may become involved in patent litigation against third parties to enforce our owned or in-licensed patent rights, to invalidate patents held by such third parties or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we or our licensors have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge include, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, lack of inventiveness, lack of written description or non-enablement. Grounds for an unenforceability assertion include, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. Even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidates. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, a court of competent jurisdiction may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current or future product candidates. Moreover, competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

If our product candidates infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell and commercialize these product candidates.

Our commercial success depends significantly on our and our collaborators' ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

There may be issued third-party patents of which we are currently unaware and there may in the future be additional third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States, China and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, or not infringed by our activities.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. 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, enforceability or priority. A court of competent jurisdiction or CNIPA could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such Chinese patent in CNIPA, we would need to overcome a presumption of validity. There is no assurance that the CNIPA would invalidate the claims of any such Chinese patent.

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, if at all, and even if we were able to obtain such licenses, they could be non exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments;
- defend litigation or administrative proceedings;

- reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming;
- cease developing, manufacturing and commercializing the infringing technology or product candidates; and
- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided consulting services to, other pharmaceutical companies including our competitors or potential competitors. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects. 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 this type of litigation. Even if we are successful in such litigations or administrative proceedings, such litigations and proceedings may be costly and time-consuming, regards of the outcome, and could result in a substantial diversion of management resources. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition and results of operations.

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 patent 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 which 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.

Intellectual property litigation may lead to unfavorable publicity, which may harm our reputation and cause the market price of our ADSs to decline, and any unfavorable outcome from such litigation could limit our development activities and/or our ability to commercialize our product candidates.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our ADSs may decline. Such announcements could also harm our reputation or the market for our product candidates, which could have a material adverse effect on our business.

In the event of intellectual property litigation, there can be no assurance that we would prevail, even if the case against us is weak or flawed. If third parties successfully assert their intellectual property rights against us, prohibitions against using certain technologies, or prohibitions against commercializing our product candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Additionally, we may be required to obtain a license from the intellectual property owner in order to continue our development programs or to commercialize any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This may not be technically or commercially feasible, may render our products less competitive or may delay or prevent the launch of our products to the market. Any of the foregoing could limit our development activities, our ability to commercialize one or more product candidates, or both.

Many of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our preclinical studies and clinical trials, continue our internal research programs, in-license needed technology or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of competitors or their current or former employers or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.

We could in the future be subject to claims that we or our employees, consultants or advisors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of current or former employers, competitors or other third parties. 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 improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have breached the terms of any non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer, competitor or other third parties.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, 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. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in enforcing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that 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.

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.

Our owned and in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to modify or cease the development, manufacture and commercialization of one or more of the product candidates we may develop, which could have a material adverse impact on our business.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture and commercialization of one or more of our product candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical product candidates. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Risks Related to Ownership of our Ordinary Shares or ADSs and our Status as a Public Company

We are an "emerging growth company," as defined in the Securities Act, and a "smaller reporting company," as defined in the Exchange Act, and we cannot be certain if the reduced disclosure requirements applicable to us as an "emerging growth company" and a "smaller reporting company" will make our ADSs less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and are taking advantage of, and may continue to take advantage of, certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, holders of our ADSs may not have access to certain information that they may deem important. We could be an emerging growth company through December 31, 2026, although circumstances could cause us to lose that status earlier, including if our total annual gross revenue exceeds $1.235 billion, if we issue more than $1.0 billion in non-convertible debt securities during any three-year period, or if the market value of our ordinary shares held by non-affiliates exceeds $700.0 million. We cannot predict if investors will find our ADSs less attractive because we rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard on the same timeline as other public companies, and we will not be able to revoke such election. This may make comparison of our financial statements with another emerging growth company that has not opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting ordinary shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting ordinary shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

We are incurring significantly increased costs as a result of operating as a U.S.-listed public company, and our management devotes substantial time to compliance initiatives.

As a public company in the United States, we incur significant legal, accounting and other expenses globally. These expenses will likely increase after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, compliance with these rules and regulations imposes significant legal and financial compliance costs on our business and makes some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and expensive for us to obtain director and officer liability insurance after the completion of our initial public offering, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

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

If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. However, while we remain an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting. To comply with Section 404, we are engaged in a process to document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we have dedicated and will continue to need to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal controls over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we have and will continue to need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

Despite our efforts, we might not identify one or more material weaknesses or significant deficiencies in our internal control over financial reporting in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. If we are unable to conclude that we have effective internal controls over financial reporting, 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 of the Sarbanes-Oxley Act, our ADSs may not be able to remain listed on the Nasdaq Global Market.

Recent litigation and negative publicity surrounding China-based companies listed in the United States may negatively impact the trading price of our ADSs.

We believe that recent litigation and negative publicity surrounding companies with operations in China that are listed in the United States has negatively impacted the stock prices of these companies. Certain politicians in the United States have publicly warned investors not to invest in China-based companies listed in the United States. The SEC and the PCAOB also issued a joint statement on April 21, 2020 reiterating the disclosure, financial reporting and other risks involved in investments in companies that are based in emerging markets, as well as the limited remedies available to investors who might take legal action against such companies. Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and departments with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks. Furthermore, various equity-based research organizations have recently published reports on China-based companies after examining their corporate governance practices, related party transactions, sales practices and financial statements, and these reports have led to special investigations and listing suspensions on U.S. national exchanges. Any similar scrutiny regarding our company or business, regardless of its lack of merit, could cause the market price of our ADSs to fall, divert management resources and energy, cause us to incur expenses in defending ourselves against rumors, and increase the premiums we pay for director and officer insurance.

We do not currently intend to pay dividends on our securities, and, consequently, the ability of our investors to achieve a return on their investment will depend on appreciation in the price of our ordinary shares and/or ADSs.

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on their ordinary shares and/or ADSs, at least in the near term, and the success of an investment in our ordinary shares and/or ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of our ordinary shares and/or ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our ordinary shares and/or ADSs will appreciate in value or even maintain the price at which our investors purchased their ordinary shares and/or ADSs.

An active trading market may not continue to be developed or sustained and our investors may not be able to resell our ADSs at or above the price they paid, or at all.

Prior to our initial public offering in November 2021, there was no public market in the United States for our ordinary shares or ADSs. Our ADSs are now listed on the Nasdaq Global Market. Our ordinary shares are not listed on any other exchange, or quoted for trading on any over-the-counter trading system, in the United States.

We cannot assure investors that an active trading market for our ADSs will develop or be sustained, or that the market price of our ADSs will not fluctuate, including declining below the initial public offering price. If an active trading market for our ADSs does not develop or sustain itself, the market price and liquidity of our ADSs will be materially and adversely affected.

The market price for our ADSs may be volatile.

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to factors, including the following:

- announcements of competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;
- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- fluctuations of exchange rates between the renminbi and the U.S. dollar;
- release or expiration of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. For example, in March 2020, the exchanges in the United States and China experienced a sharp decline as the COVID-19 pandemic negatively affected stock market and investor sentiment and resulted in significant volatility, including temporary trading halts. In 2021 and 2022, biotechnology and biopharmaceutical companies like us have suffered significant share price declines. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

Fluctuations in the value of the renminbi may have a material adverse effect on our results of operations and the value of any investment in our company.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. On July 21, 2005, the Chinese government changed its decade-old policy of pegging the value of the renminbi to the U.S. dollar, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that the Chinese government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the renminbi by fixing its price against the U.S. dollar 1.9%, 1.6% and 1.1% lower than the previous day's value, respectively. On October 1, 2016, the renminbi joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, the renminbi depreciated significantly while the U.S. dollar surged, and China experienced persistent capital outflows. With the development of the foreign exchange market and progress towards interest rate liberalization and renminbi internationalization, the Chinese government may in the future announce further changes to the exchange rate system. There is no guarantee that the renminbi 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 Chinese or U.S. government policy may impact the exchange rate between the renminbi and the U.S. dollar in the future.

Significant revaluation of the renminbi may have a material adverse effect on our results of operations and the value of any investment in our company. For example, to the extent that we need to convert U.S. dollars into renminbi for our operations, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we would receive from the conversion. Conversely, if we decide to convert our renminbi 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 renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the renminbi relative to U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, 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 Chinese exchange control regulations that restrict our ability to convert renminbi into foreign currency.

Substantial future sales or perceived sales of our ordinary shares, ADSs or other equity or equity-linked securities in the public market could cause the price of our ADSs to decline, even if our business is doing well.

Sales of our ordinary shares, ADSs or other equity or equity-linked securities in the public market, or the perception that these sales could occur, could cause the market price of our ADSs to decline. As of March 23, 2023, 107,161,871 ordinary shares were outstanding, of which 41,306,477 ordinary shares were held in the form of ADSs. All ADSs sold in our initial public offering are currently freely transferable without restriction or additional registration under the Securities Act. Any major disposal of our ordinary shares and/or ADSs by any of them may cause the prevailing market price of our ADSs to fall, which could negatively impact our ability to raise equity capital in the future. In addition, divestiture in the future of our ordinary shares and/or ADSs by significant shareholders, the announcement of any plan to divest our ordinary shares and/or ADSs or hedging activity by third-party financial institutions in connection with similar derivative or other financing arrangements entered into by shareholders could cause the price of our ADSs to decline.

In addition, we have filed registration statements on Form S-8 registering the issuance of approximately 29.1 million ordinary shares (which may be represented by ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Holders of ADSs have fewer rights than 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 the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our fifth amended and restated memorandum and articles of association, an annual general meeting and any extraordinary general meeting may be called with not less than seven calendar days' notice. When a general meeting is convened, holders of our ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw the ordinary shares underlying their ADSs to allow them to vote with respect to any specific matter. If we ask for instructions from such holders, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date and the depositary will send a notice about the upcoming vote and will arrange to deliver our voting materials to them. The depositary and its agents, however, may not be able to send voting instructions to them or carry out their voting instructions in a timely manner. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to such holders in a timely manner, but we cannot assure them that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. 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. Holders or beneficial owner of ADSs may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if they wish us or the depositary to participate in legal proceedings. As a result, such holders may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they request. In addition, in their capacity as ADS holders, they will not be able to call a shareholders' meeting.

Under the deposit agreement, for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying the ADSs at shareholders' meetings if the ADS holder does not give instructions to the depositary, unless (i) we have failed to timely provide the depositary with our notice of meeting and related voting materials, (ii) we have instructed the depositary that we do not wish a discretionary proxy to be given, (iii) we have informed the depositary that there is a substantial opposition as to a matter to be voted on at the meeting or (iv) a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that, if an ADS holder fails to give voting instructions to the depositary, such holder cannot prevent the ordinary shares underlying their ADSs from being voted, except under the circumstances described above. This may adversely affect an ADS holder's interests and make it more difficult for ADS holders to influence the management of the Company. Holders of our ordinary shares are not subject to this discretionary proxy.

Investors may not receive distributions on our ADSs or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distribution available to them.

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to our investors the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. Our investors will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that our investors may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available. These restrictions may cause a material decline in the value of our ADSs.

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 Perceptive and its shareholders, on the other hand. Two of our current non-employee directors have equity interests in Perceptive and, accordingly, their interests may be aligned with Perceptive's interests, which may not always coincide with our corporate interests or the interests of minority holders of our ADSs. In addition, we have entered into a director nomination agreement (the "Director Nomination Agreement") with Perceptive that provides Perceptive the right to designate nominees for election to our board of directors so long as Perceptive beneficially owns 5% or more of the total number of shares that it owned as of the completion of our initial public offering in November 2021. Perceptive may exercise its voting and other rights in a manner in which our other holders may not agree or that may not be in the best interests of our other shareholders, including with respect to elections of directors, issuances 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. Further, Perceptive and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. Any change in our directors' Perceptive ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with Perceptive, including the Director Nomination Agreement. Perceptive and its shareholders, including certain of our directors, may have interests which differ from our interests or those of the minority holders of our ADSs. Perceptive may invest in or advise businesses that directly or indirectly compete with certain portions of our business or that are suppliers or customers of our company. Any material transaction between us and Perceptive or any other subsidiary of Perceptive will be subject to a related party transaction policy we have adopted, which will require prior approval of such transaction by our audit committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

Investors' right to participate in any future rights offerings may be limited, which may cause dilution to their holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to our investors in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to our investors 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, our investors may be unable to participate in our rights offerings and may experience dilution in their holdings.

We believe we will be classified as a passive foreign investment company in the current taxable year ending December 31, 2022.

We believe we were a "passive foreign investment company" ("PFIC") for U.S. federal income tax purposes for the taxable year ended December 31, 2022, and we believe we will likely be classified as a PFIC in the taxable year ending December 31, 2023. We may or may not be a PFIC in subsequent years. Our actual PFIC status for any taxable year will not be determinable until after the end of such taxable year as our PFIC status is a factual determination made annually after the end of each taxable year. There can be no assurance that the IRS will agree with our determination and that the IRS would not successfully challenge our position in any taxable year. We will be a PFIC in any taxable year if at least (i) 75% of our gross income is "passive income" or (ii) 50% of the average gross value of our assets, determined on a quarterly basis, is attributable to assets that produce, or are held for the production of passive income. Because we believe we were a PFIC for the taxable year ended December 31, 2022 and expect to be a PFIC for our taxable year ending December 31, 2023, certain adverse U.S. federal income tax consequences could apply to U.S. persons who have acquired our ADSs or ordinary shares with respect to any "excess distribution" received from us and any gain from a sale or other disposition of our ADSs and ordinary shares.

If we are a PFIC in any taxable year in which a U.S. shareholder holds our ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. shareholder, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and the U.S. shareholder makes a "deemed sale election."

The adverse U.S. federal income tax consequences of holding interests in a PFIC may be mitigated if the U.S. shareholder makes a valid mark-to-market election or makes valid a qualified electing fund ("QEF") election with respect to all taxable years the underlying entity is a PFIC during such U.S. shareholder's holding period or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election. We do not, however, expect to provide U.S. shareholders with the information necessary to make a valid QEF election and U.S. shareholders therefore should assume that a QEF election will not be available with respect to our ADSs or ordinary shares. Further, no assurance can be given that a mark-to-market election will be available with respect to our ADSs or ordinary shares.

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

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of either the total value or total combined voting power of our ADSs or ordinary shares, such U.S. Holder may be treated as a "U.S. shareholder" with respect to each "controlled foreign corporation" ("CFC") in our group (if any). We believe that we were a CFC for the taxable years ended December 31, 2021 and 2022. In addition, we believe that certain of our subsidiaries were CFCs for the taxable years ended December 31, 2021 and 2022. We believe we will likely be a CFC for the taxable year ending December 31, 2023. Further, because our group includes at least one U.S. subsidiary that is classified as a corporation for U.S. federal income tax purposes, certain of our non-U.S. subsidiaries will be treated as CFCs (regardless of whether we are a CFC) for the current year. A U.S. shareholder of a CFC 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 such CFC, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether we are or any of our non-U.S. subsidiaries is treated as a CFC or whether such investor is treated as a U.S. shareholder with respect to any such CFC. Further, we cannot provide any assurances that we will furnish to any U.S. shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. For investors that are U.S. shareholders, failure to comply with these reporting obligations may subject them to significant monetary penalties and may prevent the statute of limitations with respect to their 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 or ordinary shares.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

We and certain of our subsidiaries are subject to taxes in the United States. As of December 31, 2022, we had U.S. federal net operating losses ("NOLs") of approximately $23.2 million that do not expire. We also had foreign NOLs of approximately $14.7 million, which if not utilized, generally begin to expire in 2026. These NOLs could expire unused and be unavailable to offset future income tax liabilities. U.S. federal NOLs generated in taxable years beginning after December 31, 2017 are generally not subject to expiration, but, for taxable years beginning after December 31, 2020, the deductibility of such NOLs is limited to 80% of our taxable income in any such taxable year.

In addition, in general, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain shareholders over a three-year period, is subject to limitations on its ability to utilize its pre-change U.S. NOLs, research and development tax credit carryforwards and disallowed interest expense carryforwards to offset future taxable income. We did not experience an ownership change from our initial public offering and as of December 31, 2022. We may experience ownership changes in the future as a result of subsequent changes in our share ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change U.S. NOLs and other tax attributes to offset such taxable income may be subject to limitations.

There is tax risk associated with the reporting of cross-border arrangements and activities between us and our subsidiaries.

We are incorporated under the laws of the Cayman Islands and currently have subsidiaries in Mainland China, Hong Kong, the Cayman Islands, Singapore and the United States. If we succeed in growing our business we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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.

LianBio Licensing, LLC is the direct licensee of licenses from Navire, QED and MyoKardia and has assigned all rights and benefits under the licenses to other subsidiaries. This arrangement is subject to review by relevant tax authorities, including in the United States. If, for example, U.S. tax authorities were to treat LianBio Licensing, LLC, rather than the subsidiaries, as the initial owner of the applicable licenses that subsequently transferred the licenses to the subsidiaries, there could be a material adverse U.S. tax impact to us and our subsidiaries.

Changes in tax law may adversely affect our business and financial results.

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. On August 16, 2022, the Inflation Reduction Act ("IRA") was signed into law in the United States. Among other provisions, the IRA includes a 15% corporate minimum tax rate which applies to certain corporations and a 1% excise tax on certain corporate stock repurchases made after December 31, 2022. We do not expect these IRA tax provisions to have a material impact on us. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (i) the jurisdictions in which profits are determined to be earned and taxed; (ii) the resolution of issues arising from any future tax audits with various tax authorities; (iii) changes in the valuation of our deferred tax assets and liabilities; (iv) our ability to use NOL carryforwards to offset future taxable income and any adjustments to the amount of the NOL carryforwards we can utilize, and (v) changes in tax laws or the interpretation of such tax laws, and changes in U.S. GAAP.

Our investors may have difficulty enforcing judgments obtained against us.

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside the United States. A majority of our current operations are conducted in China. In addition, some of our officers are nationals and residents of countries other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for our investors to effect service of process within the United States upon these persons. It may also be difficult for our investors 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 China 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 Civil Procedures Law of the People's Republic of China (the "PRC Civil Procedures Law"). Chinese 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 reciprocity with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, Chinese 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 Chinese laws or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a Chinese court would enforce a judgment rendered by a court in the United States.

We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under U.S. law, shareholders may have fewer shareholder rights than they would have under U.S. law and may face difficulties in protecting their interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be further amended from time to time), the Companies Act (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities law than the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders of these companies with the exception that the shareholders may request a copy of the amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated 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 our shareholders 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. As a Cayman Islands company, we may not have standing to initiate a derivative action in a federal court of the United States. As a result, our shareholders may be limited in their ability to protect their interests if they are harmed in a manner that would otherwise enable them to sue in a U.S. federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in U.S. federal courts.

Some of our directors and executive officers reside outside of the United States and a substantial portion of their assets are located outside of the United States. As a result, it may be difficult or impossible for our shareholders to bring an action against us or against these individuals in the Cayman Islands or in China in the event that they believe that their rights have been infringed under the securities laws of the United States or otherwise. In addition, some of our operating subsidiaries are incorporated in China. To the extent our directors and executive officers reside in China or their assets are located in China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if they are successful in bringing an action, the laws of the Cayman Islands and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

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 management, members of the board of directors or controlling shareholders than they would as public shareholders of a U.S. company.

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

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 it deems expedient in connection with the performance of its duties. 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.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders, including holders who acquire ADSs in the secondary market, waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the U.S. Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial.

If any holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, 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 the depositary. If a lawsuit is brought against either or both of us and 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 result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action. Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. 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 U.S. federal securities laws and the rules and regulations promulgated thereunder.

Holders of our ADSs or ordinary shares have limited choice of forum, which could limit their ability to obtain a favorable judicial forum for complaints against us, the depositary or our respective directors, officers or employees.

The deposit agreement governing our ADSs provides that, (i) the deposit agreement and the ADSs will be interpreted in accordance with the laws of the State of New York, and (ii) as an owner of ADSs, such owners irrevocably agree that any legal action arising out of the deposit agreement and the ADSs involving us or the depositary may only be instituted in a state or federal court in the city of New York. Any person or entity purchasing or otherwise acquiring any our ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions.

This choice of forum provision may increase cost for the holders of our ADSs or ordinary shares and limit their ability to bring a claim in a judicial forum that they find favorable for disputes with us, the depositary or our and the depositary's respective directors, officers or employees, which may discourage such lawsuits against us, the depositary and our and the depositary's respective directors, officers or employees. However, it is possible that a court could find either choice of forum provision to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable.

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, actions by holders of our ADSs or ordinary shares to enforce any duty or liability created by the Exchange Act, the Securities Act or the respective rules and regulations thereunder must be brought in a federal court in the city of New York. Holders of our ADSs or ordinary shares will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

General Risk Factors

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

Our operations, and those of our and our partners' third-party research institution collaborators, clinical trial sites, CROs, contract manufacturing organizations ("CMOs"), suppliers and other contractors and consultants could be subject to natural or man-made disasters, public health epidemics and pandemics like the COVID-19 pandemic or other business interruptions, for which we are predominantly self-insured. The occurrence of any of these business interruptions could seriously harm our operations and financial condition and increase our costs and expenses. Through our partners, we also rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by natural or man-made disasters, public health epidemics and pandemics, such as the COVID-19 pandemic, or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics, pandemics or other events could cause us to delay or cease development or commercialization of some or all of our product candidates. Although we maintain insurance coverage on our facilities, our insurance might not cover all losses under such circumstances, including damage to third-party facilities, and our business may be seriously harmed by such delays and interruption. For example, the biotechnology sector, including our company, has been impacted by the COVID-19 pandemic and could continue to experience negative impact to business operations. Other outbreaks may occur, or there could be a resurgence of the COVID-19 pandemic (including, for example, the local outbreaks and related extensive lockdowns that were experienced in certain cities in China, such as Shanghai or other cities where our offices and employees are located and in which we are conducting clinical trials), which have caused and could in the future, if they reoccur, cause business disruptions.

Our or our partners' clinical development efforts have been and could be further delayed or otherwise negatively impacted, as patients are reluctant or unable to go to hospitals or clinical testing sites to receive treatment. We have experienced delays in the enrollment of patients in our clinical trials due to the pandemic. We believe our business partners have also similarly experienced delays or difficulties in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. The ability to conduct in-person interactions between clinical and medical staff and physicians was also adversely affected. Additionally, the clinical supply of our product candidates could be negatively impacted due to reduced operations or a shutdown of our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

Our business and results of operations could be adversely affected by public health in the locations in which we, our suppliers, CROs, our licensors' CMOs and other contractors operate.

Our operations expose us to risks associated with public health crises, such as epidemics and pandemics. Our business operations and those of our and our partners' suppliers, clinical trial sites, CROs, CMOs and other contractors may potentially suffer interruptions caused by any of these events.

For example, the COVID-19 pandemic resulted in significant governmental measures being implemented around the globe to control the spread of the virus, including quarantines, lockdowns, travel restrictions, social distancing and business shutdowns.

In response to outbreaks of the COVID-19 pandemic in China, the Chinese government has in the past imposed restrictive quarantine measures, including extensive shutdowns in certain cities in China in which we operate, which have caused business disruptions. These measures, as well as other efforts and effects related to the continued COVID-19 pandemic, have adversely impacted and, if again implemented, may in the future adversely impact our and our partners' businesses, operations and financial conditions, including our or our business partners' manufacturing and supply chains, clinical trial operations and ability to advance research and development activities and pursue development of pipeline products. Each of these factors could have a material adverse impact on our business, operations and our financial results, including our ability to conduct our business in the manner and on the timelines presently planned.

The extent to which the COVID-19 pandemic may continue to impact our business will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of or resurgences of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in China and the United States and other geographies where we or our partners and our and their third-party suppliers, clinical trial sites and CMOs or CROs, or any other third parties with which we engage, operate.

In addition to in-licensing or acquiring product candidates, we may engage in future business acquisitions that may disrupt our business, cause dilution to our ADS holders and adversely affect our financial condition and operating results.

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue ordinary shares that would dilute our ADS holders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure our investors that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the acquired business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

If securities analysts do not publish research or reports about our business or if they publish inaccurate or negative evaluations of our business, the price of our ADSs could decline.

The trading market for our ADSs relies in part on the research and reports that industry or financial analysts publish about us or our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ordinary shares, and such lack of research coverage may adversely affect the market price of our ADSs. If one or more of the analysts covering our business downgrade their evaluations of our ADSs or business or publishes inaccurate research about our business, the price of our ADSs could decline. If one or more of these analysts cease to cover our ADSs, we could lose visibility in the market for our ADSs, which in turn could cause the price of our ADSs to decline.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years, including during 2021 and the early months of 2022 when we, like other biotechnology and biopharmaceutical companies, suffered significant share price declines. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

Our principal executive office and U.S. headquarters is located in Princeton, New Jersey, where we originally leased a total of approximately 1,148 square feet of office space for our administrative and other activities. On July 1, 2021, we entered into an amendment to our lease agreement and relocated to a new floor within our corporate office building, where we now occupy 7,152 square feet of office space. The term of our amended lease agreement is expected to run for three years from November 1, 2021, the date on which we occupied the new premises.

The office for our China headquarters is located in Shanghai, China, where we lease approximately 2313 square meters of office space at 16F, 5 Corporate Avenue, 150 Hubin Road, Huangpu District, Shanghai, People's Republic of China, 200021. The initial term for the lease began on November 16, 2021 and ends on March 31, 2025 (inclusive), and we have a one-time renewal right to renew the lease for a period of three years upon expiration of the initial lease term, subject to adjustment of rent based on then-prevailing market terms and certain other terms and conditions.

We have also leased premises of approximately 558 square meters of office space at Unit 12-13, 5th Floor, Block 3, No. 8 South Xinyuan Road, Chaoyang District, Beijing, China.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

To the best of our knowledge, we are not currently the subject of any material governmental investigation, private lawsuit or other legal proceeding. From time to time, we may be involved in legal and regulatory proceedings or investigations concerning matters that arise in the ordinary course of our business and that could result in significant fines or penalties, have an adverse impact on our reputation, business and financial condition or results of operations and divert the attention of our management from the operation of our business. The outcome of any future litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our business, financial condition or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market information

Our ADSs have been listed on the Nasdaq Global Market since November 1, 2021 under the symbol "LIAN." Prior to that time, there was no public market for our ordinary shares.

Holders

As of March 23, 2023, we had approximately 10 holders of record of our ordinary shares and one holder of record, being the depositary, of our ordinary shares for the purposes of representing ADSs. This number does not include beneficial owners whose ordinary shares or ADSs are held by nominees in street name. Because many ordinary shares and ADSs are held by broker nominees, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

We have never declared or paid dividends on our ordinary shares or ADSs. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

Recent Sales of Unregistered Equity Securities

Issuances of Ordinary Shares and Warrants

Each of the following issuances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions, Regulation D under the Securities Act, Rule 701 under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering. No underwriters were used in the below issuances.

In March 2021, we issued three warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology, one of our subsidiaries, in a private placement transaction. In October 2021 and November 2021, pursuant to an option agreement by and among LianBio, Lian Ophthalmology and the warrant holder, we issued two warrants to purchase an aggregate of 156,746 of our ordinary shares at an exercise price of $0.000017100448 and 78,373 of our ordinary shares, respectively. Concurrently with such issuances, the warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology were terminated. In June 2022, the warrant holder exercised one of its options to convert the warrants. Accordingly, we issued the warrant holder 78,373 of our ordinary shares at an exercise price of $0.000017100448 per share.

In May 2022, a former employee exercised certain of her vested options in accordance with their terms for 1,000,000 of our ordinary shares.

Use of Proceeds

On October 29, 2021, our Registration Statement on Form S-1, as amended (File No. 333-259978), was declared effective in connection with our initial public offering, pursuant to which we sold an aggregate of 20,312,500 ADSs representing 20,312,500 ordinary shares, at a price to the public of $16.00 per ADS.

There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on November 2, 2021. We are holding the balance of the net proceeds in cash, cash equivalents, and investments in short term, investment-grade interest-bearing securities such as money market funds, certificates of deposit, corporate bonds and commercial paper, and obligations of the U.S. government.

Issuer Purchases of Equity Securities

None.

Taxation

The following is a discussion of the material Cayman Islands, Chinese and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our ADSs or ordinary shares. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decisions to acquire ADSs or ordinary shares.

Material 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. There are no other taxes likely to be material to us or our shareholders or ADS holders 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 that are applicable to any payments made to or by the Company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Material Chinese Taxation

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of Mainland China with a "de facto management body" within Mainland China is considered a "resident enterprise," and will be subject to the EIT 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, the State Administration of Taxation issued SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a Chinese-controlled enterprise that is incorporated offshore is located in Mainland China. Although this circular only applies to offshore enterprises controlled by Chinese enterprises or Chinese enterprise groups, not those controlled by Chinese individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation'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, all offshore enterprises controlled by a Chinese enterprise or a Chinese enterprise will be regarded as a Chinese tax resident by virtue of having its "de facto management body" in Mainland China only 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 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 voting board members or senior executives habitually reside in China.

We believe that neither we nor any of its subsidiaries outside of Mainland China is a Chinese resident enterprise for Chinese tax purposes. We are not controlled by a Chinese enterprise or Chinese enterprise group, and we do not believe that we meet all of the conditions above. We are a company incorporated outside Mainland China. As a holding company, some of its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside Mainland China. For the same reasons, we believe our other subsidiaries outside of Mainland China are also non-Chinese resident enterprises for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by the Chinese tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body."

If Chinese tax authorities determine that we are a Chinese resident enterprise for EIT purposes, we may be required to withhold tax at a rate of 10% on dividends we pay to our shareholders, including holders of our ADSs, that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% Chinese withholding tax on gains realized on the sale or other disposition of ADS or ordinary shares, if such income is treated as sourced from within Mainland China. Furthermore, gains derived by our non-Chinese individual shareholders from the sale of our shares and ADSs may be subject to a 20% Chinese withholding tax. It is unclear whether our non-Chinese individual shareholders (including our ADS holders) would be subject to any Chinese tax (including withholding tax) on dividends received by such non-Chinese individual shareholders in the event we are determined to be a Chinese resident enterprise. If any Chinese tax were to apply to dividends realized by non-Chinese individuals, it will generally apply at a rate of 20%. The Chinese tax liability may be reduced under applicable tax treaties. However, it is unclear whether our non-Chinese shareholders would be able to claim the benefits of any tax treaty between their country of tax residence and Mainland China in the event that we are treated as a Chinese resident enterprise.

See "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—If we are classified as a China resident enterprise for China income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders."

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in Mainland China, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its Chinese-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a Chinese enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise is deemed the beneficial owner of any dividend paid by a Chinese enterprise by Chinese tax authorities and directly holds at least 25% of the Chinese enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements ("SAT Circular 81"), a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the Chinese resident enterprise; and (ii) it must have directly owned such percentage in the Chinese resident enterprise throughout the 12 months prior to receiving the dividends. Additionally, Mainland China has started an anti-tax treaty shopping practice since the issuance of Circular 601 in 2009. On February 3, 2018, the State Administration of Taxation released the Announcement on Issues concerning the "Beneficial Owner" in Tax Treaties ("PN9"), which provides guidelines in determining a beneficial owner qualification under dividends, interest and royalty articles of tax treaties. Chinese tax authorities in general often scrutinize fact patterns case by case in determining foreign shareholders' qualifications for a reduced treaty withholding tax rate, especially against foreign companies that are perceived as being conduits or lacking commercial substance. Furthermore, according to the Administrative Measures for Non-Resident Enterprises to Enjoy Treatments under Tax Treaties, which became effective in January 2020, where non-resident enterprises judge by themselves that they meet the conditions for entitlement to reduced tax rate according to tax treaties, they may enjoy such entitlement after reporting required information to competent tax authorities provided that they shall collect and retain relevant documents for future reference and inspections. Accordingly, our LianBio Hong Kong subsidiary may be able to enjoy the 5% tax rate for the dividends it receives from its subsidiaries incorporated in Mainland China if they satisfy the conditions prescribed under SAT Circular 81, PN9 and other relevant tax rules and regulations and complete the necessary government formalities. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, LianBio, is not deemed to be a Chinese resident enterprise, holders of our ADSs and ordinary shares who are not Chinese residents will not be subject to Chinese income tax on dividends distributed by us. With respect to gains realized from the sale or other disposition of the shares or ADSs, there is a possibility that a Chinese tax authority may impose an income tax under the indirect transfer rules set out under SAT Circular 7, except that such transaction could fall under the safe harbor thereunder. See "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises."

Material United States Federal Income Tax Considerations

The following discussion, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of our ADSs or ordinary shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire our ADSs or ordinary shares. This discussion is limited to U.S. Holders who hold our ADSs or ordinary shares as capital assets (generally, property held for investment). This discussion is based on the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the PRC and the United States (the "U.S.-PRC Tax Treaty"), as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect, which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

For purposes of this summary, a "U.S. Holder" is a beneficial owner of an ADS or ordinary share that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- real estate investment trusts;
- regulated investment companies;
- grantor trusts;
- tax-exempt organizations (including private foundations);
- governmental organizations;
- persons holding our ADSs or ordinary shares through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies (including those who use a mark-to-market method of tax accounting);
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons who acquired our ADSs or ordinary shares pursuant to the exercise of any employee share option of otherwise as compensation;
- persons holding our ADSs or ordinary shares as part of a position in a straddle or as part of a hedging, wash sale, constructive sale, conversion or integrated transaction for U.S. federal income tax purposes; or

- direct, indirect or constructive owners of 10% or more of our total combined voting power or value.

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, U.S. federal estate and gift tax and alternative minimum tax consequences of the acquisition, ownership, and disposition of ADSs or ordinary shares. We have not received nor do we expect to seek a ruling from the IRS regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Further, the current U.S. presidential administration has proposed a significant number of changes to U.S. tax laws, including an increase in the maximum tax rate applicable to U.S. corporations and certain individuals. The likelihood of any such legislation being enacted is uncertain but could adversely impact us. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of our ADSs or ordinary shares.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs or ordinary shares, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of ADSs or ordinary shares.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

ADSs

A U.S. Holder of ADSs or ordinary shares will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs or ordinary shares for the underlying shares represented by those ADSs or ordinary shares.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depositary or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

Taxation of dividends

We do not currently anticipate paying any distributions on our ADSs or ordinary shares in the foreseeable future. However, subject to the discussion below in " *—Passive foreign investment company considerations*," to the extent there are any distributions made with respect to our ADSs or ordinary shares, the gross amount of any distribution on the ADSs or ordinary shares (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to the ADSs or ordinary shares as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions on the ADSs or ordinary shares, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a "qualified foreign corporation" may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than one that is a PFIC in the taxable year or the preceding taxable year in which such dividends are paid) if (i) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (ii) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes. However, we believe we were a PFIC for the taxable year ended December 31, 2022, and we believe we will be a PFIC for the taxable year ending December 31, 2023. Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year. U.S. Holders should consult their own tax advisors regarding the availability of the reduced tax rates on dividends in light of their particular circumstances.

In the event that we were deemed to be a Chinese resident enterprise under the EIT Law (see "–Material Chinese Taxation" above), U.S. Holders might be subject to Chinese withholding taxes on dividends paid with respect to our ADSs or ordinary shares. In that case, subject to certain conditions and limitations, such Chinese withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder's U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on the ADSs or ordinary shares will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-China Tax Treaty benefits, any China taxes on dividends will not be creditable against such U.S. Holder's U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-China Tax Treaty rate. An eligible U.S. Holder who does not elect to claim a foreign tax credit for Chinese tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit or deduction rules in light of their particular circumstances.

Taxation of capital gains

Subject to the discussion in "*–Passive foreign investment company considerations*" below, upon the sale, exchange, or other taxable disposition of ADSs or ordinary shares, a U.S. Holder generally will recognize gain or loss on the taxable sale or exchange in an amount equal to the difference between the amount realized on such sale or exchange and the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares. The initial tax basis of ADSs or ordinary shares to a U.S. Holder will generally be the U.S. Holder's U.S. dollar purchase price for the ADSs or ordinary shares.

Subject to the discussion in " – *Passive foreign investment company considerations*" below, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses may be subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a Chinese resident enterprise for EIT Law purposes and Chinese tax were imposed on any gain (see " –Material Chinese Taxation" above), and if a U.S. Holder is eligible for the benefits of the U.S.-China Tax Treaty, the U.S. Holder may be able to treat such gain as Chinese source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-China Tax Treaty benefits if (for purposes of the treaty) such U.S. Holder is a resident of the United States and satisfies the other requirements specified in the U.S.-China Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a U.S. Holder's particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-China Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their own tax advisors regarding the tax consequences in the event Chinese tax were to be imposed on a disposition of our ADSs or ordinary shares, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as Chinese source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances. On the other hand, if we are not deemed to be a Chinese resident enterprise for EIT law purposes and we directly or indirectly hold Chinese subsidiaries, with respect to gains realized from the sale or other disposal of our ordinary shares or ADSs, there is a possibility that a Chinese tax authority may impose an income tax under the indirect transfer rules set out under SAT Circular 7, except that such transaction could fall under the safe harbor thereunder. Please refer to "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises."

Passive foreign investment company considerations

Status as a PFIC

The rules governing PFICs can have adverse tax effects on U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (i) 75% or more of our gross income consists of certain types of passive income (the Income Test), or (ii) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income (including cash) is 50% or more of the value of all of our assets (the Asset Test).

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year applying principles, methodologies and legal rules that in some circumstances are unclear and subject to varying interpretation and which depends on the composition and nature of our income and the composition, nature and value of our assets for the relevant taxable year. The fair market value of our assets for purposes of the PFIC rules (including goodwill) may be determined in large part by reference to the quarterly market price of our ADSs or ordinary shares, which is likely to fluctuate significantly. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash in our business, including any cash that is raised in a financing transaction.

We believe we were a PFIC for the taxable year ended December 31, 2022 and we believe we will likely be classified as a PFIC for the taxable year ending December 31, 2023. Our actual PFIC status for any taxable year will not be determined until after the end of such taxable year as our PFIC status is a factual determination made annually after the end of each taxable year. Because we hold a substantial amount of passive assets, including cash, and because the value of our assets (including goodwill) may be determined by reference to the market value of our ADSs or ordinary shares, which may be especially volatile due to the early stage of our product candidates, we cannot give any assurance that we will not be a PFIC for our taxable year ending December 31, 2023 or any future taxable year. We cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our determination and that the IRS would not successfully challenge our position.

If we are a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and the U.S. Holder makes (i) the "deemed sale election" described below in "U.S. federal income tax treatment of a shareholder of a PFIC", (ii) the U.S. Holder has a valid mark-to-market election in effect as described below, or (iii) the U.S. Holder makes a QEF election with respect to all taxable years in which we are a PFIC during such U.S. Holder's holding period or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election (as discussed below). If a U.S. Holder makes a deemed sale election, such U.S. Holder will be deemed to have sold the shares held by such U.S. Holder at their fair market value, and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, a U.S. Holder's ADSs or ordinary shares subject to such election will not be treated as shares in a PFIC, and the rules described below with respect to any "excess distributions" or any gain from an actual sale or other disposition of the ADSs or ordinary shares will not apply. Prospective investors should consult their own tax advisors regarding our PFIC status for the current or any future taxable years.

U.S. federal income tax treatment of a shareholder of a PFIC

If we are a PFIC for any taxable year during which a U.S. Holder owns our ADSs or ordinary shares, the U.S. Holder, absent certain elections (including the mark-to-market and QEF elections described below), generally will be subject to adverse rules (regardless of whether we continue to be a PFIC) with respect to (i) any "excess distributions" (generally, any distributions received by the U.S. Holder on its ADSs or ordinary shares in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for its ADSs or ordinary shares) and (ii) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs or ordinary shares.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder's holding period in which we were a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year. Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we were a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs ("lower-tier PFICs"), and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

If we are classified as a PFIC and then cease to be so classified, a U.S. Holder may make an election (a "deemed sale election") to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's ADSs or ordinary shares on the last day of our taxable year during which we were a PFIC. A U.S. Holder that makes a deemed sale election would then cease to be treated as owning stock in a PFIC by reason of ownership of our ADSs or ordinary shares. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

PFIC "mark-to-market" election

In certain circumstances if we are a PFIC for any taxable year, a U.S. Holder of our ADSs (but not our ordinary shares) can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs or ordinary shares, provided that the ADSs or ordinary shares are "marketable." ADSs or ordinary shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury Regulations. ADSs or ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs or ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. A "qualified exchange" includes a national securities exchange that is registered with the SEC.

Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on the Nasdaq Global Market (which constitutes a qualified exchange) and such ADSs are "regularly traded" for purposes of the mark-to-market election (for which no assurance can be given).

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S. Holder's ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in its ADSs. Accordingly, such mark-to-market election may accelerate the recognition of income without a corresponding receipt of cash. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in its ADSs over the fair market value of its ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. The adjusted tax basis of a U.S. Holder's ADSs will be adjusted to reflect amounts included in gross income or allowed as a deduction because of such mark-to-market election. If a U.S. Holder makes an effective mark-to-market election, gains from an actual sale or other disposition of our ADSs in a year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of our ADSs will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are a PFIC for any taxable year in which a U.S. Holder owns our ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs (unless the shares of such subsidiaries are themselves marketable). Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

PFIC "QEF" election

Alternatively, a U.S. Holder can be subject to rules different from those described above by electing to treat us (and each lower-tier PFIC, if any) as a qualified electing fund under Section 1295 of the Code (a "QEF") in the first taxable year that we (and each lower-tier PFIC) are treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder's timely filed U.S. federal income tax return.

If the Company is a PFIC, we currently do not intend to provide the information necessary for a U.S. Holder to make a QEF election. U.S. Holders are urged to consult their own tax advisors in this regard.

If you make a QEF election with respect to a PFIC, you will be taxed currently on your pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC, even if no distributions were received. If a U.S. Holder makes a QEF election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs or ordinary shares by an amount equal to any income included under the QEF election and will decrease its tax basis by any amount distributed on the ADSs or ordinary shares that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of the ADSs or ordinary shares in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares, as determined in U.S. dollars. Once made, a QEF election remains in effect unless invalidated or terminated by the IRS or revoked by the U.S. Holder. A QEF election can be revoked only with the consent of the IRS. A U.S. Holder will not be currently taxed on the ordinary income and net capital gain of a PFIC with respect to which a QEF election was made for any taxable year of the non-U.S. corporation for which such corporation does not satisfy the PFIC Income Test or Asset Test.

U.S. Holders should note that if they make QEF elections with respect to us and any lower-tier PFIC, they may be required to pay U.S. federal income tax with respect to their ADSs or ordinary shares for any taxable year significantly in excess of any cash distributions received on the ADSs or ordinary shares for such taxable year. U.S. Holders should consult their tax advisers regarding the advisability of, and procedure for, making QEF elections in their particular circumstances.

Proposed Treasury Regulations related to PFICs (which will not be effective until finalized) may affect the taxation and reporting obligations of partners of certain U.S. partnerships that invest in PFICs.

PFIC information reporting requirements

If we are a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ADSs or ordinary shares, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership of our ADSs or ordinary shares.

THE U.S. FEDERAL INCOME TAX RULES RELATING TO PFICS ARE COMPLEX. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

U.S. backup withholding and information reporting

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, our ADSs or ordinary shares that are held by U.S. Holders. The payor may be required to withhold U.S. backup withholding tax on payments made with respect to the ADSs or ordinary shares to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of our ADSs or ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax return for each year in which they hold our ADSs or ordinary shares. U.S. Holders should consult their own tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of our ADSs or ordinary shares.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs OR ORDINARY SHARES.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections of this report for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Some of the numbers included herein have been rounded for the convenience of presentation.

Overview

We are a clinical stage biopharmaceutical company dedicated to bringing innovative medicines to patients with unmet medical needs in Asia. Our initial focus is to in-license assets for development and commercialization in Greater China and other Asian markets. We have assembled a pipeline of eight therapeutic candidates across cardiovascular, oncology, ophthalmology and inflammation indications, each with its own distinct value proposition and the potential to drive new standards of care. With operations in China, Asia Pacific, and the United States, we have built a cross-border platform to provide our licensing partners access to our regulatory, development, and commercial expertise in China and other Asian markets. We have created a diverse, balanced portfolio of highly differentiated assets that represent our broad program scope and significant potential market opportunity across various stages of development, providing multiple avenues for value creation. We intend to continue to evaluate innovative, complementary product candidates with the potential to become new standards of care in Asia to deepen our pipeline.

Recent Business Highlights and Clinical Development Updates

Mavacamten

In January 2022, we announced the first patient had been dosed in the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy ("oHCM").

In February 2022, we announced that the Center for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA") granted Breakthrough Therapy Designation in China for mavacamten for the treatment of patients with oHCM.

In February 2022, our partner Bristol Myers Squibb ("BMS") announced positive topline results from Phase 3 VALOR-HCM trial, evaluating mavacamten in patients with obstructive hypertrophic cardiomyopathy who are eligible for septal reduction therapy.

In April 2022, BMS presented data from two clinical trials of mavacamten at the American College of Cardiology 71st Annual Scientific Session. Data from the EXPLORER-LTE clinical trial demonstrated sustained improvements in clinically meaningful cardiovascular outcomes at weeks 48 and 84 in patients with symptomatic obstructive hypertrophic cardiomyopathy ("oHCM") receiving mavacamten. Data from the Phase 3 VALOR-HCM clinical trial demonstrated the addition of mavacamten significantly reduced the need for septal reduction therapy ("SRT") in patients with severely symptomatic oHCM who had been appropriate for SRT at baseline.

In April 2022, BMS announced FDA approval of mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM to improve functional capacity and symptoms.

In May 2022, we announced topline results from a Phase 1 pharmacokinetics ("PK") study evaluating mavacamten in Chinese healthy volunteers. A single oral administration of mavacamten in Chinese healthy adult subjects showed no new safety signals. The data demonstrated a favorable PK, safety and tolerability profile comparable to that observed in the Phase 1 PK study of mavacamten, conducted by our partner MyoKardia Inc. ("MyoKardia"), now a wholly owned subsidiary of BMS, in healthy volunteers in the United States.

In May 2022, we submitted an NDA to the Singapore Health Sciences Authority for mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM. The submission was based on the FDA approval of mavacamten.

In August 2022, we announced that enrollment was completed in the Phase 3 EXPLORER-CN clinical trial in Chinese patients with obstructive hypertrophic cardiomyopathy. We expect to report topline results from the trial in mid-2023.

In September 2022, we collaborated with Beijing Lisheng Cardiovascular Health Foundation to launch Joy from Heart, a hypertrophic cardiomyopathy ("HCM") disease awareness campaign in China. Joy from Heart is China's first disease awareness program dedicated to improving HCM diagnosis rates and supporting HCM education initiatives for patients and healthcare providers.

In January 2023, mavacamten was added to The Joint Committee of Cardiomyopathy Specialty Alliance, National Center for Cardiovascular Diseases/Cardiovascular Precision Medicine Branch of China International Exchange and Promotive Association for Medical and Health Care's 2023 Guidelines for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy.

In February 2023, we submitted an NDA for mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III obstructive hypertrophic cardiomyopathy (oHCM) in the Macau Special Administrative Region. The submission was based on the U.S. Food and Drug Administration (FDA) approval of mavacamten. LianBio has now filed New Drug Applications to support approval of mavacamten in Hong Kong, Singapore and Macau.

In March 2023, patient visits in the double-blinded placebo-controlled treatment period were completed in the Phase 3 EXPLORER-CN study of mavacamten in Chinese symptomatic oHCM patients.

TP-03

In May 2022, our partner Tarsus Pharmaceuticals, Inc. ("Tarsus") announced topline data from Saturn-2. The trial met all primary and secondary endpoints and TP-03 was found to be generally well tolerated.

In August 2022, Tarsus announced the initiation of a Phase 2a clinical trial of TP-03 in patients with meibomian gland disease.

In September 2022, Tarsus announced the submission of an NDA to the FDA for TP-03 for the treatment of Demodex blepharitis ("DB"). Tarsus subsequently communicated that the FDA accepted the NDA with a Prescription Drug User Fee Act ("PDUFA") target action date of August 25, 2023.

In November 2022, we announced the initiation of the Phase 3 LIBRA clinical trial of TP-03 in Chinese DB patients. We expect to report topline data from the trial in the fourth quarter of 2023.

BBP-398

In November 2022, we announced the initiation of a Phase 1 monotherapy dose escalation trial of BBP-398 in Chinese patients with advanced solid tumors.

NBTXR3

In January 2022, our partner Nanobiotix announced enrollment of the first patient in the NANORAY-312 global Phase 3 registrational study of NBTXR3 in head and neck ("H&N") cancer.

In September 2022, we announced that we began treating patients in Asia in the global Phase 3 NANORAY-312 trial evaluating NBTXR3 for the treatment of H&N cancer.

Infigratinib

In July 2022, we submitted an NDA to the Department of Health, the Hong Kong Special Administrative Region, China, for infigratinib for the treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma ("CCA") with a fibroblast growth factor receptor 2 ("FGFR2") fusion or other rearrangement. The submission was based on the FDA approval of infigratinib.

In October 2022, we reported that our partner, BridgeBio Pharma, Inc. ("BridgeBio"), informed us that Helsinn Healthcare SA, which holds the Truseltiq (infigratinib) NDA in the United States, is permanently discontinuing distribution of the drug and anticipates requesting withdrawal of the NDA in the United States due to business reasons. Due to the planned withdrawal of the NDA, BridgeBio informed us that it intends to close the ongoing global Phase 3 PROOF-301 clinical trial of infigratinib in first-line CCA. Consequently, we are terminating activities related to the PROOF-301 clinical trial in China and no longer plan to pursue development and commercialization of infigratinib in CCA indications in our licensed territories. Subject to physician determination, we intend to continue to support patients who are currently being treated with infigratinib under the special pilot program implemented in the Bo'ao Lecheng pilot zone in Hainan Province.

We expect to continue the ongoing Phase 2a China standalone proof of concept clinical trial of infigratinib in patients with locally advanced, metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 genetic amplification and other solid tumors with FGFR alterations. We expect to report topline data from this clinical trial in the second half of 2023.

We plan to initiate a Phase 2b trial of infigratinib in locally advanced or metastatic gastric cancer with FGFR2 gene amplification in the first half of 2024. If successful, we expect this trial to support regulatory approval in China.

LYR-210

In January 2022, our partner Lyra announced the initiation of the Phase 3 ENLIGHTEN I clinical trial of LYR-210 in adult, surgically naïve chronic rhinosinusitis ("CRS") patients. In February 2022, Lyra announced dosing of the first patient in ENLIGHTEN I.

In August 2022, we refined our development strategy for LYR-210. We plan to conduct a Phase 3 China standalone trial to support regulatory approval in China, leveraging the results of the ongoing Phase 3 trials of Lyra. Lyra is expected to complete enrollment in ENLIGHTEN I, the first trial in Lyra's Phase 3 program, in mid-2023.

In September 2022, Lyra announced that it had initiated ENLIGHTEN II, the second of two global pivotal Phase 3 trials of LYR-210 in surgically naive CRS patients. In November 2022, Lyra further communicated a temporary pause in ENLIGHTEN II enrollment to align with internal manufacturing timelines for clinical trial supply.

NX-13

In August 2022, our partner Landos announced positive topline results for the Phase 1b trial of NX-13 in moderate UC patients. The data showed favorable safety and tolerability profiles across a range of doses, as well as signals of clinical improvement in as soon as two weeks in patient symptoms and four weeks by endoscopy in exploratory endpoints. Landos subsequently communicated that the company expects to initiate a Phase 2 proof-of-concept trial for NX-13 in the second quarter of 2023 and report topline data by the fourth quarter of 2024.

Omilancor

In January 2023, Landos announced that following an in-depth review of their pipeline and overall development plans, omilancor was poised for partnering and continued clinical development in the future and that Landos would continue to explore collaborations and other arrangements that would provide additional resources and/or capabilities to advance omilancor. In February 2023, Landos announced the transfer of omilancor to Dr. Josep Bassaganya-Riera, Ph.D., the founder of Landos who previously served as its Chairman, President and CEO, and certain affiliated individuals and entities. Dr. Bassaganya-Riera subsequently launched NImmune Biopharma, Inc. ("NImmune") to continue the development of its LANCL portfolio including omilancor.

In February 2023, we entered into an amendment to the Landos Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor, and we have entered into a direct license agreement with NImmune setting forth the terms of our continued development and commercialization of omilancor in LianBio territories.

Sisunatovir

In December 2022, we entered into a commercial agreement (the "Pfizer Commercial Agreement") with Pfizer Inc. ("Pfizer") and ReViral Ltd. ("ReViral," now a wholly owned subsidiary of Pfizer) with respect to sisunatovir (a fusion inhibitor product for treatment of respiratory syncytial virus ("RSV")) as the first Opted-in Product under our existing Strategic Collaboration Agreement with Pfizer. Pursuant to the Pfizer Commercial Agreement, we assigned and transferred our development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore (the "Territory") to Pfizer.

Under the Pfizer Commercial Agreement, we received a $20 million upfront payment, which was released as part of previously restricted cash paid to us by Pfizer in 2020 pursuant to the Pfizer Collaboration Agreement. We are eligible to receive up to $135 million in potential development and sales milestones contingent on sisunatovir achieving a specified regulatory milestone event prior to the end of October 2035 and specified net sales milestone events.We are further entitled to receive tiered payments in the low single digits on a percentage of net sales of sisunatovir in the Territory.

Factors Affecting our Results of Operations

Impact of the COVID-19 pandemic on our operations

Beginning in December 2019, the outbreak of the COVID-19 pandemic created business interruptions for companies globally, including us. For example, in the biotechnology sector, companies, including our company, have experienced delays in their ability to enroll patients at clinical trial sites because of the pandemic, potentially leading to delays in the regulatory approval process. Other outbreaks may occur, or there could be further resurgences of the COVID-19 pandemic (including locations in which we are conducting clinical trials), which have caused and could further cause business disruptions in the future.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business. We have taken important steps to ensure the workplace safety of our employees when working within our administrative offices, or when traveling to our clinical trial sites. We may take further actions as may be required by federal, state or local authorities.

To date, we have been able to continue our key business activities and advance our clinical programs. However, COVID has impacted our clinical trial enrollment and it is possible that our clinical development timelines and business plans could be adversely affected. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations.

See "Part I—Item 1A—Risk Factors" included in this Annual Report on Form 10-K for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Key Components of Results of Operations

Research and development expenses

We believe our ability to successfully develop product candidates will be a significant factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investment in this area.

We expect our research and development expense to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our product candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. These expenses include:

- payments made under third party licensing and asset acquisition agreements;
- employee-related expense, including salaries, related benefits, equity-based compensation and travel expenses for employees engaged in research and development functions;
- expense incurred in connection with the clinical development of our product candidates, including expenses incurred under agreements with CROs;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and amortization, insurance and other direct and allocated expense incurred as a result of research and development activities.

The following table sets forth the components of our research and development expenses for the years indicated:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Research and development expenses (in thousands):		
Licensing fees	$ 35,000	$ 136,915
Reimbursement of licensing fees	(7,000)	—
Employee related expense	11,413	7,601
CRO costs	17,354	11,117
Other costs	2,987	3,059
Total	$ 59,755	$ 158,692

Licensing arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are generally required to make upfront payments upon entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant product candidate under these agreements, as well as tiered royalties based on net sales of the license products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements and totaled $35.0 million and $136.9 million, for the years ended December 31, 2022 and 2021, respectively.

The following table sets forth a breakdown of licensing fees by program for the years indicated:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Licensing fees (in thousands):		
Mavacamten	$ 5,000	$ —
BBP-398	—	8,500
Sisunatovir	—	14,000
TP-03	25,000	64,415
Omilancor and NX-13	—	18,000
NBTXR3	—	20,000
LYR-210	5,000	12,000
Total	$ 35,000	$ 136,915

General and administrative expenses

Our general and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance and administrative functions. General and administrative expense also includes professional fees for legal, consulting, auditing, tax services and insurance costs.

We expect that our general and administrative expense will increase in the future to support continued development and commercialization of our product candidates. These increases will likely include increased costs related to hiring additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, we have incurred and will continue to incur increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and office insurance costs, and investor and public relations costs.

Interest income, net

Interest income, net consists of interest income received on our cash balances and marketable securities and from the amortization/accretion on the premiums/discounts on marketable securities.

Other income (expense), net

Other income (expense), net consists of unrealized gains and losses on foreign currencies held in our China subsidiary, Shanghai LianBio Development Co., Ltd., unrealized foreign exchange activity from the remeasurement of our intercompany payables, bank fees incurred on our cash balances, depositary fees related to our ADSs and income recorded due to the Pfizer Commercial Agreement.

Income tax (benefit) expenses

Provision for income taxes consists of U.S. federal and state income taxes and income taxes in certain foreign jurisdictions in which we conduct business. We expect income tax expense to increase over time as the Company continues to grow net income.

As required by Accounting Standards Codification ("ASC") Topic 740, Income Taxes, our management has evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, which are composed principally of NOL carryforwards, intangible assets, share compensation, and accrued expenses. Management has determined that it is more likely than not that we will not realize the benefits of the deferred tax assets. As a result, a valuation allowance of $13.5 million was recorded as of December 31, 2022.

Cayman Islands

We are incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands.

People's Republic of China

Our subsidiaries incorporated in Mainland China are governed by the PRC Enterprise Income Tax Law ("EIT Law"), and regulations. Under EIT Law, the standard Enterprise Income Tax ("EIT") rate is 25.0% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years.

Hong Kong

Our subsidiaries incorporated and carrying on a trade or business in Hong Kong are generally subject to profits tax at a rate of 16.5%. Tax losses incurred may be carried forward indefinitely to offset any taxable profits in subsequent years. Hong Kong does not levy tax on capital gains or non-Hong Kong sourced income. Payments of dividend and interest are not subject to withholding tax in Hong Kong. However, certain payments (such as payment for right to use intellectual properties) made to non-resident persons may be subject to withholding tax.

Singapore

Our subsidiary incorporated and carrying on a trade or business in Singapore is generally subject to income tax at the prevailing corporate income tax rate (currently, 17.0%). Tax losses and capital allowances may be carried forward indefinitely to offset any taxable profits in subsequent years provided conditions are met. Singapore does not levy tax on capital gains. Payment of dividends by the Singapore subsidiary are not subject to withholding tax in Singapore, however, certain payments (such as interest and royalty or payment for the use or right to use intellectual properties) made to non-resident persons may be subject to Singapore withholding tax.

Results of operations

Comparison of the years ended December 31, 2022 and December 31, 2021

The following table sets forth a summary of our consolidated results of operations for the periods indicated.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating expenses (in thousands):		
Research and development	$ 59,755	$ 158,692
General and administrative	65,598	36,878
Total operating expenses	125,353	195,570
Loss from operations	(125,353)	(195,570)
Other income (expense):		
Interest income, net	4,321	243
Other income (expense), net	10,409	(455)
Net loss before income taxes	(110,623)	(195,782)
Income tax (benefit) expenses	(333)	518
Net loss	$ (110,290)	$ (196,300)

Research and development expenses

Research and development expenses decreased by $98.9 million from $158.7 million for the year ended December 31, 2021 to $59.8 million for the year ended December 31, 2022. For the year ended December 31, 2022, research and development cost was primarily attributable to (i) $25.0 million in development milestone payments payable pursuant to our development and license agreement with Tarsus (the "Tarsus Agreement"), (ii) a $5.0 million related to a development milestone payment payable pursuant to our exclusive license agreement with MyoKardia (the "MyoKardia Agreement"), (iii) a $5.0 million related to a development milestone payment payable pursuant to our license and collaboration agreement with Lyra (the "Lyra Agreement"), (iv) $17.4 million attributable to development activities to support our clinical trials and (v) $11.5 million attributable to personnel-related expenses, including share-based compensation expense. Additionally, within research and development expenses is a reimbursement of licensing fees of $7.0 million related to the Pfizer Commercial Agreement. The remaining expense was attributable to professional fees.

For the year ended December 31, 2021, research and development cost was primarily attributable to (i) $55.0 million in upfront and development milestone payments and $9.4 million of expenses related to warrants issued in connection with the Tarsus Agreement, (ii) a $20.0 million upfront payment pursuant to our license, development and commercialization agreement with Nanobiotix (the "Nanobiotix Agreement"), (iii) a $18.0 million upfront payment pursuant to our license and collaboration agreement with Landos (the "Landos Agreement"), (iv) a $14.0 million upfront payment pursuant to our co-development and license agreement with ReViral (the "ReViral Agreement"), (v) a $12.0 million upfront payment pursuant to the Lyra Agreement, and (vi) a $8.5 million development milestone payment pursuant to our exclusive license agreement with Navire (the "Navire Agreement"). The remaining expense was attributable to personnel-related expenses, including share-based compensation expense, development activities to support our clinical trials and professional fees.

General and administrative expenses

General and administrative expenses increased by $28.7 million from $36.9 million for the year ended December 31, 2021 to $65.6 million for the year ended December 31, 2022. The increase was primarily attributable to a $19.5 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and a $10.5 million increase in additional costs incurred due to operating as a publicly traded company.

Interest income, net

Interest income, net increased by $4.1 million from $0.2 million for the year ended December 31, 2021 to $4.3 million for the year ended December 31, 2022. The increase was primarily attributable to our investments in marketable securities and interest earned on cash holdings in foreign countries.

Other income (expense), net

Other income (expense), net increased by $10.9 million from $(0.5) million for the year ended December 31, 2021 to $10.4 million for the year ended December 31, 2022. The increase was primarily attributable to the income recorded attributable to the Pfizer Commercial Agreement and depositary fees related to our ADSs, partially offset by a $4.1 million write-off of a non-recourse secured promissory note.

Income tax (benefit) expenses

Our income tax (benefit) was $(0.3) million for the year ended December 31, 2022, resulting in an effective income tax rate of 0.30% for the year ended December 31, 2022, as compared to an income tax expense of $0.5 million, or an effective income tax rate of (0.27)%, for the same period in 2021. A reconciliation of the statutory federal income tax rate to the effective income tax rate for each period is included in "Note 11: Income Taxes" in the notes to our consolidated financial statements.

Liquidity and capital resources

Sources of liquidity

Since our incorporation, our operations have been substantially financed with proceeds from sales of preferred shares as part of the Series Seed financing, the Series A financing, the issuance of the 2020 Convertible Notes and our initial public offering, which was completed in November 2021 (the "IPO"). As of December 31, 2022, we had cash and cash equivalents and marketable securities of $302.4 million.

On November 3, 2021, the Company completed its IPO through an underwritten sale of 20,312,500 ADSs representing 20,312,500 ordinary shares at a price of $16.00 per share. On December 1, 2021, the underwriters partially exercised their option to purchase additional shares and purchased an additional 593,616 ADSs at the initial public offering price of $16.00 per ADS. We received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters' option and aggregate net proceeds of $304.8 million after deducting underwriting discounts, commissions and other offering expenses.

We are a holding company with no operations of our own and, as such, we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. Deterioration in the financial condition, earnings or cash flow of our subsidiaries for any reason, as well as any changes in Chinese laws or regulations, could limit or impair their ability to pay such distributions. See "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business."

Funding requirements

Our primary use of cash is to fund our operating expenditures, consisting of research and development expense (including activities within our clinical and regulatory initiatives and upfront and milestone payments) and general and administrative expense. Our use of cash is impacted by the timing and extent of the required payments for each of these activities.

To date, we have not generated any material revenue. We do not expect to generate revenue from the sale of our products unless and until we (i) complete development of any of our product candidates; (ii) obtain applicable regulatory approvals; and (iii) successfully commercialize or enter into collaborative agreements for our product candidates. We do not know with certainty when, or if, any of these items will ultimately occur. We expect to incur continuing significant losses for the foreseeable future and for our losses to increase as we ramp up our clinical development programs and begin activities related to commercial launch readiness. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business. Moreover, since the completion of our IPO, we have incurred and will continue to incur additional costs associated with operating as a publicly traded company.

We will require additional capital to develop our product candidates and fund our operations into the foreseeable future. We anticipate that we will eventually need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the number and scope of clinical programs we decide to pursue;

- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the cost and timing associated with commercializing our product candidates, if they receive regulatory approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- the impact of the COVID-19 pandemic on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development and regulatory approval of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our ordinary shares, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our shareholders.

Adequate funding may not be available to us on acceptable terms or at all. Our potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our additional licensing opportunities.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net cash (used in) provided by (in thousands):		
Operating activities	$ (99,185)	$ (163,953)
Investing activities	(69,201)	(155,937)
Financing activities	1,710	313,273

Net cash used in operating activities

During the year ended December 31, 2022, operating activities used approximately $99.2 million of cash, primarily due to our net loss of $110.3 million and $20.0 million of non-cash consideration recognized related to the Pfizer Commercial Agreement, partially offset by non-cash consideration of $19.1 million related to share-based compensation expense, $4.1 million related to the write off of a non-recourse promissory note, and other changes related to operating assets and liabilities.

During the year ended December 31, 2021, operating activities used approximately $164.0 million, primarily due to our net loss of $196.3 million, partially offset by non-cash consideration of $9.4 million related to the warrants granted to Tarsus, $20.0 million of other receivables related to Pfizer in-licensing and co-development activities, $8.7 million related to share-based compensation expense, and other changes related to operating assets and liabilities.

Net cash used in investing activities

During the year ended December 31, 2022, investing activities used approximately $69.2 million, consisting of approximately $303.1 million for the purchases of marketable securities and approximately $1.8 million for the purchases of property and equipment partially offset by the sales and redemption of marketable securities of approximately $235.8 million.

During the year ended December 31, 2021, investing activities used approximately $155.9 million, consisting of approximately $155.0 million for the purchases of marketable securities and approximately $0.9 million for the purchases of property and equipment.

Net cash provided by financing activities

During the year ended December 31, 2022, financing activities provided approximately $1.7 million in net proceeds due the exercise of share options.

During the year ended December 31, 2021, financing activities provided approximately $313.3 million in net proceeds due to our issuance of Series A Preferred shares of $2.9 million, net proceeds from the IPO of $304.8 million and the exercise of share options of $5.5 million.

Contractual and other obligations

Contractual obligations

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. These obligations include operating lease commitments and other liabilities. See “Note 8: Commitments and Contingencies” in the notes to our consolidated financial statements in this Annual Report on Form 10-K for further information on material cash requirements from known contractual and other obligations.

Other obligations

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies, and testing, manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments have not been included separately within these contractual and other obligations disclosures.

Off-balance sheet arrangements

In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and significant judgments and estimates

We prepare our financial statements in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”), which requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and notes to the financial statements. We continually evaluate these estimates and assumptions based on the most recently available information, our own historical experiences and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in our estimates. Some of our accounting policies require a higher degree of judgment than others in their application and require us to make significant accounting estimates.

The selection of critical accounting policies, the judgments and other uncertainties affecting application of those policies and the sensitivity of reported results to changes in conditions and assumptions are factors that should be considered when reviewing our financial statements. While our significant accounting policies are described in more detail in "Note 2: Significant Accounting Policies" in the notes to our consolidated financial statements included in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements:

Research and development expenses

Research and development expenses, including clinical trial costs and accruals, consist primarily of costs incurred for our research activities, including the development of our product candidates, which include:

- payments made under third party licensing and asset acquisition agreements;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the clinical development of our product candidates, including expenses incurred under agreements with CROs;
- the cost of consultants and our licensors' CMOs that manufacture product candidates for use in our preclinical studies and clinical trials; and
- facilities, depreciation, and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

We expense research and development costs to operations as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid assets. Our prepaid assets are expensed as the related goods are delivered or the services are performed.

We monitor research and development expenses directly associated with our clinical assets at the program level to some degree, however, indirect costs associated with clinical development and the balance of our research and development expenses are not tracked at the program or candidate level.

Equity-based compensation expense

We account for share-based payments under the guidance as set forth in the Share-Based Payment Topic 718 of the FASB Accounting Standards Codification ("AS 2018-07"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, officers, directors and consultants, including employee stock options, based on estimated fair values. We adopted ASU 2018-07 upon our incorporation, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. As a result, non-employee share-based transactions are measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions.We account for forfeitures as they occur.

We recognize share-based compensation expense for stock options on a straight-line basis over the requisite service period and the compensation expense for performance-based awards reflect the cost of awards that are probable to vest and the estimated vesting date. Our share-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes-Merton option pricing model. We recognize share-based compensation expense for performance stock option awards with market conditions over the vesting period regardless of the value that the award recipients ultimately receive. The fair value of performance stock option awards with market conditions is estimated at the date of grant, using the Monte-Carlo simulation model. The Black-Scholes and Monte Carlo simulation valuation models utilize various inputs, and these assumptions include:

- **Expected Term.** The expected term represents the period that the share-based awards are expected to be outstanding. We use the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.
- **Expected Volatility.** Since we have historically been privately held and do not have any trading history for our Ordinary Shares, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of the price of our ADSs becomes available.

- **Risk-Free Interest Rate.** The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- **Expected Dividend.** We have never paid dividends on our ordinary shares and have no plans to pay dividends on our ordinary shares. Therefore, we used an expected dividend yield of zero.

We recorded share-based compensation expense of $19.1 million and $8.7 million for the years ended December 31, 2022 and December 31, 2021, respectively. While we were a private company, the fair values of the ordinary shares underlying our share-based awards were estimated on each grant date by our board of directors. Our board of directors considered, among other things, valuations of our ordinary shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. In determining a fair value for our ordinary shares, the unrelated third-party valuation firm used the Backsolve Method, which utilizes a recent equity financing to estimate the equity value at the valuation date, to estimate the fair value of our ordinary shares. The equity value was then allocated to the equity classes using an option pricing method and then reducing the implied ordinary share value by a discount for lack of marketability. For the independent third-party valuations prepared as of March 31, 2021 and May 1, 2021, the unrelated third-party valuation firm used the Calibration Method of the Market Approach. When the transaction is at fair value at initial recognition, the Calibration Method of the Market Approach is used at subsequent periods with valuation techniques and assumptions that are consistent with the observed transaction, updated to take into account any changes in Company-specific factors as well as current market conditions. At subsequent measurement dates, the valuation would consider our progress and changes in observable market data to estimate the fair value under current market conditions. The equity value is then allocated to the equity classes using an option pricing method and then reducing the implied ordinary share value by a discount for lack of marketability. Subsequent to the IPO, the Company utilizes the closing price of our publicly traded ADSs as the input for the fair value of our ordinary shares.

The assumptions used in determining the fair value of stock-based awards represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different in the future.

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. In evaluating our valuation allowance, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Due to uncertainty with respect to ultimate realizability of deferred tax assets, we have provided a valuation allowance against the U.S., Mainland China, Singapore, and Hong Kong deferred tax assets. We intend to maintain a full valuation allowance on the U.S. federal and state deferred tax assets and foreign deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. We have not identified nor recorded any liabilities for unrecognized tax benefits as of December 31, 2022.

Under Sections 382 and 383 of the Code, substantial changes in our ownership may limit the amount of NOL and research and development tax credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of U.S. federal and state NOL carryforwards, research and development tax credit carryforwards and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds 50% within any three-year period.

Recently issued accounting standards

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in “Note 2: Significant Accounting Policies” in the notes to our consolidated financial statements included in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk including foreign exchange currency risk, credit risk and interest rate risk.

Foreign exchange currency risk

Our business mainly operates in China with transactions in renminbi, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risk should be limited, the value of any investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the renminbi because a portion of the value of our business is effectively denominated in renminbi, while the ADSs will be traded in U.S. dollars.

Renminbi is not a freely convertible currency. The SAFE, under the authority of the People's Bank of China ("PBOC"), controls the conversion of renminbi into foreign currencies. The value of renminbi is subject to changes in the central government policies and to international economic and political developments affect supply and demand in the China Foreign Exchange Trading System market.

Translation of the net proceeds that we received from our IPO into renminbi will also expose us to currency risk. The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affect by, among other things, changes in China's political and economic conditions. To the extent that we need to convert U.S. dollars into renminbi for our operations or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into renminbi, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we receive from the conversion. Conversely, if we decide to convert renminbi to 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 renminbi would have a negative effect on the U.S. dollar amounts available to us.

Interest rate risk and credit risk

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. At any time, sharp changes in interest rates can affect the fair value of the investment portfolio and its interest earnings. There were no investments classified as long-term at December 31, 2022. At December 31, 2022, we held $302.4 million in cash and cash equivalents and marketable securities.

Currently, we do not hedge these interest rate exposures. We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

Item 8. Financial Statements and Supplementary Data

LIANBIO

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
LianBio:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of LianBio and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

New York, New York

March 28, 2023

LianBio
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 79,221	$ 228,182
Marketable securities	223,142	155,067
Prepaid expenses and other current assets	8,640	10,354
Other receivable	1,770	6,044
Total current assets	312,773	399,647
Restricted cash, non-current	73	20,000
Property and equipment, net	3,116	1,882
Operating lease right-of-use assets	3,978	4,763
Other non-current assets	20	51
Total assets	$ 319,960	$ 426,343
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,453	$ 3,231
Accrued expenses	19,826	9,976
Current portion of operating lease liabilities	1,851	1,125
Other current liabilities	485	760
Total current liabilities	23,615	15,092
Operating lease liabilities	2,488	3,709
Other liabilities	210	206
Nonrefundable research deposit	—	20,000
Total liabilities	26,313	39,007
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of December 31, 2022; 107,043,924 shares issued and outstanding at December 31, 2022; Authorized 2,923,900,005 shares as of December 31, 2021; 107,275,458 shares issued and outstanding at December 31, 2021	2	2
Additional paid-in capital	732,476	713,269
Accumulated other comprehensive (loss) income	(2,080)	526
Accumulated deficit	(470,525)	(360,235)
Total LianBio shareholders' equity	259,873	353,562
Non-controlling interest	33,774	33,774
Total shareholders' equity	293,647	387,336
Total liabilities and shareholders' equity	$ 319,960	$ 426,343

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating expenses:		
Research and development	$ 59,755	$ 158,692
General and administrative	65,598	36,878
Total operating expenses	125,353	195,570
Loss from operations	(125,353)	(195,570)
Other income (expense):		
Interest income, net	4,321	243
Other income (expense), net	10,409	(455)
Net loss before income taxes	(110,623)	(195,782)
Income tax (benefit) expenses	(333)	518
Net loss	(110,290)	(196,300)
Other comprehensive (loss) income:		
Foreign currency translation (loss) income, net of tax	(1,712)	512
Unrealized (loss) gain on marketable securities, net of tax	(894)	54
Comprehensive loss	$ (112,896)	$ (195,734)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (1.02)	$ (5.71)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,923,296	34,394,622

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statement of Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Shares		Ordinary Shares		Treasury Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Equity (Deficit)	Non-Controlling Interest	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount						
Balance, December 31, 2020	10,971,231	$ 349,789	20,477,338	$ —	—	$ —	$ 31,132	$ (40)	$ (163,935)	$ (132,843)	$ 34,773	$ (98,070)
Share-based compensation expense	—	—	—	—	—	—	8,664	—	—	8,664	—	8,664
Issuance of Series A Preferred Shares at $56.66, net of issuance costs	52,947	2,940	—	—	—	—	—	—	—	—	—	—
Conversion of preferred shares into ordinary shares upon initial public offering	(11,024,178)	(352,729)	64,467,176	2	—	—	352,728	—	—	352,730	—	352,730
Issuance of ordinary shares upon initial public offering, net of issuance costs	—	—	20,906,116	—	—	—	304,785	—	—	304,785	—	304,785
Warrants issued in license agreement	—	—	—	—	—	—	—	—	—	—	9,415	9,415
Conversion of Warrants issued in license agreement into LianBio ordinary shares and LianBio warrants	—	—	78,373	—	—	—	10,414	—	—	10,414	(10,414)	—
Exercise of options	—	—	1,346,455	—	—	—	5,546	—	—	5,546	—	5,546
Net Loss	—	—	—	—	—	—	—	—	(196,300)	(196,300)	—	(196,300)
Comprehensive Income	—	—	—	—	—	—	—	566	—	566	—	566
Balance, December 31, 2021	—	$ —	107,275,458	$ 2	—	$ —	$ 713,269	$ 526	$ (360,235)	$ 353,562	$ 33,774	$ 387,336
Share-based compensation expense	—	—	—	—	—	—	19,148	—	—	19,148	—	19,148
Redemption of ordinary shares pursuant to non-recourse secured promissory note	—	—	—	—	1,309,907	—	—	—	—	—	—	—
Retirement of treasury shares	—	—	(1,309,907)	—	(1,309,907)	—	(1,651)	—	—	(1,651)	—	(1,651)
Conversion of Warrants issued in license agreement into LianBio ordinary shares and LianBio warrants	—	—	78,373	—	—	—	—	—	—	—	—	—
Exercise of options	—	—	1,000,000	—	—	—	1,710	—	—	1,710	—	1,710
Net Loss	—	—	—	—	—	—	—	—	(110,290)	(110,290)	—	(110,290)
Comprehensive Loss	—	—	—	—	—	—	—	(2,606)	—	(2,606)	—	(2,606)
Balance, December 31, 2022	—	$ —	107,043,924	$ 2	—	$ —	$ 732,476	$ (2,080)	$ (470,525)	259,873	$ 33,774	$ 293,647

LianBio
Consolidated Statement of Cash Flows
(In thousands)

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net loss	$ (110,290)	$ (196,300)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash share consideration, issued in acquisition of IPR&D	—	9,415
Non-cash operating lease expense (benefit)	303	(106)
Depreciation expense	1,006	525
Share based compensation expense	19,148	8,664
Amortization of discounts on investments, net	(1,607)	(23)
Unrealized foreign currency transaction loss, net	127	87
Non-cash consideration relating to Pfizer Commercial Agreement	(20,000)	—
Non-cash write off of non-recourse promissory note	4,133	—
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	1,328	(8,176)
(Increase) decrease in other receivable	(1,400)	14,216
Decrease (increase) in other non-current assets	27	(40)
Decrease in accounts payable	(1,705)	(1,708)
Increase in accrued expenses	9,842	8,761
(Decrease) increase in other current liabilities	(97)	732
Net cash used in operating activities	(99,185)	(163,953)
Cash flows from investing activities:		
Purchase of property and equipment	(1,845)	(947)
Purchase of marketable securities	(303,136)	(154,990)
Sales and redemptions of marketable securities	235,780	—
Net cash used for investing activities	(69,201)	(155,937)
Cash flows from financing activities:		
Proceeds from exercise of share options	1,710	5,546
Proceeds from issuance of ordinary shares upon initial public offering	—	311,083
Issuance costs for initial public offering	—	(6,296)
Proceeds from issuance of redeemable convertible preferred shares	—	3,000
Issuance costs related to redeemable convertible preferred shares	—	(60)
Net cash provided by financing activities	1,710	313,273
Effect of exchange rate changes on cash and cash equivalents	(2,212)	449
Net decrease in cash, cash equivalents and restricted cash	$ (168,888)	$ (6,168)
Cash and cash equivalents, and restricted cash—beginning of period	248,182	254,350
Cash and cash equivalents, and restricted cash—ending of period	$ 79,294	$ 248,182
Cash and cash equivalents—end of period	$ 79,221	$ 228,182
Restricted cash—end of period	$ 73	$ 20,000
Cash and cash equivalents, and restricted cash—ending of period	$ 79,294	$ 248,182
Supplemental disclosure of cash information		
Cash paid for income taxes	$ 375	—
Supplemental disclosure of non-cash financing and investing activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 1,110	$ 5,160
Ordinary shares received as consideration for non-recourse promissory note default	1,650	—
Issuance costs in accounts payable and other accrued liabilities	—	1,496

Purchase of property and equipment in accounts payable	551	613
Conversion of Preferred Shares to ordinary shares upon initial public offering	—	352,730
Conversion of Warrants issued in license agreement into LianBio ordinary shares and LianBio warrants	—	10,414

See accompanying notes to the consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Tabular Dollars in Thousands, Except Share and per Share Data)

1. Nature of Business

LianBio ("LianBio" or the "Company") is a clinical stage biopharmaceutical company dedicated to bringing innovative medicines to patients with unmet medical needs in Asia. The Company's initial focus is to in-license assets for development and commercialization in Greater China and other Asian markets.

The Company was incorporated in the Cayman Islands in July 2019 and maintains its Chinese headquarters in Shanghai, China. The Company conducts its corporate activities at its United States headquarters located in Princeton, New Jersey.

On November 3, 2021, the Company completed its initial public offering ("IPO") through an underwritten sale of 20,312,500 American Depositary Shares ("ADSs") representing 20,312,500 ordinary shares at a price of $16.00 per share. Following the close of the IPO, on December 1, 2021, the underwriters partially exercised their option to purchase additional shares and purchased an additional 593,616 ADSs at the initial public offering price of $16.00 per ADS. The Company received gross proceeds of $334.5 million in connection with the IPO and subsequent exercise of the underwriters' option and aggregate net proceeds of $304.8 million after deducting underwriting discounts, commissions and other offering expenses.

Concurrent with the IPO, all of the Company's convertible preferred shares then-outstanding (see Note 10) were automatically converted into an aggregate of 64,467,176 ordinary shares and were reclassified into permanent equity. Following the IPO, there were no preferred shares outstanding.

2. Significant Accounting Policies

(A) Basis of presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, which include the People's Republic of China ("PRC") registered entities directly owned by the Company. All intercompany accounts and transactions have been eliminated in consolidation.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported financial position at the date of the financial statements and the reported results of operations during the reporting period. Such estimates and assumptions affect the reported amounts of assets, liabilities, and expenses, and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. The only material estimates in the accompanying financial statements are the fair value of warrants, share-based compensation, and share options. Actual results could differ from those used in evaluating these accounting estimates.

(i) Concentration of Credit Risk and Other Risks and Uncertainties

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 ("COVID-19") outbreak a pandemic. The Company's operations have not been significantly impacted by the COVID-19 pandemic. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including planned clinical trials. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy continue to be highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to material credit risk due to the financial position of the banking institutions. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

The Company's results of operations involve numerous risks and uncertainties. Factors that could affect the Company's operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials, uncertainty of regulatory approval of the Company's potential product candidates, uncertainty of market acceptance of its product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Each of the Company's product candidates require approvals from the National Medical Products Administration ("NMPA") in China and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any product candidate, such events could have a materially adverse impact on the Company's business.

(ii) Liquidity

The Company has incurred operating losses since inception and had an accumulated deficit of $470.5 million as of December 31, 2022 and $360.2 million as of December 31, 2021. The Company's cash and cash equivalents and marketable securities were $302.4 million and $383.2 million as of December 31, 2022 and December 31, 2021, respectively. The Company has financed its operations to date primarily through equity capital raises.

The Company believes that existing capital resources, including the net proceeds from the IPO in November 2021, will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying consolidated financial statements, though it expects to continue to incur operating losses and negative operating cash flows. The Company will be required to raise additional capital to fund future operations, however, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to preserve cash resources. These factors may adversely impact the Company's ability to achieve its business objectives and would likely have an adverse effect on its future business prospects, or even its ability to remain a going concern.

(C) Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of ordinary shares outstanding for the period determined using the treasury stock method. During periods in which the Company incurs net losses, both basic and diluted loss per share is calculated by dividing the net loss by the weighted average shares outstanding—potentially dilutive securities are excluded from the calculation because their effect would be anti-dilutive. Dilutive common stock equivalents are comprised of convertible preferred shares, options to purchase ordinary shares, restricted share units and unexercised warrants.

(D) Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates and manages its business as one reportable and operating segment, which is the business of license acquisitions, regulatory approvals, clinical trials, and commercial activity related to the current portfolio of in-licensed products. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance.

(E) Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not avail itself of this exemption and, as a result, will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

(F) Fair Value of Financial Instruments

FASB guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

a. Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

b. Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies.

c. Level 3 – Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when the fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company had no Level 3 assets or liabilities as of December 31, 2022 and December 31, 2021.

(G) Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are carried at cost which approximates fair value due to their short-term nature. The Company maintains cash balances at both U.S.-based and foreign-based commercial banks.

Amounts included in restricted cash represent those required to be set aside by a contractual agreement with Pfizer, Inc. ("Pfizer"), and was released as part of the commercial agreement entered into on December 16, 2022.

A summary of cash, cash equivalents and restricted cash is as follows:

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 79,221	$ 228,182
Restricted cash, non-current	73	20,000
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 79,294	$ 248,182

(H) Marketable Securities

The Company considers securities with original maturities of greater than 90 days to be available for sale securities. Securities under this classification are recorded at fair value and unrealized gains and losses within accumulated other comprehensive income (loss). The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. For available for sale debt securities in an unrealized loss position, the Company assesses whether it intends to sell or if it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value. If the criteria are not met, the Company evaluates whether the decline in fair value has resulted from a credit loss or other factors. In making this assessment, management considers, among other factors, the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of the cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized costs basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income. For the twelve-month periods ended December 31, 2022 and 2021, no allowance was recorded for credit losses.

(I) Concentration of credit risk

The Company's financial instruments that are exposed to credit risks consist primarily of cash and cash equivalents and available-for-sale marketable securities. The Company maintains its cash and cash equivalents in bank accounts, which, at times, exceed federally insured limits. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these funds. The Company's investment policy includes guidelines on the specific credit quality standards and limits the credit exposure of any single issuer the Company is allowed to invest in, which the Company believes minimizes the exposure to concentration of credit risk.

(J) Property and Equipment

Property and equipment are stated at cost net of accumulated depreciation, which is computed by the straight-line method based on the estimated useful lives of the respective assets, as discussed below. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the leased assets. Maintenance and repair costs are charged to expense as incurred, and expenditures for major renewals and improvements are capitalized. The Company assesses the net book value of its property and equipment for impairment at least annually or when events or circumstances indicate that the carrying amounts may not be recoverable in the ordinary course of its business.

(K) Foreign Currency

The functional currencies of the Company's foreign subsidiaries primarily are the local currencies of the country in which the subsidiary operates. The Company's asset and liability accounts are translated using the current exchange rate as of the balance sheet date. Shareholders' equity (deficit) accounts are translated using historical rates at the balance sheet date. Revenue and expense accounts are translated using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders' equity (deficit) within accumulated other comprehensive income (loss).

(L) Research and Development

Costs incurred for research and development are expensed as incurred. Included in research and development expense are personnel related costs, expenditures for laboratory equipment and consumables, payments made pursuant to licensing and acquisition agreements related to in-process research and development ("IPR&D"), and the cost of conducting clinical trials. Expenses incurred associated with conducting clinical trials include, but are not limited to, drug development trials and studies, drug manufacturing, laboratory supplies, external research, and payroll. Prepayments the Company makes for research and development services prior to services being rendered are recorded as prepaid expenses in the balance sheet and expensed as the services are provided.

(M) Acquisition of In-Process Research and Development

The Company has entered into agreements with third parties to acquire or license pharmaceutical product candidates for development. Such agreements generally require an initial payment by the Company when the contract is executed, and additional payments upon the achievement of certain milestones. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the pharmaceutical product candidate and achieves a certain sales volume. In accordance with FASB ASC Topic 730, "Research and Development," expenditures for research and development, including upfront licensing fees and milestone payments associated with products that have not yet been approved by the NMPA, are charged to research and development expense as incurred as there is no alternative future use. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable. Once a product candidate receives regulatory approval, subsequent license payments are recorded as an intangible asset and will be amortized over its estimated useful life.

(N) Accruals for Research and Development Expense and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to recognize its expense resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. This process involves reviewing open contracts and purchase orders, communicating with the applicable personnel to identify services that have been performed on behalf of the Company and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company records estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to the Company at that time. The Company's clinical trials accruals are dependent on the timely and accurate reporting of contract research organization and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. The Company periodically confirms the accuracy of its estimates with the service providers and records adjustments if necessary.

(O) Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, the amount of taxes currently payable or refundable is accrued, and deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax basis of existing assets and liabilities. Deferred tax assets also include realizable tax losses.

The deferred tax assets may be reduced by a valuation allowance, which is established when it is more likely than not that some portion or all of the deferred tax assets will not be realized. In addition, management is required to evaluate all available evidence, both positive and negative, when making its judgment to determine whether to record a valuation allowance for a portion, or all, of its deferred tax assets. Deferred tax assets and liabilities are measured using enacted income tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in income tax rate is recognized in the period that includes the enactment date.

The Company accounts for uncertainty in income taxes using a two-step approach. The first step requires the Company to conclude that a tax position, based solely on its technical merits, is more likely than not to be sustained upon examination by a tax authority. The second step requires the Company to measure the largest amount of benefit, determined on a cumulative probability basis, that is more likely than not to be realized upon ultimate settlement with tax authority. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Further, the benefit to be recorded in the consolidated financial statements is the amount most likely to be realized assuming a review by the tax authorities having all relevant information and applying current conventions. The Company's policy is to recognize interest and penalties related to income tax positions taken as a component of the provision for income taxes.

The Company does not anticipate any significant changes to its uncertain tax positions during the next 12 months. As of December 31, 2022, the Company was not aware of any anticipated audits by the IRS or any other state, local, or foreign taxing authorities for any other matters.

(P) Leases

In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of 12 months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing leases are for office space.

In addition to rent, leases may require the Company to pay additional costs, such as utilities, maintenance, and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components for its office leases. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as a right-of-use asset and liability. Rent expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments and is included in operating expense in the Consolidated Statements of Operations and Comprehensive Loss.

(Q) Share-Based Compensation

ASC 718 requires companies to measure the cost of employee services incurred in exchange for the award of equity instruments based on the estimated fair value of share-based award on the grant date. The share compensation awards issued to employees are equity classified, and the related expense is recognized over the requisite service period. The Company recognizes share-based award forfeitures only as they occur rather than an estimate by applying a forfeiture rate in accordance with ASU 2016-09.

The Company uses a Black-Scholes option-pricing model to value the Company's share option awards and the Monte Carlo simulation model to value the Company's performance share awards with market conditions. The performance share awards vest upon meeting certain market conditions and service conditions. The share option awards generally vest pro-rata annually. Performance share awards vest upon meeting certain regulatory approvals and service conditions. Using these option-pricing models, the fair value of each share option award and performance share award is estimated on the grant date. The fair value of the share options and performance share awards with market conditions is expensed on a straight-line basis over the vesting period. For awards that vest or begin vesting upon achievement of a performance condition, the Company estimates the likelihood of satisfaction of the performance condition and recognizes compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution model. The expected volatility assumption used is based on the volatility of the share price of comparable public companies. The expected life used in share options is determined using the "simplified method." The expected life used in performance award is determined as the midpoint between the requisite service period (the longer of the service or performance periods) and the contractual term. The risk-free interest rate used in both models is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted. The dividend yield used in both models is zero, as the Company has never declared a cash dividend.

Restricted share units ("RSUs") are measured and recognized over the vesting period and are based on the quoted market price of the Company's ADSs on the grant date.

(R) Ordinary Share Split

On October 7, 2021, the Company's board of directors approved a 5.8478-for-1 forward share split, which was approved by the Company's shareholders on October 14, 2021. Effective as of October 14, 2021, the Company's issued and outstanding ordinary shares were impacted by the forward share split. All share and per share data in the consolidated financial statements and notes thereto have been retrospectively revised to reflect the forward share split. Ordinary shares underlying outstanding share options and other equity instruments and the respective exercise prices, if applicable, were proportionately adjusted in accordance with the terms of the appropriate securities agreements. The respective conversion prices related to ordinary shares reserved for issuance upon the conversion of the Company's convertible preferred shares were proportionately adjusted.

(S) Other Recently Adopted Accounting Pronouncements

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, the Company has elected to "opt out" of such extended transition period for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards on the same timeline as other public companies. The Company has evaluated recent accounting pronouncements and believes that there are none that will have a material impact on its financial position or results of operations upon adoption.

(T) Recently Issued Accounting Pronouncements Not Yet Adopted

The Company has evaluated recent accounting pronouncements through the date the financial statements were issued and filed with the SEC and believes that there are none that will have a material impact on the Company's consolidated financial statements.

3. Material Agreements

License Agreement with QED Therapeutics, Inc.

In October 2019, the Company entered into a license agreement (the "QED License Agreement") with QED Therapeutics, Inc. ("QED"), as subsequently amended, under which the Company obtained an exclusive license under certain patents and know-how (including patents and know-how that QED licensed from QED's upstream licensor) to develop, manufacture, use, sell, import, and commercialize QED's ATP-competitive, FGFR1-3 tyrosine kinase inhibitor, infigratinib, in pharmaceutical products in the licensed territory of Mainland China, Macau, Hong Kong, Taiwan, Thailand, Singapore and South Korea, in the licensed field of human prophylactic and therapeutic uses in cancer indications. In September 2020, the Company entered into an amendment with QED to reduce the licensed territories to include Mainland China, Macau and Hong Kong. In December 2021, the Company entered into a second amendment with QED to modify the Company's development obligations with respect to certain clinical trials, and change the development milestone payments the Company owes to QED and the royalty rates for the tiered royalties on net sales of licensed products the Company will pay to QED. Under the QED License Agreement, QED received a nonrefundable upfront payment of $10.0 million and was granted warrants to purchase 100,000 ordinary shares in Lian Oncology, a subsidiary of LianBio, valued at $1.0 million. Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling 10% of the fully diluted equity of Lian Oncology as of the issue date. Vesting of the warrant shares are linked to regulatory milestones and the warrants expire 10 years from the issue date. The amended and restated option agreement also provides QED with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. In the event QED chooses to convert the Subsidiary Warrant into Parent Company Shares, the number of Parent Company Shares QED is entitled to receive would be calculated as the aggregate fair market value of the ordinary shares of Lian Oncology that are under the Subsidiary Warrant, divided by the per share fair market value of the Parent Company Shares, on a fully diluted and as-converted basis and as of the date the Company sent QED the notice of the IPO. In the event QED chose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant QED was entitled to receive would have been calculated as the aggregate intrinsic value of the Subsidiary Warrant (the number of the ordinary shares of Lian Oncology under the Subsidiary Warrant multiplied by the difference between the strike price of the Subsidiary Warrant and the per share fair market value of Lian Oncology), divided by the per share intrinsic value of the Parent Company Warrant (the difference between the strike price of the Parent Company Warrant and the per share fair market value of Parent Company Shares), on a fully diluted and as-converted basis on the date of the warrant conversion. This conversion feature was not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. On October 18, 2021, based on the conversion feature, LianBio issued to QED a warrant to purchase 347,569 of its ordinary shares at an exercise price of $0.000017100448 per share and, concurrently with such issuance, the Subsidiary Warrant was deemed to be performed and settled in full and was irrevocably terminated. Additionally, QED is entitled to receive from the Company development milestone payments of up to $7.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of infigratinib, in addition to tiered royalties on net sales of licensed products at the greater of (a) percentage rates in the mid- to high-teens on the net sales of the licensed products, or (b) the applicable rate payable under QED's agreement with its upstream licensor (capped in the mid-teens). No payments were made under this agreement during the twelve months ended December 31, 2022.

License Agreement with MyoKardia

In August 2020, the Company entered into an exclusive license agreement (the "MyoKardia License Agreement") with MyoKardia Inc. ("MyoKardia," now a wholly owned subsidiary of Bristol-Myers Squibb ("BMS")), under which the Company obtained an exclusive license under certain patents and know-how of MyoKardia to develop, manufacture, use, sell, import and commercialize MyoKardia's proprietary compound, mavacamten, in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore, and in the licensed field of any indication in humans, which includes any prophylactic or therapeutic use in humans. Under the MyoKardia License Agreement, MyoKardia received a nonrefundable upfront payment of $40.0 million and was granted a warrant to purchase 170,000 ordinary shares in Lian Cardiovascular, a subsidiary of LianBio, valued at $33.8 million. Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model and the underlying assumptions are discussed in further detail in Note 10. The warrants, representing 17% of the fully diluted equity of Lian Cardiovascular, are exercisable by MyoKardia at any time after issuance. The amended and restated option agreement also provides MyoKardia with the option to choose to either convert the warrant ("Subsidiary Warrant") into ordinary shares of the Company ("Parent Company Shares") or a warrant to purchase a certain number of Parent Company Shares ("Parent Company Warrant") immediately prior to an IPO of the Company. MyoKardia was entitled to choose to convert the Subsidiary Warrant into Parent Company Shares, and the number of Parent Company Shares MyoKardia was entitled to receive would have been calculated as the aggregate fair market value of the ordinary shares of Lian Cardiovascular that are under the Subsidiary Warrant, divided by the per share fair market value of the Parent Company Shares, on a fully diluted and as-converted basis on the date the Company sent MyoKardia the notice of the IPO. Alternatively, MyoKardia was entitled to choose to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant MyoKardia was entitled to receive would be calculated as the aggregate intrinsic value of the Subsidiary Warrant (the number of the ordinary shares of Lian Cardiovascular under the Subsidiary Warrant multiplied by the difference between the strike price of the Subsidiary Warrant and the per share fair market value of Lian Cardiovascular), divided by the per share intrinsic value of the Parent Company Warrant (the difference between the strike price of the Parent Company Warrant and the per share fair market value of Parent Company Shares), on a fully diluted and as-converted basis on the date of the warrant conversion. This conversion feature was not required to be bifurcated as it was clearly and closely related to the equity host instrument, pursuant to ASC 815. As of October 12, 2021, MyoKardia elected not to exercise this option and, therefore, continues to hold its warrant to purchase 170,000 ordinary shares in Lian Cardiovascular. MyoKardia's option to convert the warrant irrevocably terminated upon the completion of the Company's IPO. Additionally, MyoKardia was entitled to receive a nonrefundable financing milestone payment of $35.0 million upon a specified financing event, which occurred on October 29, 2020. The financing milestone was recorded at present value upon execution of the MyoKardia License Agreement, with total imputed interest of $2.3 million accreted under the effective interest method through the date the liability was settled. The financing milestone was paid to MyoKardia in December 2020 as a result of the Series A Preferred financing. Additionally, MyoKardia is entitled to receive from the Company development milestone payments of up to $60.0 million upon achievement of specified development milestones, and sales milestone payments of up to $87.5 million based on cumulative net sales of mavacamten, plus tiered royalties on net sales ranging from the low to upper-teens. As of December 31, 2022, the Company has paid $5.0 million to MyoKardia upon the completion of the first development milestone under the MyoKardia License Agreement.

License Agreement with Navire

In August 2020, pursuant to the BridgeBio exclusivity agreement, the Company entered into an exclusive license agreement with Navire Pharma, Inc. ("Navire"), a BridgeBio affiliate. Pursuant to the license agreement, Navire granted to the Company an exclusive, sublicensable license under certain patents and know-how of Navire to develop, manufacture, use, sell, import and commercialize Navire's proprietary SHP2 inhibitor, BBP-398 (formerly known as IACS-15509) in the licensed territory of Mainland China, Hong Kong, Macau, Taiwan, Thailand, Singapore, and South Korea. Under the license agreement, Navire received a nonrefundable upfront payment of $8.0 million. Additionally, Navire is entitled to receive from the Company development milestone payments of up to $24.5 million upon achievement of specified development milestones, and sales milestone payments of up to $357.6 million upon achievement of specified commercialization milestones, plus tiered royalties on net sales ranging from approximately 5-15% on the net sales of the licensed products. The Company had recorded and paid the first development milestone of $8.5 million for IND acceptance in the PRC during the twelve months ended December 31, 2021. No payments were made under this agreement during the twelve months ended December 31, 2022.

Pfizer Strategic Collaboration

In November 2020, the Company entered into a strategic collaboration agreement (the "Pfizer Collaboration Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which Pfizer will contribute up to $70.0 million of restricted, non-dilutive capital (the "Funds"), including a $20.0 million upfront payment, toward the Company's in-licensing and co-development activities in Greater China. The Company has accounted for the Pfizer Collaboration Agreement as a contract to perform research and development services for others under ASC 730-20 and the consideration received for performing these services will be recognized as contra-R&D in the Consolidated Statement of Operations and Comprehensive Loss as the services are performed.

Upon receipt in 2021, the upfront payment was recorded as restricted cash within the consolidated balance sheet and will remain restricted until such time as the upfront payment is utilized for specified in-licensing and co-development activities or until the Pfizer Collaboration Agreement terminates. Under the Pfizer Collaboration Agreement, Pfizer and LianBio will form a joint collaboration committee to discuss potential third party in-license opportunities and development and commercialization of the Company's products in Greater China. In the event the Company seeks to engage a third-party commercialization partner with respect to the commercialization of the Company's future products in Greater China, Pfizer will have a right to opt into such product. Upon opting in, a portion of the Funds will be used to pay for development and commercialization costs of such product and Pfizer will thereafter have a right of first negotiation and right of last refusal to obtain the commercialization rights of such product in Greater China, in each instance for additional, separate financial consideration. During the collaboration, Pfizer may provide in-kind support to us for marketing, development, and regulatory activities.

In December 2022, the Company, Pfizer, and ReViral Ltd. ("ReViral," now a wholly owned subsidiary of Pfizer) entered into a commercial agreement (the "Pfizer Commercial Agreement") with respect to sisunatovir (a fusion inhibitor product for treatment of RSV) as the first Opted-in Product under the Pfizer Collaboration Agreement. Pursuant to the Pfizer Commercial Agreement, LianBio will assign and transfer its development and commercialization rights to sisunatovir in Mainland China, Hong Kong, Macau and Singapore (the "Territory") to Pfizer.

Under the Pfizer Commercial Agreement, the $20.0 million upfront payment, which was previously received and recorded as restricted cash, paid by Pfizer to LianBio in 2020 pursuant to the Pfizer Collaboration Agreement, was released as there are no further obligations and the associated contingencies were resolved. In addition, LianBio could also receive up to $135.0 million in potential development and sales milestones contingent on sisunatovir achieving a specified regulatory milestone event prior to the end of October 2035 and specified net sales milestone events. LianBio is further entitled to receive tiered payments in the low single digits on a percentage of net sales of sisunatovir in the Territory. Pfizer will lead all development and commercial activities, use commercially reasonable efforts to develop and seek regulatory approval for sisunatovir as a fusion inhibitor product for treatment of RSV as a single active pharmaceutical product in Mainland China, assume all costs in the Territory, and will waive LianBio's milestone payment and royalty payment obligations previously due to ReViral pursuant to the Co-Development and License Agreement dated March 1, 2021 by and between LianBio Respiratory Limited and ReViral, which was superseded in its entirety by the Pfizer Commercial Agreement.

The Company has accounted for the Pfizer Commercial Agreement under ASC 450-30 and the consideration received under the agreement will be recognized as other income as they become realizable. The Company accounted for $7.0 million of the $20.0 million upfront payment as the partial reimbursement of the upfront payment paid pursuant to our exclusive license agreement with ReViral and is recognized as a contra-research and development expense in Research and development in the Consolidated Statement of Operations and Comprehensive Loss. The remaining $13.0 million was released and recognized in Other income in the Consolidated Statement of Operations and Comprehensive Loss.

License Agreement with ReViral

In March 2021, the Company entered into an exclusive license agreement (the "ReViral License Agreement") with ReViral Ltd. ("ReViral", now a wholly owned subsidiary of Pfizer). Pursuant to the license agreement, ReViral granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize novel antiviral therapeutics that target RSV in Mainland China, Macau, Hong Kong, and Singapore. Under the license agreement, ReViral received a nonrefundable upfront payment of $14.0 million. Additionally, ReViral is entitled to receive payments from the Company totaling an aggregate of up to $105.0 million upon the achievement of specified development and commercial milestones, up to $45.0 million and $60.0 million, respectively, plus tiered royalties on net sales ranging from ten to the low-teens. No payments were made under this agreement during the twelve months ended December 31, 2022.

As part of the Pfizer Commercial Agreement, the Company has no further obligations for payments of milestones or royalties under the ReViral License Agreement.

License Agreement with Tarsus

In March 2021, the Company entered into an exclusive license agreement (the "Tarsus License Agreement") with Tarsus Pharmaceuticals, Inc. ("Tarsus"). Pursuant to the license agreement, Tarsus granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize TP-03 for the treatment of patients with Demodex blepharitis ("DB") and Meibomian Gland Disease ("MGD") in Mainland China, Macau, Hong Kong, and Taiwan. Under the license agreement, Tarsus received a nonrefundable upfront payment of $15.0 million and was granted three warrants to purchase 125,000 ordinary shares in Lian Ophthalmology, a subsidiary of LianBio, valued at $9.4 million (the "Tarsus Warrants"). Pursuant to ASC 505-50, as the fair value of the warrants were more reliably determinable than the fair value of the benefits received from the licensing agreement, the Company valued the warrants using the Black-Scholes Model and the underlying assumptions are discussed in further detail in Note 10. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling 12.5% of the fully diluted equity of Lian Ophthalmology as of the issue date. Vesting of the warrant shares are linked to regulatory milestones and the warrants expire 10 years from the issue date. Pursuant to a related option agreement (the "Tarsus Option Agreement"), Tarsus also had the option to convert the warrants into ordinary shares of the Company ("Parent Company Shares") or warrants to purchase a certain number of the Company's ordinary shares ("Parent Company Warrants") based on appreciation of the value in the Lian Ophthalmology since the inception of the Tarsus License Agreement. This conversion feature was not required to be bifurcated as it was clearly and closely related to the equity host instrument, pursuant to ASC 815. On October 18, 2021, Tarsus exercised its option to convert the Tarsus Warrants under the Tarsus Option Agreement. On October 18, 2021, Tarsus exercised its options to convert the Tarsus Warrants under the Tarsus Option Agreement and the Company subsequently issued to Tarsus 78,373 of its ordinary shares and two warrants to purchase an aggregate of 156,746 of its ordinary shares at an exercise price of $0.000017100448 per share. Following the issuances, the Tarsus Warrants were irrevocably terminated. On June 6, 2022, Tarsus exercised one warrant and the Company subsequently issued 78,373 of its ordinary shares at an exercise price of $0.000017100448 per share. Additionally, Tarsus is entitled to receive a nonrefundable second milestone payment of $10.0 million due and payable within forty-five days following the effective date. Additionally, Tarsus is entitled to receive payments from the Company totaling an aggregate of up to $175.0 million upon the achievement of specified development and commercial milestones, up to $75.0 million and $100.0 million, respectively, plus tiered royalties at percentage rates ranging from the low- to high-teens on net sales. During 2022, the Company was notified that Tarsus had achieved certain development milestones. During the twelve months ended December 31, 2022 and 2021, the Company paid $25.0 million and $30.0 million, respectively, to Tarsus as a result of the achievement of these milestones.

License Agreement with Landos

In May 2021, the Company entered into an exclusive license agreement (the "Landos License Agreement") with Landos BioPharma, Inc. ("Landos"). Pursuant to the license agreement, Landos granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize novel, gut-restricted small molecule omilancor (formerly known as BT-11) and NX-13 for the treatment of inflammatory bowel disease, that targets the NLRX1 pathway in Mainland China, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand, and Vietnam. Under the license agreement, Landos received a nonrefundable upfront payment of $18.0 million. Additionally, Landos is entitled to receive payments from the Company totaling an aggregate of up to $200.0 million upon the achievement of specified development and commercial milestones, up to $95.0 million and $105.0 million, respectively, plus tiered royalties at percentage rates ranging from the low- to the mid-teens on net sales. No payments were made under this agreement during the twelve months ended December 31, 2022.

In February 2023, the Company entered into an amendment to the Landos License Agreement, reflecting that Landos has transferred and assigned substantially all of its rights in omilancor to NImmune. As a result, the Landos License Agreement will relate only to NX-13, and the Company has entered into a direct license agreement with NImmune setting forth the terms of its continued development and commercialization of omilancor in its licensed territories.

License Agreement with Nanobiotix

In May 2021, the Company entered into an exclusive license agreement (the "Nanobiotix License Agreement") with Nanobiotix S.A. ("Nanobiotix"). Pursuant to the license agreement, Nanobiotix granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop and commercialize NBTXR3, a potential first-in-class radioenhancer in Mainland China, Hong Kong, Taiwan, and Macau, South Korea, Singapore and Thailand. Under the license agreement, Nanobiotix received a nonrefundable upfront payment of $20.0 million. Additionally, Nanobiotix is entitled to receive payments from the Company totaling an aggregate of up to $220.0 million upon the achievement of specified development and commercial milestones, up to $65.0 million and $155.0 million, respectively, plus tiered royalties of 10-13% of net sales. No payments were made under this agreement during the twelve months ended December 31, 2022.

License Agreement with Lyra

In May 2021, the Company entered into an exclusive license agreement (the "Lyra License Agreement") with Lyra Therapeutics, Inc. ("Lyra"). Pursuant to the license agreement, Lyra granted to the Company an exclusive, sublicensable license under the licensed patent rights and know-how to develop and commercialize LYR-210, an anti-inflammatory, intra-nasal drug matrix in late-stage development that is designed to treat chronic rhinosinusitis ("CRS") in Mainland China, Hong Kong, Taiwan, and Macau, South Korea, Singapore and Thailand. Under the license agreement, Lyra received a nonrefundable upfront payment of $12.0 million. Additionally, Lyra is entitled to receive payments from the Company totaling an aggregate of up to $135.0 million upon the achievement of specified development and commercial milestones, up to $40.0 million and $95.0 million, respectively, plus tiered royalties from the low- to high-teens on net sales. As of December 31, 2022, the Company has paid $5.0 million to Lyra upon the completion of the first development milestone under the Lyra License Agreement.

4. Marketable Securities and Fair Value Measurements

The following is a summary of marketable securities accounted for as available-for-sale securities at December 31, 2022 and 2021:

As of December 31, 2022 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 120,570	$ 5	$ (313)	$ 120,262
Corporate debt securities	14,146	—	(16)	14,130
Government obligations & agency securities	89,265	4	(519)	88,750
Total	$ 223,981	$ 9	$ (848)	$ 223,142

As of December 31, 2021 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 145,894	$ 55	$ —	$ 145,949
Corporate debt securities	4,138	—	—	4,138
Government obligations	4,986	—	(6)	4,980
Total	$ 155,018	$ 55	$ (6)	$ 155,067

The unrealized losses and fair values of available-for-sale securities that have been in an unrealized loss position for a period of less than and greater than 12 months as of December 31, 2022 and 2021 are as follows:

As of December 31, 2022 (in thousands)	Securities in an unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ (313)	$ 110,370	$ —	$ —	$ (313)	$ 110,370
Corporate debt securities	(16)	14,130	—	—	(16)	14,130
Government obligations & agency securities	(455)	70,771	(64)	14,897	(519)	85,668
Total	$ (784)	$ 195,271	$ (64)	$ 14,897	$ (848)	$ 210,168

As of December 31, 2021 (in thousands)	Securities in an unrealized loss position less than 12 months		Securities in an unrealized loss position greater than 12 months		Total	
	Unrealized losses	Fair Value	Unrealized losses	Fair Value	Unrealized losses	Fair Value
Commercial paper	$ —	$ —	$ —	$ —	$ —	$ —
Corporate debt securities	—	—	—	—	—	—
Government obligations	(6)	4,980	—	—	(6)	4,980
Total	$ (6)	$ 4,980	$ —	$ —	$ (6)	$ 4,980

Marketable securities on the balance sheet at December 31, 2022 and 2021 mature as follows:

	December 31, 2022	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ 120,262	$ —
Corporate debt securities	14,130	—
Government obligations	70,771	17,979
Total Marketable securities	$ 205,163	$ 17,979

	December 31, 2021	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ 145,949	$ —
Corporate debt securities	4,138	—
Government obligations	—	4,980
Total Marketable securities	$ 150,087	$ 4,980

The Company classifies all of its securities as current as they are all available for sale and are available for current operations.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

As of December 31, 2022 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 11,242	$ —	$ —	$ 11,242
Commercial paper	—	—	—	—
Corporate debt securities	—	—	—	—
Marketable securities:				
Commercial paper	—	120,262	—	120,262
Corporate debt securities	—	14,130	—	14,130
Government obligations & agency securities	—	88,750	—	88,750
Total	$ 11,242	$ 223,142	$ —	$ 234,384

As of December 31, 2021 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 67,289	$ —	$ —	$ 67,289
Commercial paper	—	80,541	—	80,541
Corporate debt securities	—	8,165	—	8,165
Marketable securities:				
Commercial paper	—	145,949	—	145,949
Corporate debt securities	—	4,138	—	4,138
Government obligations	—	4,980	—	4,980
Total	$ 67,289	$ 243,773	$ —	$ 311,062

5. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2022	December 31, 2021
Leasehold improvements	$ 3,372	$ 807
Furniture and fixtures	113	65
Computer equipment and software	1,111	471
Construction in progress	67	1,145
	4,663	2,488
Accumulated depreciation	(1,547)	(606)
Total property and equipment, net	$ 3,116	$ 1,882

Total depreciation related to property and equipment for the years ended December 31, 2022 and 2021 was $1.0 million and $0.5 million, respectively.

6. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	December 31, 2022	December 31, 2021
Advance payments to suppliers and rent deposit	$ 1,957	$ 1,499
Prepaid insurance	2,953	7,378
VAT receivable	2,640	1,176
Other prepaid expenses	1,090	301
Total prepaid expenses and other current assets	$ 8,640	$ 10,354

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2022	December 31, 2021
Employee compensation and related benefits	$ 7,833	$ 2,309
Professional fees	4,438	3,625
Consulting and contracted research	7,379	3,925
Other	176	117
Total accrued expenses	$ 19,826	$ 9,976

8. Commitments and Contingencies

(A) Leases

In 2019, the Company entered into a real estate lease in Shanghai, effective December 23, 2019 for office space on the 9th floor of the Kerry Parkside building. The lease term ended on April 6, 2022.

In 2020, the Company entered into two real estate leases for office space, one in Princeton, New Jersey, effective June 18, 2020 and one in Shanghai on the 7th floor of the Kerry Parkside building, effective August 31, 2020. The initial lease term of the 7th floor Kerry Parkside building ends on April 6, 2022 with an option to renew for one additional period of 24 months. The Company did not renew either of the leases for office space in the Kerry Parkside buildings.

In November 2021, the Company entered into an amendment to increase the office space in Princeton, New Jersey. The amended lease term ends on October 31, 2024 with an option to renew for one additional period of 36 months.

In November 2021, the Company entered into a real estate lease for office space in Shanghai, effective November 16, 2021. The initial lease term ends on March 31, 2025 with an option to renew for one additional period of 36 months.

In April 2022, the Company entered into a real estate lease for office space in Beijing, effective April 1, 2022. The initial lease term ends on June 30, 2025, with an option to renew for one additional period of 36 months.

The components of total lease costs were as follows:

	December 31, 2022	December 31, 2021
Operating lease cost	$ 1,830	$ 1,148
Short-term lease cost	381	181
Total lease cost	$ 2,211	$ 1,329

Supplemental lease term and discount rate information related to leases was as follows:

	December 31, 2022	December 31, 2021
Weighted-average remaining lease terms—operating leases (years)	2.26	3.11
Weighted-average discount rate—operating leases	9.10 %	9.37 %

Supplemental cash flow information related to leases was as follows:

	December 31, 2022	December 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,502	$ 1,117
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 1,110	$ 5,160

Commitments

As of December 31, 2022, future minimum lease payments, were as follows:

	Operating Leases
2023	$ 2,127
2024	2,092
2025	561
Total	$ 4,780
Less imputed interest	(441)
Present value of lease liabilities	$ 4,339

(B) Litigation and Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. As of December 31, 2022, and December 31, 2021, there have been no such matters identified. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within the range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. The Company is not currently party to any material legal proceedings.

9. Share-Based Compensation

In December 2020, the Company adopted a shareholder-approved share-based compensation plan (the "2019 Plan"), which permits the granting of incentive share options, nonqualified share options, share awards and certain other awards to its employees, members of its Board of Directors, and consultants.

In connection with the IPO, the Company adopted a shareholder-approved share-based compensation plan (the "2021 Equity Plan"), which permits the granting of incentive share options, nonqualified share options, share awards and certain other awards to its employees, members of its Board of Directors, and consultants. The maximum number of shares that may be delivered in satisfaction of awards under the 2021 Equity Plan is approximately 14.2 million shares, plus that number of shares that remain available for issuance under the 2019 Plan and that may again become available for issuance under such plan, not to exceed approximately 10.7 million shares in the aggregate, and an annual increase, to be added as of January 1st of each year from January 1, 2022, to January 1, 2031, equal to the lesser of (i) four percent (4%) of the number of shares outstanding as of such date; and (ii) the number of shares determined by our board on or prior to such date for such year. Subsequent to the effectiveness of the 2021 Equity Plan, no additional awards will be made pursuant to the 2019 Plan. However, any outstanding awards granted under the 2019 Plan will remain outstanding, subject to the terms of the 2019 Plan and award agreements. Through December 31, 2022, there were awards issued for approximately 8.5 million ordinary shares under the 2019 Plan and approximately 5.7 million ordinary shares under the 2021 Equity Plan.

Share Option Awards

Share option grants provide the right to purchase a specified number of ordinary shares from the Company at a specified price during a specified period of time. The share option exercise price per share is the fair market value of the Company's ordinary shares on the date of the grant of the share option.

During the twelve months ended December 31, 2022, the Company issued 673,574 options to purchase ordinary shares to various employees, directors and board members with a weighted-average exercise price of $2.83 per share option.

During the twelve months ended December 31, 2021, the Company issued 7,426,136 options to purchase ordinary shares at exercise prices ranging from $6.16 to $16.00 per share.

The fair values of service-based stock options granted during each of the periods presented below were estimated using the Black-Scholes Model based on the following assumptions:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected Dividend Yield	— %	— %
Expected Volatility	76.83%—79.65%	60.00% —76.65%
Expected Term (years)	5.50—6.08	0.50—6.25
Risk Free Interest Rate	2.56%—3.90%	0.09%—1.36%
Exercise Price	$ 1.63—4.95	$ 6.16—16.00
Weighted Average grant date fair value per stock option	$1.95	$6.44

A summary of share option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Terms in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2021	11,377,777	$ 8.25	9.19	$ 8,900
Granted	673,574	$ 2.83		
Exercised	(1,000,000)	$ 1.71		
Expired or forfeited	(392,174)	$ 9.39		
Outstanding at December 31, 2022	10,659,177	$ 8.48	8.38	$ 2
Vested or expected to vest at December 31, 2022	10,659,177	$ 8.48	8.38	$ 2
Exercisable at December 31, 2022	4,073,624	$ 7.34	8.04	$ —

As of December 31, 2022, $34.9 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 2.64 years from the date of grant. Options granted to senior management and employees generally vest in equal annual increments over four years and grants issued subsequent to the IPO generally vest over four years with 25% vesting over the first year and monthly thereafter.

Performance Share Awards

There were no performance share awards granted during the twelve months ended December 31, 2022. During the twelve months ended December 31, 2021, the Company granted certain option awards with both market-vesting conditions and service-vesting conditions to a member of management. The market condition is based on the Company's enterprise value. Per the terms of the award, these options will vest in two equal tranches based on the following thresholds:

1. 25% of the performance options shall vest upon the satisfaction of the Company achieving an enterprise value of not less than $2.0 billion at any time after the grant date in accordance with the service condition described below.
2. 25% of the performance options shall vest upon the satisfaction of the Company achieving an enterprise value of not less than $4.0 billion at any time after the grant date in accordance with the service condition described below.

The enterprise value shall be equal to the number of outstanding ordinary shares of the Company multiplied by the volume weighted average price of a single ordinary share averaged over a period of thirty days ending one day prior to the date of the valuation.

Subject to the market conditions described above, the option contains explicit service vesting conditions, with one-fourth vesting each year over four years.

A summary of the activity associated with these awards is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Term of Options in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2021	1,938,615	$ 6.90	9.37	
Granted	—	—		
Vested	—	—		
Exercised	—	—		
Expired or forfeited	—	—		
Outstanding at December 31, 2022	1,938,615	$ 6.90	8.37	—
Non-vested options as of December 31, 2022	1,938,615	$ 6.90	8.37	—

The Company used a Monte-Carlo simulation to determine the grant date fair value for these awards, which takes into consideration the possible outcomes pertaining to the enterprise value market condition. The assumptions used in the Monte-Carlo simulation for the performance options along with the weighted-average grant date fair value for awards granted in the periods presented are as follows:

Expected volatility	47.07%—80.64%
Dividend Yield	0%
Risk-free interest rate	0.81%—1.63%
Expected term, in years	4.87—10.00
Weighted average grant date fair value per share	$4.72

As of December 31, 2022, there was $5.4 million total unrecognized of compensation cost related to the performance share units.

There were no performance-based share units (“PSUs”) granted during the twelve months ended December 31, 2022. During the twelve months ended December 31, 2021, 733,926 PSUs were granted to certain management employees. 60% of the total number of PSUs will vest on the one-year anniversary of the date on which the mavacamten NDA acceptance in China is obtained. The remaining 40% of the PSUs will vest on the six-month anniversary of the date on which the mavacamten NMPA approval in China is obtained. Upon termination of an employee’s service with the Company for any reason, any of these PSUs that are outstanding and not yet vested will be immediately forfeited.

A summary of the activity associated with these PSUs is as follows:

	Number of PSUs	Weighted Average Exercise Price	Average Remaining Term of PSUs in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2021	733,926	$ 6.16	10.00	
Granted	—	—		
Vested	—	—		
Exercised	—	—		
Expired or forfeited	(19,078)	$ 6.16		
Outstanding at December 31, 2022	714,848	$ 6.16	9.00	—
Non-vested PSUs as of December 31, 2022	714,848	$ 6.16	9.00	—

The fair values of PSUs granted during the period presented below were estimated using the Black-Scholes Model based on the following assumptions:

Expected volatility	76.55%
Dividend Yield	0%
Risk-free interest rate	1.37%
Expected term, in years	6.24
Weighted average grant date fair value per share	$4.16

As of December 31, 2022, there was $1.8 million of total unrecognized of compensation cost related to the PSUs.

Restricted Share Units

During the twelve months ended December 31, 2022, 68,708 restricted share units ("RSUs") were granted to certain employees. During the twelve months ended December 31, 2021, 479,673 RSUs were granted. One fourth of the RSUs will vest and be released from the restrictions on each yearly anniversary from the date of the grant. Upon termination of an employee's service with the Company for any reason, any RSUs that are outstanding and not yet vested will be immediately forfeited. The Company measured the fair value of the non-vested RSUs as of respective grant dates.

The following table summarized the non-vested RSU activity in 2022:

	Numbers of nonvested RSUs	Weighted average grant date fair value $
Non-vested as of December 31, 2021	479,673	6.16
Granted	68,708	2.03
Vested	(117,947)	6.16
Forfeited	(7,765)	6.16
Non-vested as of December 31, 2022	422,669	5.49

As of December 31, 2022, there was $2.3 million of total unrecognized compensation expense related to non-vested RSUs. The Company recorded compensation expense related to the RSUs of $0.7 million and $0.0 million for the years ended December 31, 2022 and 2021, respectively.

During the twelve months ended December 31, 2022, 217,985 performance-based RSUs were granted to certain employees. During the twelve months ended December 31, 2021, 146,786 performance-based RSUs were granted. 60% of the total number of RSUs will vest on the one-year anniversary of the date on which the mavacamten NDA acceptance in China is obtained. The remaining 40% of the RSUs will vest on the six-month anniversary of the date on which the mavacamten NDA acceptance in China is obtained. Upon termination of an employee's service with the Company for any reason, any performance-based RSUs that are outstanding and not yet vested will be immediately forfeited. The Company measured the fair value of the non-vested performance-based RSUs as of respective grant dates.

The following table summarized the non-vested performance-based RSU activity in 2022:

	Numbers of nonvested restricted shares	Weighted average grant date fair value $
Non-vested as of December 31, 2021	146,786	6.16
Granted	217,985	2.17
Vested	—	—
Forfeited	(3,816)	6.16
Non-vested as of December 31, 2022	360,955	3.75

As of December 31, 2022, there was $0.9 million of total unrecognized compensation expense related to non-vested performance-based RSUs. The Company recorded compensation expense related to the performance-based RSUs of $0.4 million and $0.0 million for the years ended December 31, 2022 and 2021, respectively.

10. Equity

Ordinary Shares

As of December 31, 2022 and 2021, the Company was authorized to issue up to 2,923,900,005 ordinary shares, each with a par value of $0.000017100448.

Preferred Shares

On November 3, 2021, upon the closing of the IPO, all Series Seed Preferred Shares were automatically converted into an aggregate 32,162,900 of the Company's ordinary shares, after giving effect to the 5.8478-for-1 share split effected October 14, 2021 and $55.0 million of mezzanine equity was reclassified to ordinary shares and additional paid-in capital.

On November 3, 2021, upon the closing of the IPO, all Series A Preferred Shares were automatically converted into an aggregate 32,304,276 of the Company's ordinary shares, after giving effect to the 5.8478-for-1 share split effected October 14, 2021 and $297.7 million of mezzanine equity was reclassified to ordinary shares and additional paid-in capital.

There were no preferred shares outstanding as of December 31, 2022 and 2021.

The Company's redeemable convertible preferred shares are not liability classified as they do not embody an unconditional obligation requiring the issuer to redeem the instrument by transferring its assets at a specified date or an event certain to occur. Due to the conversion at the option of the holder and redemption upon an occurrence that is not solely within the Company's control, the Company classified the redeemable convertible preferred shares in mezzanine equity rather than as a component of shareholders' deficit.

The characteristics of the redeemable convertible preferred shares are as follows:

Voting

The holders of the redeemable convertible preferred shares have one vote for each ordinary share into which the shares of redeemable convertible shares may be converted, subject to certain limitations.

Dividends

The holders of redeemable convertible preferred shares are entitled to receive non-cumulative dividend preference over the ordinary shareholders only when and if declared by the Board of Directors. As of December 31, 2022 and December 31, 2021, no dividends have been declared or paid.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, the holders of the then outstanding redeemable convertible preferred shares will have distribution preference over the ordinary shareholders in the amount of 100% of their original purchase price plus accrued but unpaid dividends. If the assets and funds to be distributed among the holders of redeemable convertible preferred shares are insufficient to permit the full payment to which the holders are entitled, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of redeemable convertible preferred shares in proportion to the preferential amount each such holder is otherwise entitled to receive before distribution is made to the ordinary shareholders.

Conversion

The Series Seed Preferred Shares are convertible, at the option of the holder, into such number of fully paid shares of the Company's ordinary shares as is determined by dividing the original issuance price by the conversion price in effect at the time of conversion. Based on the conversion ratios in effect as of December 31, 2021, after giving effect to the 5.8478-for-1 share split effected October 14, 2021, the Series Seed Preferred Shares converted into an aggregate of 32,162,900 of the Company's ordinary shares on November 3, 2021.

Based on the conversion ratios in effect as of December 31, 2021, after giving effect to the 5.8478-for-1 share split effected October 14, 2021, the Series A Preferred Shares converted into an aggregate of 32,304,276 of the Company's ordinary shares on November 3, 2021.

Redemption

No redeemable convertible preferred shares are unilaterally redeemable by either the shareholders or the Company.

Warrants

In March 2021, the Company issued three warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology (the "Tarsus Warrants"). The Tarsus Warrants are equity classified and were issued by Lian Ophthalmology, a wholly owned subsidiary of the Company, as partial consideration to Tarsus for the Tarsus License Agreement. The Tarsus Warrants, if exercised, represent 12.5% of the fully diluted equity of Lian Ophthalmology. The Tarsus Warrants are accounted for under ASC 718 Compensation – Stock Compensation and are fair valued on the grant date using the Black-Scholes Model based on the following weighted average assumptions:

Current Price of the Underlying Share	$	109.00
Exercise Price	$	109.00
Expected Term		10 years
Risk Free Interest Rate		1.70 %
Dividend Yield		0 %
Expected Volatility		62.50 %

On October 18, 2021, Tarsus exercised its option to convert the Tarsus Warrants under the Tarsus Option Agreement. Accordingly, the Company subsequently issued to Tarsus 78,373 of its ordinary shares and two warrants to purchase an aggregate of 156,746 of its ordinary shares at an exercise price of $0.000017100448 per share. On June 6, 2022, Tarsus exercised one warrant and the Company subsequently issued 78,373 of its ordinary shares at an exercise price of 0.000017100448 per share.

Non-controlling Interest

The equity classified warrants issued at the subsidiary level allow the holder to purchase ordinary shares of the Company's respective wholly owned subsidiaries, thus creating a non-controlling interest. The Company recorded the fair value of the warrants as non-controlling interest in the equity section of the balance sheet. As of December 31, 2022 and 2021, the MyoKardia Warrant was unexercised and no earnings were attributed to the non-controlling interest.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential ordinary shares had been issued for other dilutive securities. For the years ended December 31, 2022 and 2021, diluted and basic net loss per ordinary share were identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Numerator		
Net Loss attributable to ordinary shareholders	$ (110,290)	$ (196,300)
Denominator		
Weighted-average shares – basic and diluted	107,923,296	34,394,622
Net loss per ordinary share – basic and diluted	$ (1.02)	$ (5.71)

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share, because including them would have been anti-dilutive.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Redeemable Convertible Preferred Shares	—	11,024,178
Employee Share Options	13,312,640	14,050,317
Non-vested restricted shares	783,624	626,459
QED Warrants	—	100,000
MyoKardia Warrant	170,000	170,000
Tarsus Warrants	—	125,000
Warrants in LianBio issued to QED and Tarsus	425,942	504,315

11. Income Taxes

The components of pre-tax income (loss) before income taxes are as follows:

	December 31, 2022	December 31, 2021
Domestic	$ (12,723)	$ (24,006)
Foreign	(97,900)	(171,776)
Total	$ (110,623)	$ (195,782)

The components of income tax (benefit) expense are as follows:

	December 31, 2022	December 31, 2021
Federal	$ (320)	$ 461
State and local	(13)	57
Foreign	—	—
Total current tax (benefit) expense	$ (333)	$ 518

	December 31, 2022	December 31, 2021
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
Total deferred tax (benefit) expense	$ —	$ —

	December 31, 2022	December 31, 2021
Total Provision	$ (333)	$ 518

The following table shows the principle reasons for the difference between the effective income tax rate and the statutory federal income tax rate:

	December 31, 2022	December 31, 2021
Income tax provision at the statutory rate of 0%	— %	— %
State income tax, net of federal benefit	0.01 %	(0.03)%
Foreign Rate Differential	1.39 %	3.25 %
License transfers	— %	(15.85)%
Other	(0.45)%	(0.41)%
Valuation Allowance	(0.65)%	12.77 %
Effective Tax Rate	0.30 %	(0.27)%

The effective income tax rate is 0.30% and (0.27)% for the years ended December 31, 2022 and December 31, 2021, respectively. The primary reconciling items between the Cayman Islands statutory income tax rate of 0% and the effective income tax rate is the current tax expense in foreign jurisdictions with a statutory tax rate greater than 0%.

The tax effects of temporary differences that give rise to deferred tax assets and liabilities are summarized as follows:

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Accrued expenses	$ 1,768	$ 568
Net operating loss carryforwards	8,370	6,354
Share based compensation	2,421	1,773
Right of use liability	891	975
Intangible Assets	785	785
Other	129	87
Total Gross Deferred Tax Asset	14,364	10,542
Less: Valuation Allowance	(13,504)	(9,579)
Total Deferred Tax Asset	$ 860	$ 963
Deferred tax liabilities:		
Property and equipment	$ (59)	$ (37)
Right of use asset	(801)	(926)
Total gross deferred tax liabilities	(860)	(963)
Net deferred tax assets (liabilities)	$ —	$ —

The net change in the total valuation allowance resulted in an increase of $(3.9) million in 2022, primarily related to stock compensation expense add back and net operating loss carryforwards. The Company has considered and weighed the available evidence, both positive and negative, to determine whether it is more-likely-than-not that some portion, or all, of the DTAs will not be realized. The Company has a history of worldwide and U.S. pre-tax book losses, does not have the ability to carryback its losses to offset income in prior periods, does not have significant taxable temporary differences that could offset current losses and deductible temporary differences, and is currently in a cumulative three-year loss position, which represent significant negative evidence for evaluation of realizability of deferred tax assets. Additionally, the Company has considered tax planning strategies for its U.S. and foreign structure and has not identified any opportunities to generate taxable income from such strategies as of December 31, 2022. As a result, the Company has concluded that the future realization of deferred tax assets is not more-likely-than-not to occur. The cumulative valuation allowance was $(13.5) million at December 31, 2022.

At December 31, 2022, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $23.2 million which do not expire. The Company had foreign net operating loss carryforwards of $14.7 million which will begin to expire if unused in 2026. In addition, the Company has capital loss carryforwards of $4.2 million, which will expire if unused in 2027.

Foreign undistributed earnings were considered permanently reinvested, therefore no provision for income taxes was accrued as of December 31, 2022 and 2021. The Company has not identified nor recorded any reserves for uncertain tax positions as of December 31, 2022 and December 31, 2021. As of December 31, 2022, the Company was not aware of any anticipated audits by the IRS or any other state, local, or foreign taxing authorities for any other matters. The Company is not a U.S. shareholder and is therefore not expected to be subject to tax on Global Intangible Low-Taxed Income ("GILTI").

12. Accumulated other comprehensive (loss) income

Other comprehensive (loss) income includes changes in equity that are excluded from net loss, such as unrealized gains and losses on marketable securities.

The following table summarizes other comprehensive (loss) income and the changes in accumulated other comprehensive items, by component, for the years ended December 31, 2022, and 2021, respectively.

	Unrealized Gain (Loss) on Marketable Securities, net of tax	Foreign Currency Translation (Loss) Income, net of tax	Total Accumulated Other Comprehensive Items
Balance at December 31, 2020	$ —	$ (40)	$ (40)
Other comprehensive income before reclassifications	54	512	566
Amounts reclassified from other comprehensive items	—	—	—
Other comprehensive income	54	512	566
Balance at December 31, 2021	$ 54	$ 472	$ 526
Other comprehensive loss before reclassifications	(894)	(1,712)	(2,606)
Amounts reclassified from other comprehensive items	—	—	—
Other comprehensive loss	(894)	(1,712)	(2,606)
Balance at December 31, 2022	$ (840)	$ (1,240)	$ (2,080)

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Management's Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers, or persons performing similar functions, and effected by our board of directors, management and other personnel, 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 and includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. We continue to review our internal control over financial reporting and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, our senior management has concluded that the internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for "emerging growth companies".

Changes in Internal Control over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout our company. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission (the "SEC") not later than 120 days after the close of our fiscal year ended December 31, 2022.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022.

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements (included in Part II of this Annual Report on Form 10-K):

- *Report of Independent Registered Public Accounting Firm*
- *Consolidated Balance Sheets*
- *Consolidated Statement of Operations and Comprehensive Loss*
- *Consolidated Statement of Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)*
- *Consolidated Statement of Cash Flows*
- *Consolidated Notes to Financial Statements*

(2) Financial Statement Schedules:

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements

(b) The following exhibits are included herein or incorporated herein by reference:

Exhibit No.	Description
3.1	Fifth Amended and Restated Memorandum and Articles of Association of LianBio (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40947), filed with the Securities and Exchange Commission on November 3, 2021)
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
4.2	Form of American Depositary Receipt (included in Exhibit 4.1).
4.3	Second Amended and Restated Shareholders Agreement dated October 28, 2020, by and among LianBio and the investors party thereto (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
4.4	Joinder Agreements to Second Amended and Restated Shareholders Agreement (incorporated by reference to Exhibit 4.13 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.5	Specimen Certificate evidencing the Ordinary Shares (incorporated by reference to Exhibit 4.4 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.6	Information Rights Letter of BridgeBio Pharma LLC, dated October 16, 2019, by and between the Company and BridgeBio Pharma LLC (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.7	Amended and Restated Option Agreement, dated as of August 10, 2020, by and among LianBio and MyoKardia, Inc. and QED Therapeutics, Inc. (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.8	Equity Holders Agreement, dated August 10, 2020, by and among LianBio, Lian Cardiovascular and MyoKardia, Inc. (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.9	Form of Warrant to Purchase Ordinary Shares, dated October 16, 2019, issued by Lian Oncology (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)
4.10	Lian Cardiovascular Warrant to Purchase Ordinary Shares, dated August 10, 2020, issued by Lian Cardiovascular (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 1, 2021)

Exhibit No.	Description
4.11	Director Nomination Agreement, dated October 8, 2021, by and among LianBio and Perceptive Life Sciences Master Fund, Ltd., LEV LB Holdings, LP, Perceptive Xontogeny Venture Fund, LP and C2 Life Sciences LLC (incorporated by reference to Exhibit 4.10 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
4.12	Form of Warrant to Purchase Ordinary Shares, dated October 18, 2021, issued by LianBio to Tarsus (incorporated by reference to Exhibit 4.11 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.13	Option Agreement, dated October 18, 2021, by and among LianBio, LianBio Ophthalmology and Tarsus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.12 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.14	Warrant to Purchase Ordinary Shares, dated October 18, 2021 issued by LianBio to QED (incorporated by reference to Exhibit 4.14 to Amendment No. 2 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
4.15*	Description of Securities
10.1†	Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.2†	Amendment to the Exclusive License Agreement, dated October 8, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.3†	Second Amendment to the Exclusive License Agreement, dated January 4, 2021, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.4	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Cardiovascular, and LianBio relating to the Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc., as subsequently amended (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.5	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Cardiovascular, Lian Cardiovascular Limited and LianBio relating to the Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc., as subsequently amended (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.6†	Exclusivity Agreement, dated October 16, 2019, by and between LianBio and BridgeBio Pharma LLC (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.7†	Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.8†	Amendment to the Exclusive License Agreement, dated September 26, 2020, by and between LianBio and QED Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.9†	Novation Agreement, dated October 11, 2020, by and among LianBio, LianBio Licensing LLC and QED Therapeutics, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)

Exhibit No.	Description
10.10	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Oncology and LianBio relating to the Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc., as subsequently amended (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.11	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Oncology, Lian Oncology Limited and LianBio relating to the Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc., as subsequently amended (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.12†	Second Amendment to the Exclusive License Agreement, dated December 14, 2021, by and between Lian Oncology Limited, LianBio Licensing, LLC, Lian Oncology and QED Therapeutics, Inc. (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.13†	Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc. (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.14†	First Amendment to the Exclusive License Agreement, dated September 23, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc. (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.15†	Second Amendment to the Exclusive License Agreement, dated September 28, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc. (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.16†	Third Amendment to the Exclusive License Agreement, dated December 17, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.17	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among LianBio Licensing, LLC, Lian Oncology and LianBio relating to the Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc., as subsequently amended (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.18	Contribution, Assignment and Assumption Agreement, dated as of September 28, 2021, by and among Lian Oncology, Lian Oncology Limited and LianBio relating to the Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc., as subsequently amended (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.19†	Strategic Collaboration Agreement, dated November 17, 2020, by and between LianBio and Pfizer Inc. (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.20	Assignment and Assumption Agreement related to Pfizer Agreement, dated December 15, 2021, by and among LianBio and LianBio Development (HK) Limited (incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.21†	Development and License Agreement, dated March 26, 2021, by and between LianBio Ophthalmology Limited and Tarsus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.22†	License, Development and Commercialization Agreement, dated May 11, 2021, by and between Nanobiotix S.A. and LianBio Oncology Limited (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)

Exhibit No.	Description
10.23†	License and Collaboration Agreement, dated May 14, 2021, by and between LianBio Respiratory Limited and Landos BioPharma, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.24†	License and Collaboration Agreement, dated May 31, 2021, by and among LianBio Inflammatory Limited, LianBio and Lyra Therapeutics, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.25†	Co-Development and License Agreement, dated March 1, 2021, by and between LianBio Respiratory Limited and ReViral Ltd. (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.26	Lease and Lease Agreement, dated June 18, 2020, by and between LianBio dba Lian Pharma and Carnegie 103 Associates, LLC (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.27	Amendment No. 1 to Lease and Lease Agreement, dated as of July 1, 2021, between Carnegie 103 Associates, LLC and LianBio, LLC (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.28	Shanghai Municipality Lease Contract for Premises, dated December 23, 2019, by and between Shanghai LianBio Development Co. Ltd. and Shanghai Pudong Kerry Parkside Real Estate Co., Ltd. (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.29	Supplemental Agreement II to Lease Contract of Kerry Parkside Office Building, dated as of August 31, 2020, by and between Shanghai LianBio Development Co. Ltd. and Shanghai Pudong Kerry Parkside Real Estate Co. Ltd. (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.30	Lease Contract for Office Building of Corporate Avenue dated November 4, 2021, by and between Shanghai Xingqiao Real Estate Co., Ltd. and Shanghai LianBio Development Co., Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40947), filed with the Securities and Exchange Commission on November 10, 2021)
10.31	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.32	Indemnification Agreement, dated October 28, 2020 by and among LianBio, Konstantin Poukalov and Perceptive Life Sciences Master Fund, Ltd., Perceptive Xontogeny Venture Fund, LP, and LEV LB Holdings, LP. (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.33#	Executive Employment Agreement, dated as of September 26, 2019, by and between LianBio and Bing Li (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.34#	Separation Agreement, dated as of February 24, 2021, by and between LianBio and Bing Li (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.35#	Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Debra Yu, M.D. (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.36#	Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Brianne Jahn (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.37#	Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LLC and Yizhe Wang (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)

Exhibit No.	Description
10.38#	LianBio 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-259978), filed with the Securities and Exchange Commission on October 1, 2021)
10.39#	LianBio 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.40#	Form of Non-Statutory Share Option Agreement (Non-Employee Directors) (incorporated by reference to Exhibit 10.36 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.41#	Form of Non-Performance Based Restricted Share Unit Agreement (incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.42#	Form of Performance Based Restricted Share Unit Agreement (incorporated by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.43#	Form of Non-Performance Based Share Option Agreement (Employees) (incorporated by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.44#	Form of Performance Based Share Option Agreement (incorporated by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K (File No. 011-40947), filed with the Securities and Exchange Commission on March 31, 2022)
10.45#	LianBio 2021 Cash Incentive Plan (incorporated by reference to Exhibit 10.39 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 8, 2021)
10.46#	LianBio Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.40 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-259978) filed with the Securities and Exchange Commission on October 20, 2021)
10.47*#	Employment Contract and Addendum to Employment Contract, dated as of March 14, 2023, by and between Shanghai LianBio Development Co., Ltd., and Yi Larson
10.48†	Amendment No. 1 to License and Collaboration Agreement, dated as of September 26, 2022, by and among LianBio Inflammatory Limited and Lyra Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40947) filed with the Securities and Exchange Commission on November 10, 2022)
10.49*†	Commercialization Agreement, dated as of December 16, 2022, by and among LianBio Development (HK) Limited, LianBio Respiratory Limited, ReViral Ltd. and Pfizer Inc.
10.50*#	Separation Agreement, dated as of December 13, 2022, by and between LianBio and Debra Yu
10.51*#	Consulting Agreement, dated as of December 13, 2022, by and between LianBio and Debra Yu
10.52*†	First Amendment to License and Collaboration Agreement, dated as of February 28, 2023 by and between LianBio Respiratory Limited and Landos BioPharma, Inc.
10.53*†	License and Collaboration Agreement, dated as of February 28, 2023, by and between LianBio Development (HK) Limited and NImmune Biopharma, Inc.
10.54*	Amendment No. 1 to the License, Development and Commercialization Agreement, dated as of March 16, 2023, by and between Nanobiotix S.A. and Lian Oncology Limited
21.1*	Subsidiaries of the Registrant
23.1*	Consent of KPMG LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit No.	Description
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Database*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

^ These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Certain portions of this exhibit have been omitted because they are not material and are the type of information that the Registrant treats as private or confidential

# Indicates a management contract or any compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

LianBio

Date: March 28, 2023

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Yizhe Wang and Yi Larson, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Yizhe Wang **Yizhe Wang**	Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2023
/s/ Yi Larson **Yi Larson**	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2023
/s/ Konstantin Poukalov **Konstantin Poukalov**	Chairman of the Board	March 28, 2023
/s/ Adam Stone **Adam Stone**	Director	March 28, 2023
/s/ Neil Kumar **Neil Kumar**	Director	March 28, 2023
/s/ Tassos Gianakakos **Tassos Gianakakos**	Director	March 28, 2023
/s/ Susan Silbermann **Susan Silbermann**	Director	March 28, 2023
/s/ Wei Wei Chen **Wei Wei Chen**	Director	March 28, 2023

Exhibit 4.15

DESCRIPTION OF SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our share capital is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our fifth amended and restated memorandum and articles of association ("our articles"), which is incorporated by reference as an exhibit to our Annual Report on Form 10-K ("Annual Report"), of which this Exhibit 4.15 is a part. The terms "we," "our," and "us" refer solely to LianBio.

We are an exempted company incorporated in the Cayman Islands with limited liability and our affairs are governed by our articles, the Companies Law (as amended) of the Cayman Islands and the common law of the Cayman Islands.

As of December 31, 2021, the registrant had the following series of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended:

Title of each class:		Name of each exchange on which registered:
American Depositary Shares, each representing 1 Ordinary Share, par value $0.000017100448 per share	**LIAN**	**The Nasdaq Global Market**

Citibank, N.A. acts as the depositary bank for the American Depositary Shares pursuant to the Deposit Agreement, dated as of November 3, 2021. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank has appointed a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A.—Hong Kong Branch, located at 9/F., Citi Tower, One Bay East, 83 Hoi Bun Road, Kwun Tong, Kowloon, Hong Kong.

As of March 15, 2022, our authorized share capital consists of $50,000 divided into 2,923,900,005 ordinary shares, par value $0.000017100448 per share.

We are providing a summary description of the material terms of the ADSs and of the material rights of ADS owners. This summary does not contain all the details that are in the information being summarized and the rights and obligations of ADS owners will be determined by reference to the terms of the Deposit Agreement and not by this summary. ADS holders should review the Deposit Agreement in its entirety.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, one ordinary share that is on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADS-to-ordinary share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

An ADS holder will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents such ADSs. The deposit agreement and the ADR specify our rights and

obligations as well as ADS holders' rights and obligations as owner of ADSs and those of the depositary bank. ADS holders appoint the depositary bank to act on their behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require ADS holders to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. ADS holders are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on ADS holders' behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

We will not treat ADS holders as our shareholders and ADS holders will not have direct shareholder rights. The depositary bank will hold on ADS holders' behalf the shareholder rights attached to the ordinary shares underlying the ADSs. ADS holders will be able to exercise the shareholders rights for the ordinary shares represented by the ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement, an ADS holder will, as an ADS owner, need to arrange for the cancellation of such ADSs and become a direct shareholder.

The manner in which ADS holders own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect the holders' rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to the holders. An ADS holder may hold the ADSs either by means of an ADR registered in such holder's name, through a brokerage or safekeeping account, or through an account established by the depositary bank in such holder's name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If an ADS holder decides to hold the ADSs through such holder's brokerage or safekeeping account, the holder must rely on the procedures of his/her broker or bank to assert his/her rights as an ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit an ADS holder's ability to exercise such holder's rights as an owner of ADSs. ADS holders should consult with their broker or bank if they have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes ADS holders have opted to own the ADSs directly by means of ADSs registered in such holders' name and, as such, we will refer to ADS holders as the "holders."

The registration of the ordinary shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and distributions

Holders of ADSs generally have the right to receive the distributions we make on the securities deposited with the custodian. ADS holders' receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will

arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to Cayman Islands laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary share ratio, in which case each ADS holders hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary share ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). Holders may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of such rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary bank will not distribute the rights to holders if:

- We do not timely request that the rights be distributed to holders or we request that the rights not be distributed to holders; or
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

Elective distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to holders. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to holders only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable holders to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to holders, holders will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

Other distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to holders. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to holders and if we provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will not distribute the property to holders and will sell the property if:

- We do not request that the property be distributed to holders or if we request that the property not be distributed to holders; or
- We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to holders is not reasonably practicable; or
- The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. Holders may have to pay fees, expenses, taxes and other governmental charges upon the redemption of the ADSs. If less than all ADSs are being redeemed, the ADSs to be redeemed will be selected by lot or on a pro rata basis, as the depositary bank may determine.

Changes affecting ordinary shares

The ordinary shares held on deposit for the ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, the ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to holders, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of holders' existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary bank may not lawfully distribute such property to holders, the depositary bank may sell such property and distribute the net proceeds to holders as in the case of a cash distribution.

Issuance of ADSs upon deposit of ordinary shares

Our ordinary shares have been and will be deposited with the custodian. The depositary bank may create ADSs on a holder's behalf if such holder or such holder's broker deposits ordinary shares with the custodian. The depositary bank will deliver these ADSs to the person such holder indicates only after such holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Holders' ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When a holder makes a deposit of ordinary shares, such holder will be responsible for transferring good and valid title to the depositary bank. As such, the holder will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- The holder is duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at the holder's cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, combination and split up of ADRs

Holders will be entitled to transfer, combine or split up their ADRs and the ADSs evidenced thereby. For transfers of ADRs, a holder will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have the ADRs either combined or split up, a holder must surrender his/her ADRs in question to the depositary bank with such holder's request to have them combined or split up, and such holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of ordinary shares upon cancellation of ADSs

Holders will be entitled to present their ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Holders' ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by the ADSs, holders will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. Holders assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If a holder holds ADSs registered in his/her name, the depositary bank may ask such holder to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel the ADSs. The withdrawal of the ordinary shares represented by the ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

Holders will have the right to withdraw the securities represented by the ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.

- Obligations to pay fees, taxes and similar charges.

- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

- The deposit agreement may not be modified to impair holders' right to withdraw the securities represented by the ADSs except to comply with mandatory provisions of law.

Voting rights

Holders generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by ADSs.

At our request, the depositary bank will distribute to holders any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs.

If the depositary bank timely receives voting instructions from a holder, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions as follows:

- *In the event of voting by show of hands*, the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders who provide timely voting instructions.

- *In the event of voting by poll, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders.*

In the event of voting by poll, holders in respect of which no timely voting instructions have been received shall be deemed to have instructed the depositary bank to give a discretionary proxy to a person designated by us to vote the

ordinary shares represented by such holders' ADSs; provided, that no such instructions shall be deemed given and no such discretionary proxy shall be given with respect to any matter as to which we inform the depositary bank that we do not wish such proxy to be given; provided, further, that no such discretionary proxy shall be given (x) with respect to any matter as to which we inform the depositary that (i) there exists substantial opposition, or (ii) the rights of holders or the shareholders of our company will be materially adversely affected, and (y) in the event that the vote is on a show of hands.

Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure holders that they will receive voting materials in time to enable them to return voting instructions to the depositary bank in a timely manner.

Fees and charges

Holders will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. $0.05 per ADS issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to-share ratio, or for any other reason)	Up to U.S. $0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. $0.05 per ADS held
Distribution of ADSs pursuant to (i) dividends or other distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. $0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. $0.05 per ADS held
Depositary services fees	Up to U.S. $0.05 per ADS held on the applicable record date(s) established by the depositary bank
Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason)	Up to U.S. $0.05 per ADS transferred
Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of partial entitlement ADSs for full entitlement ADSs, or upon conversion of restricted ADSs into freely transferable ADS, and vice versa)	Up to U.S. $0.05 per ADS transferred

Holders will also be responsible to pay certain charges such as:

- Taxes (including applicable interest and penalties) and other governmental charges;
- The registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- Certain cable, telex and facsimile transmission and delivery expenses;
- The fees, expenses, spreads, taxes and other charges incurred by the depositary bank and/or service providers (which may be a division, branch or affiliate of the depositary bank) in connection with the conversion of foreign currency;
- The reasonable and customary out-of-pocket expenses incurred by the depositary bank in such conversion and/or on behalf of the holders and beneficial owners in connection with compliance with currency exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs;

- The fees, charges, costs and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the ADR program; and
- The amounts payable to the depositary bank by any party to the deposit agreement pursuant to any ancillary agreement to the deposit agreement in respect of the ADR program, the ADSs and the ADRs.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to holders. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of an ADS offering. Note that the fees and charges holders may be required to pay may vary over time and may be changed by us and by the depositary bank. Holders will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Amendments and termination

We may agree with the depositary bank to modify the deposit agreement at any time without holders' consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to holders' substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act of 1933, as amended, or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges holders are required to pay. In addition, we may not be able to provide holders with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders will be bound by the modifications to the deposit agreement if they continue to hold their ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent holders from withdrawing the ordinary shares represented by the ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to holders at least 30 days before termination. Until termination, holders' rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until holders request the cancellation of their ADSs) and may sell the securities held on deposit.

After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary shares program established by the depositary. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Books of depositary

The depositary bank will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on obligations and liabilities

The deposit agreement limits our obligations and the depositary bank's obligations to holders. Please note the following:

- we and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- the depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- the depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to holders on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- we and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- we and the depositary bank disclaim any liability if we or the depositary bank, or our respective controlling persons or agents are prevented or forbidden from, or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our articles, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- we and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles or in any provisions of or governing the securities on deposit.

- we and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.

- we and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to holders.

- we and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.

- we and the depositary bank also disclaim liability for any consequential, indirect or punitive damages for any breach of the terms of the deposit agreement, or otherwise.

- no disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

- nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and holders.

- nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

Taxes

Holders will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. Holders will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on holders' behalf. However, holders may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. Holders are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes arising out of any refund of taxes, reduced rate of withholding or of the tax benefit obtained for or by the holders.

Foreign currency conversion

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practicable, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. Holders may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practicable or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practicable and lawful and distribute the U.S. dollars to holders for whom the conversion and distribution is lawful and practicable.

- Distribute the foreign currency to holders for whom the distribution is lawful and practicable.

- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing law/waiver of jury trial

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of the Cayman Islands.

By holding an ADS or an interest therein, ADS holders irrevocably agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement, ADSs or ADRs, may only be instituted in a state or federal court in New York, New York, and ADS holders irrevocably waive any objection to the laying of venue and irrevocably submit to the exclusive jurisdiction of such courts with respect to any such suit, action or proceeding.

AS A PARTY TO THE DEPOSIT AGREEMENT, ADS HOLDERS IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF, OR RELATED TO, THE DEPOSIT AGREEMENT, ANY ADR AND ANY TRANSACTIONS CONTEMPLATED THEREIN (WHETHER BASED ON CONTRACT, TORT, COMMON LAW OR OTHERWISE) AGAINST US AND/OR THE DEPOSITARY BANK.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

劳动合同

Employment Contract

签订日期：2023年3月14日

Execution Date: **March 14, 2023**

本合同由以下双方签订：

THIS CONTRACT is entered into by and between

上海联拓生物科技有限公司，注册地址为：中国（上海）自由贸易试验区芳春路400号1幢3层，法定代表人为：王轶喆（“**公司**”）；

Shanghai LianBio Development Co., Ltd., having its registered address at 3rd Floor, Building 1, No. 400 Fangchun Road, China (Shanghai) Pilot Free Trade Zone, and with Yizhe Wang as its legal representative (the “**Company**”); and

Yi Larson，在中国境内地址为上海市闵行区金辉路100弄丰尚国际公寓2号楼1201室，国籍为：美国，护照号码为：559066992（“**员工**”，与公司合称“**双方**”）。

Yi Larson, having her address in China at 100 Jinhui Road, Fengshang International Apartment, Building No.2, Apt. 1201, Minhang District, Shanghai, a citizen of the United States with the passport number of 559066992 (the “**Employee**”, together with the Company, collectively referred to as the “**Parties**”).

鉴于，员工与公司关联方LianBio, LLC（“**美国LianBio**”）于2021年9月30日签订了《经修订和重述的高管劳动合同》（“**原劳动合同**”），根据原劳动合同第3条的约定，员工同意与公司或美国LianBio的其他中国关联方采用公司提供的格式签订劳动合同，并完全取代原劳动合同；及

Whereas, the Employee and LianBio, LLC (“**LianBio US**”), an affiliate of the Company, entered into an Amended and Restated Executive Employment Agreement, dated as of September 30, 2021 (the “**Original Employment Agreement**”), pursuant to Section 3 of which the Employee agreed to enter into an employment agreement with the Company or other PRC affiliate of LianBio US in the form provided by the Company, which shall replace the Original Employment Agreement in its entirety; and

鉴于，本合同将完全取代原劳动合同，但员工与美国LianBio于2021年3月11日签订的、作为原劳动合同附件A的《员工保密、知识产权转让及竞业限制协议》（“**遵从协议**”）应继续完全有效。为免疑义，遵从协议应附加于而非替代员工与公司或其关联方签署的任何其他协议中员工对公司、美国LianBio或其任何关联方承担的任何其他义务，包括但不限于本合同第7条、第8条、第9条和第10条中载明的义务。

Whereas, this Contract will replace the Original Employment Agreement in its entirety, except that the Employee Confidentiality, IP Assignment and Non-Competition Agreement, which was entered into between the Employee and LianBio US as of March 11, 2021 and attached to the Original Employment Agreement as Exhibit A (the “**Compliance Agreement**”), shall remain in full force and effect. For the avoidance of doubt, the Compliance Agreement shall be in addition to, and not in lieu of any other obligations of Employee to the Company, LianBio US or any of their affiliates in any other agreement by and between the Employee and the Company or its affiliates, including but not limited to those set forth in Sections 7, 8, 9 and 10 of this Contract.

根据《中华人民共和国劳动法》、《中华人民共和国劳动合同法》及其他的相关法律、法规（合称“**中国法律法规**”），在自愿平等和一致的基础上，双方协议如下：

In accordance with the *Labor Law of the People's Republic of China*, the *Employment Contract Law of the People's Republic of China* and other laws and regulations in respect thereof (“**PRC Law**”), on a willing, equal and unanimous basis, the Parties hereby agree as follows:

1. 劳动合同期限

TERM OF EMPLOYMENT

1.1. 本合同于2022年10月1日（“生效日”）生效。

This Contract shall take effect from **October 1, 2022** (“**Effective Date**”).

1.2. 除非公司或员工根据本合同条款或适用法律、法规的规定提前解除本合同，本合同有效期为3年，自2022年10月1日起至2025年9月30日止（“**初始期限**”）。除非公司或员工根据本协议条款或适用法律法规的规定提前解除，公司在本协议项下与员工的劳动关系应在初始期限后自动续约一（1）年（每一次续约，“**续约期限**”），除非任何一方在不迟于该初始期限或续约期限到期前九十（90）天向另一方发出不续约通知（如适用）（此类通知，“**不续约通知**”）。尽管有前述约定，如果在劳动关系期间内（定义见下文）发生控制权变更（定义见下文），当时的初始期限或续约期限（如适用）将转换为无固定限期，这意味着 (a) 员工或公司可根据本协议第12.2、12.3、12.4或12.5条随时解除员工的劳动关系，以及（b）本协议关于续约和/或不续约员工劳动合同的条款将停止适用。“劳动关系期间”是指初始期限以及续约期限（如适用）或根据本协议第12.2、12.3、12.4和12.5条劳动关系解除所导致的任何更短期限。

Unless earlier terminated by the Company or the Employee in accordance with the terms hereunder or provisions of applicable laws and regulations, this Contract shall have a term of 3 years, commencing on October 1, 2022 and concluding on September 30, 2025 (the “**Initial Term**”). Unless earlier terminated by the Company or the Employee in accordance with the terms hereunder or provisions of applicable laws and regulations, the Employee’s employment by the Company hereunder shall automatically be renewed following the Initial Term for subsequent one (1) year periods (each, a “**Renewal Term**”) unless either party gives a notice of non-renewal to the other party not later than ninety (90) days prior to the expiration of such Initial Term or Renewal Term, as applicable (such notice, “**Non-Renewal Notice**”). Notwithstanding the foregoing, in the event of a Change in Control (as defined below) occurring during the Employment Period (as defined below), the then current Initial Term or Renewal Term, as applicable, will be converted to an indefinite term, meaning that (a) the Employee or the Company may terminate the Employee’s employment at any time pursuant to Sections 12.2, 12.3, 12.4 or 12.5 hereof, and (b) the terms hereof with respect to the renewal and/or non-renewal of the term of the Employee’s employment shall cease to apply. The term “**Employment Period**” shall mean the Initial Term and, if applicable, the Renewal Term or any shorter period resulting from any termination of employment under Sections 12.2, 12.3, 12.4 and 12.5 hereof.

2. 工作职务、职责和地点

POSITION, DUTIES AND PLACE OF WORK

1.1. 公司聘用员工担任首席财务官（“**首席财务官**”）一职。

The Employee will serve as the Chief Financial Officer (“**CFO**”) of the Company.

1.2. 员工应按照附件一中的岗位描述的约定履行和上述职务相对应的职责，并完成相应的工作任务。

The Employee shall perform the specific duties set out in the job description in Schedule 1 of this Contract and other duties customarily performed by the above-mentioned position, and complete corresponding work tasks.

1.3. 公司可根据经营需要或员工的身体健康状况、工作表现等情况合法合理地调配员工的工作岗位和工作内容，员工应服从公司的安排。

The Company is entitled to legally and reasonably adjust the Employee’s position and work tasks according to the operational needs, health status and work performance of the Employee, and the Employee shall follow the Company’s instructions.

1.4. 在劳动关系期间，公司经与员工协商，为实现公司的目标，可以调配员工的工作岗位和/或要求员工承担更多的职责。

During the Employment Period, the Company, after due consultation with the Employee, may transfer the Employee to a new position and/or require the Employee to perform additional duties to fulfill the Company's objectives.

1.5. 员工应根据本合同的条款全职并专注履行其职责。

The Employee shall devote her full time and attention to the performance of her duties pursuant to the provisions of this Contract.

1.6. 员工应主要在**上海**工作，但也可能应公司的业务需求而不时出差。公司有权根据业务的需要，在与员工协商一致后将员工调派到中国境内或境外的其它地点任职。

The Employee shall work principally in **Shanghai** but may be required to travel from time to time to meet the operational needs of the Company. Subject to the consent of the Employee, the Company may, based on the business needs of the Company, re-deploy the Employee to work in another location within or outside the People's Republic of China.

3. 工作时间和法定假期

WORKING HOURS AND STATUTORY HOLIDAYS

1.1. 根据工作岗位的性质，员工将按以下方法确定工作时间：

Based on the nature of the Employee's position, the Company will arrange for the Employee to work under the following Working Hours System:

员工每周的工作小时应不超过四十（40）小时，并且每个工作日不超过八（8）小时，除非员工获准适用不定时工作制（按中国法律法规的定义），在此情况下，不适用上述限制。员工的具体工作时间为：星期一至星期五的上午9:00到下午6:00（其中包括一（1）个小时的午餐时间）。公司可根据员工工作地点和工作性质来合理地调整具体工作的起止时间。

The Employee's hours of work shall not exceed forty (40) hours per week or eight (8) hours per day, unless the Employee is approved to work under the Flexible Working Hours System (as defined under PRC Law) in which the above limitation shall not apply. The Employee's office hours are from 9:00 a.m. to 6:00 p.m. (including one (1) hour for lunch), from Monday to Friday. The Company can reasonably adjust the actual working time in line with the location of the work and the nature of the work performed by the Employee.

1.2. 员工的任何加班，必须事先向上级提出申请并得到批准，否则不视为加班，员工无权获得加班费。

An application for overtime work shall be made prior to the commencement of such work by the Employee and must be approved in advance by the Employee's supervisors, otherwise it shall not be deemed as overtime work and the Employee will not be entitled to overtime compensation.

1.3. 员工可以享受中国法律法规规定的公共假日。

The Employee is entitled to rest on public holidays as stipulated by PRC Law.

1.4. 除公共假日以外，根据法律规定，员工连续工作满一（1）年的，可以享受带薪年休假（简称"**法定年假**"），法定年假的天数将根据中国法律法规规定确定。

In addition to public holidays and under applicable laws and regulations, after one (1) full year of continuous employment, the Employee is entitled to paid annual leave ("**Statutory Annual Leave**"). The total length of the Statutory Annual Leave is subject to PRC Law.

4. 工资和福利待遇

COMPENSATION AND BENEFITS

1.1. 员工的工资为：（税前）510,000美元/年，每年分十二（12）个月支付，即月工资为税前42,500美元/月（"**基本工资**"）。公司应于每月最后一天（或之前）向员工支付该月基本工资。员工在公司的第一个月和最后一个月工资应按照该月实际受雇时间所占该月工作日总数的比例按比例计算当月月薪。

The Employee's salary (before tax) is USD$510,000 per year, to be paid by twelve (12) monthly instalments of USD$42,500 (before tax) per instalment ("**Base Salary**"). The monthly instalment of Base Salary shall be paid on, or before, the last day of each calendar month. The Employee's first month's and last month's entitlement shall be proportionate to the period of actual employment in such month.

1.2. 公司将根据经营情况、员工的晋升情况（如有）及员工的工作表现，对员工工资每年评审一次。但是，公司并不因该评审结果或在其他任何时候有加薪义务。并且，员工不应将员工工资评审视为是一项权利。

The Company will review the Employee's salary annually based on the business performance of the Company, promotions of the Employee's position (if any), and the Employee's performance, provided that, the Company is under no obligation to increase the Employee's salary as a result of any such review or at any other time, and the Employee is not entitled to a right to such review of her salary.

1.3. 在劳动关系期间内的每一日历年度结束时，员工有机会可以获得（税前）255,000美元（相当于其基本工资50%）的酌情年终奖（"**年终奖**"）。年终奖的实际金额（如有）由公司根据员工的职位、表现和公司的业绩全权自主决定、员工如要有资格获得酌情年终奖（如有），员工在年终奖支付时应处于"**在职工作状态**"。就本合同而言，"**在职工作状态**"是指，员工未辞职（或未提交辞职通知）或未被解除或终止劳动关系（或未被告知解除或终止劳动关系）。

At the conclusion of each calendar year during the Employment Period, the Employee may be entitled to receive a discretionary annual bonus ("**Annual Bonus**") with a target of (before tax) USD$255,000 (50% of the Employee's base salary). The actual amount of the Annual Bonus, if any, shall be determined by the Company in its sole and exclusive discretion based on an evaluation of the Employee's position, performance, and the performance of the Company. In order to be eligible for a discretionary Annual Bonus, if any, the Employee must be in "**active working status**" at the time of the bonus payment. For purposes of this Contract, "**active working status**" means that the Employee has not resigned (or given notice of resignation) or been terminated (or been given notice of termination).

1.4. 公司将根据中国有关法律和法规的要求支付一切适用的社会保险。

The Company will make all applicable social insurance in accordance with PRC Law.

1.5. 公司将为员工办理有关社会保险，但员工应向公司提交办理保险所必需的资料以保证公司可以办理相关手续。公司不承担因员工拒绝、延迟提交相关资料或提交的资料不真实或不准确导致的任何责任。

The Company will be responsible for the application and administration of social insurance for the Employee, provided that the Employee shall provide the Company with all the required information to enable the Company to apply for and administer such social insurance. The Company shall not be liable for any responsibility arising from the Employee's refusal or delay in providing any such information or the Employee's provision of false or inaccurate information.

1.6. 员工病假期间工资标准应按中国法律法规和员工工作地的地方政府规定执行。

The Employee's sick leave salary shall be paid in accordance with PRC Law and local government regulations where the employee is located.

5. 劳动保护、劳动条件和职业危害防护

LABOR PROTECTIONS, WORKING CONDITIONS AND PROTECTION AGAINST OCCUPATIONAL HAZARDS

1.1. 公司将为员工提供其岗位所必要的劳动条件和职业危害防护。

The Company will provide the Employee with the necessary working conditions and protections against occupational hazards required for the position.

1.2. 公司将为员工提供与职业道德、劳动安全、劳动纪律和公司有关规章制度相关的资料。

The Company will provide the Employee with information relating to professional ethics, labor security, labor discipline and the policies and regulations of the Company.

1.3. 员工患职业病或因工负伤的工资或医疗保险待遇按中国法律法规有关规定。

Any compensation or medical insurance entitlement for an occupational disease or work-related injury shall be determined in accordance with the PRC Law.

6. 劳动纪律和职业操守

DISCIPLINARY PROCEDURES AND PROFESSIONAL MORALS

1.1. 员工应遵守《员工手册》中的所有规定或公司颁布的其他规章制度，包括其他规章制度中有关劳动纪律、工作规章和程序的所有规定。

The Employee shall comply with all aspects of the Company's rules and policies contained in the Employee Handbook or otherwise issued by the Company, including all rules and policies relating to labor disciplinary procedures and other work-related rules and procedures of the Company.

1.2. 诚信是公司的重要原则，员工保证不会做出不诚信的行为。不诚信的行为将构成对公司规章制度以及劳动纪律的严重违反，公司有权立即解除本合同，并不支付任何经济补偿。

Honesty is an important principle of the Company and the Employee shall not engage in any dishonest behavior. A dishonest behavior constitutes material violation of the Company's rules and disciplines and the Company is entitled to immediately terminate this Contract without any compensation.

1.3. 在劳动关系期间内，未经公司事先书面同意，员工不得同时受雇于或为其他公司、组织或个人提供服务，不论是否就此获取经济利益。

During the Employment Period, the Employee shall not, without the prior written consent of the Company, be employed by or provide service to any other company, organization or individual (whether or not compensated).

1.4. 员工特此同意参加任何公司要求的合规培训并在涉及任何代表公司或任何直接或间接控制或受控于公司或与公司一同直接或间接地受控的实体（“**关联公司**”）或与公司或其关联公司业务相关的所有活动中遵守与反贿赂、反腐败、反洗钱、记录保存和内部控制法律有关的所有适用法律，包括但不限于中华人民共和国刑法、中华人民共和国反不正当竞争法、美国反海外腐败法和英国反贿赂法（统称“**ABAC政策**”）。员工进一步同意，员工不得直接或间接提供、授权、承诺、纵容或参与以下活动：(a) 任何人或实体向任何公职人员提供礼物或支付任何有价物品以获取任何不当利益，促使或影响任何上述公职人员的作为或决定，或协助公司或其关联公司为任何人或实体获取或保留业务，与任何人或实体进行业务交易或将业务引导给任何人或实体；(b) 任何人或实体采取的任何行动 (i) 违反ABAC政策（如果受ABAC政策约束的实体采取的行动），或 (ii) 可以合理地预期构成违反任何适用法律的行为；(c) 任何人或实体在公司或其关联公司的账簿或记录中做出任何虚假或虚构的条目；或 (d) 使用公司或其关联公司的任何资产来建立任何非法或非法款项或其他资产的原始资金，或进行任何非法或未公开的付款。

The Employee hereby agrees to attend any and all compliance trainings required by the Company and to comply with all applicable laws relating to anti-bribery, anti-corruption, anti-money laundering, record keeping and internal control laws, including but not limited to the People's Republic of China Criminal Law, the People's Republic of China Anti-Unfair Competition Law, the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act (together, "**ABAC Policies**"), with respect to all activities undertaken on behalf or in connection with the business of the Company or any other entity directly or indirectly controlling or controlled by or under direct or indirect common control with the Company ("**Affiliates**"). The Employee further agrees that the Employee will not, directly or indirectly, offer, authorize, promise, condone or participate in: (a) the making of any gift or payment of anything of value to any public official by any person or entity to obtain any improper advantage, affect or influence any act or decision of any such public official, or assist the Company or its Affiliates in obtaining or retaining business for, or with, or directing business to, any person or entity; (b) the taking of any action by any person or entity which (i) would violate ABAC Policies, if taken by an entity subject to ABAC Policies, or (ii) could reasonably be expected to constitute a violation of any applicable law; (c) the making of any false or fictitious entries in the books or records of the Company or its Affiliates by any person or entity; or (d) the using of any assets of the Company or its Affiliates for the establishment of any unlawful or unrecorded fund of monies or other assets, or the making of any unlawful or undisclosed payment.

7. 利益冲突义务

CONFLICT OF INTEREST

1.1. 员工向公司承诺，在劳动关系期间内，员工及其配偶和直系亲属将不会直接或间接地从事任何被合理认为与公司构成竞争关系、与公司存在利益冲突或与其在本合同项下的各项义务有冲突的活动、商业安排，或在任何有此类情况的商号、公司或组织中担任雇员。鉴于员工所提供的服务的敏感性，在不限制公司根据本合同所享有的其他权利的情况下，作为一项额外权利，如公司自主认定员工或其配偶的任何活动或商业安排与公司的利益相冲突，公司有权随时立即解除本合同。为此，员工同意事先向公司披露参与该等利益冲突活动的任何计划。

The Employee covenants with the Company that she, or her spouse and immediate family, shall not during the Employment Period directly or indirectly be engaged in any activity or business or act as an employee of any firm, company or organization, that can reasonably be considered to be in competition or have conflict of interest with the Company or the Employee's obligations under this Contract. In view of the sensitive nature of the services provided by the Employee, and in addition to and not in limitation of any other rights of the Company pursuant to this Contract, the Company shall have the option of terminating this Contract immediately at any time if, in its sole discretion it determines that any activity or business arrangement of the Employee or her spouse would conflict with the interests of the Company. For this purpose, the Employee agrees to disclose to the Company any plans to engage in such conflicting activity prior to the implementation of such plans by the Employee.

1.2. 如果违反第7.1条的约定，员工应当承担所有相应的法律责任，包括但不限于：劳动合同解除（无任何经济补偿金）、赔偿公司损失、停止侵害行为、返还所获收益和可能存在的刑事责任。

In the event of any violation of Section 7.1, the Employee shall bear all relevant legal liabilities including but not limited to termination of this Contract without any compensation, indemnification for all losses suffered by the Company, cessation of all violations, return of any and all benefits earned in connection with the violation and/or any criminal liabilities, if applicable.

8. 保密

CONFIDENTIALITY

1.1. 保密信息以下材料和信息，不论是否在员工在职期间曾经存在、目前存在、或者正在开发或创建，不论是口头、书面、电子或可机读的形式（合称"**保密信息**"），都适用本合同的规定：

Confidential Information. The following materials and information, whether having existed, now existing, or to be developed or created during the term of the Employee's employment with the Company, whether in oral, written, electronic or machine-readable form (herein referred to collectively as the "**Confidential Information**"), are covered by this Contract:

1.1.1. 所有与现存或拟议的基于公司或其关联公司专有技术的产品或服务相关的信息，不论是否由公司及/或其关联公司拥有或授权，以及不被公众普遍所知的处于研发不同阶段的专有技术（例如发明、商业秘密、技术诀窍、设计规格、方法、程序、技术、以及信息管理过程）；

All information relating to existing or proposed products or services based on proprietary technology of the Company or its Affiliates, whether owned or licensed by the Company and/or its Affiliates, and proprietary technology in various stages of research and development that are not generally known to the public (such as inventions, trade secrets, know-how, design specifications, methodologies, procedures, techniques, and information management processes);

1.1.2. 所有不被公众普遍知悉的，关于公司或其任何关联公司的产品或服务的信息，不论是否存在或在研发的不同阶段（例如技术诀窍、规格、技术或医疗数据、程序、技术、方法及策略）；

All information relating to the products or services of the Company or any of its Affiliates, whether existing or in various stages of research and development, which is not generally known to the public (such as know-how, specifications, technical or medical data, processes, techniques, methodologies, and strategies);

1.1.3. 所有不被公众普遍知悉的，与该公司或其任何关联公司开展其业务的方式有关的信息，包括但不限于商业手段、内部业务流程、控制、计划、授权技术、合同和实践、供应商、承包商和总承包人名字和合同以及其他供应商信息、电脑系统密码和其他电脑安全控制措施、财务信息、经销商信息、客户和公司及其关联公司顾客和客户提供的信息，以及员工数据（包括但不限于本合同的条款和条件以及员工技能和薪酬等信息）；

All information not generally known to the public concerning or relating to the way the Company or any of its Affiliates conducts its business, including but not limited to business methods, internal business procedures, controls, plans, licensing techniques, contracts and practices, names and contracts of supplier, subcontractor and prime contractor and other vendor information, computer system passwords and other computer security controls, financial information, distributor information, information supplied by clients and customers of the Company or any of its Affiliates, and employee data (including but not limited to the terms and conditions of this Contract and the information regarding the skills and compensation of the employees);

1.1.4. 所有不被公众普遍知悉的与公司或其关联公司相关的市场计划和策略；预测和推测；市场惯例、流程和政策；折扣；利润；成本；信用条件；定价策略、流程和政策；程序和政策；以及包括潜在、现有和过去的客户名单、信息、合同、代表、要求和需要、规格、偏好，由潜在、现有或过去的客户提供的或与他们相关的数据以及对这些客户适用的合同条款（例如客户名单、打印资料、数据库、市场计划、市场报告、策略性商业计划、市场分析和管理报告，以及潜在客户和潜在订单的列表）；

All information not generally known to the public that pertains to the Company's or any of its Affiliates' marketing plans and strategies; forecasts and projections; marketing practices, procedures and policies; discounts; margins; costs; credit terms; pricing practices, procedures and policies; procedures and policies; and customer data including lists of past, present and prospective customers, information, contracts, representatives, requirements and needs, specifications, preferences, data provided by or about prospective, existing or past customers and contract terms applicable to such customers (such as customer lists, printouts, databases, marketing plans, marketing reports, strategic business plans, marketing analyses and management reports, and listings of potential customers and leads);

1.1.5. 公司和/或公司的任何关联公司与任何第三方之间存在任何业务讨论、谈判或协议的信息；

The existence of any business discussions, negotiations or agreements between the Company and/or any of its Affiliates, on the one hand, and any third party, on the other hand;

1.1.6. 由员工制成的所有文件和其他工作成果，其中包含公司披露的任何信息、就公司披露的任何信息提出意见或者以任何方式与公司披露的任何信息相关；

All documents and other work product generated by the Employee which contain, comment upon, or relate in any way to any information disclosed by the Company;

1.1.7. 公司或其任何关联公司持有的、其负有保密义务的所有第三方信息；

All third-party information held in confidence by the Company or any of its Affiliates;

1.1.8. 除上述情况外，任何与公司或其任何关联公司相关的、不为公众所普遍所知悉的、或在公司或其关联公司的行业或业务领域内给公司或其关联公司以相较其竞争对手而言任何优势的信息；以及

Any information pertaining to Company or any of its Affiliates in addition to the foregoing that is not generally known to the public or within the industry or trade areas in which the Company or any of its Affiliates competes which gives the Company or any of its Affiliates any advantage over its competitors; and

1.1.9. 所有以上信息的任何有形的物理载体。

All physical embodiments of the foregoing information in any tangible form.

1.2. 普遍知识 在员工于公司在职期间可公开获得的普遍技巧、知识、经验或信息不被视为保密信息。同样的，员工与公司的劳动关系因任何原因结束时，受限于以下第10.1和10.2条的规定，在遵守本合同项下其持续性义务的前提下，员工不会被限制与独立开发了与保密信息类似信息或材料的人员或实体一同工作。

General Knowledge. The general skills, knowledge, and experience gained during the Employee's employment with the Company or information publicly available is not considered Confidential Information. Also, upon termination of the Employee's employment with the Company for any reason, the Employee shall not, subject to the provisions of Sections 10.1 and 10.2 below, be restricted from working with a person or entity which has independently developed information or materials similar to Confidential Information as long as the Employee complies with her continuing obligations under this Contract.

1.3. 员工义务 在员工于公司就职期间，员工认可并同意其将有机会接触保密信息，并且其职位涉及保守公司事务和业务秘密。员工进一步确认并同意，本合同规定的保密义务适用于在生效日之前、当日或之后向员工披露的、员工有权接触的或员工以其他方式知悉的任何及所有保密信息。员工同意将采取以下步骤来保护保密信息的秘密性和专有性。

Employee Obligations. During her employment with the Company, the Employee acknowledges and agrees that she will have access to Confidential Information and will occupy a position of trust and confidence with respect to the Company's affairs and business. The Employee further acknowledges and agrees that the confidentiality restrictions set forth herein shall apply to any and all Confidential Information disclosed to the Employee, to which the Employee have access or of which the Employee have otherwise become aware, whether before, on or after the Effective Date. The Employee agrees to take the following steps to preserve the confidential and proprietary nature of Confidential Information.

1.1.1. 不使用；不泄露 在其于公司在职期间和之后的任何时间，不论离职的原因为何，除经公司于员工职责范围内的书面授权，员工不得使用、泄露、允许泄露和使用或转移任何保密信息，并且除了在公司业务中，不得以任何方式使用任何保密信息，包括公司从其他人收到、公司打算由收件人保密的信息或材料。员工理解其不能出卖、授权或以其他方式利用包含或以其他方式全部或部分利用任何保密信息的任何产品或服务。

Non-Use; Non-Disclosure. During and at any time after her employment with the Company, regardless of the reason of the termination of her employment, the Employee shall not use, disclose, permit to be disclosed or used, or transfer any Confidential Information other than as authorized in writing by the Company within the scope of her duties with the Company, and will not use in any way other than in the Company's business any Confidential Information, including information or material received by the Company from others and intended by the Company to be kept in confidence by its recipients. The Employee understands that she is not allowed to sell, license, or otherwise exploit any products or services which embody or otherwise exploit in whole or in part any Confidential Information.

1.1.2. 防止泄露 员工应当采取一切合理的预防措施，防止保密信息的无意或意外泄露。

Disclosure Prevention. The Employee shall take all reasonable precautions to prevent the inadvertent or accidental disclosure of Confidential Information.

1.1.3. 保密信息的移除 员工不应从公司或其任何关联公司经营场所移除任何保密信息或含有保密信息的文件、材料、或者财产，除按照符合公司有关保密信息安全的政策的方式用于公司业务外，不应复制该等文件、材料或财产。

Removal of Confidential Information. The Employee shall not remove any Confidential Information or documents, materials, or property containing Confidential Information from the Company's or any of its Affiliates' premises or make copies of such documents, materials, or property except for use in the Company's business and in accordance with the Company's policies regarding security of confidential information.

1.1.4. 交还所有材料 在公司要求时和/或因任何原因在从公司离职时，员工应尽快交还所有保密信息和其他所有公司文件、材料和财产（包括上述文件的任何副本）。员工同意，在其离职后，不论原因为何，不保留包含任何保密信息或属于公司的其他信息的任何文件、材料或财产（包括副本）。员工同意，在员工未交还任何该等保密信息或其他公司文件、材料或财产（包括上述文件的任何副本）的情况下，公司有权留置应当支付给员工的未支付补偿。员工进一步同意，在公司要求和/或因任何原因从公司离职时，员工应：

Return All Materials. At any time upon the Company's request and/or upon the termination (for any reason) or expiration of her employment with the Company, the Employee shall return to the Company all Confidential Information and all other documents, materials, and property of the Company (including any copies of the foregoing) as soon as possible. The Employee agrees not to retain any documents, materials, or property (including copies) containing any Confidential Information or otherwise belonging to the Company after the termination (for any reason) or expiration of her employment with the Company. The Employee agrees that the Company may withhold the Employee's outstanding compensation against return of any of such Confidential Information or other documents, materials, and property of the Company (including any copies of the foregoing). The Employee further agrees that, at any time upon the Company's request and/or upon termination (for any reason) or expiration of her employment with the Company, the Employee shall:

(a) 向公司交付所有公司知识产权（如以下第9.3条定义）（无论完成与否），以及公司提供给员工使用的所有硬件、软件、工具、设备或其他材料；

Deliver to the Company all Company Intellectual Property (as defined in Section 9.3 below) (whether complete or incomplete) and all hardware, software, tools, equipment or other materials provided for the Employee's use by the Company;

(b) 向公司交付包含、反映、吸收或基于保密信息的所有有形文件和材料（及其副本）；

Deliver to the Company all tangible documents and materials (and any copies) containing, reflecting, incorporating or based on the Confidential Information;

(c) 在员工的电脑系统中永久地删除所有保密信息；并

Permanently erase all of the Confidential Information from the Employee's computer systems; and

(d) 交付并签署附件二中的《离职确认书》（如适用）。

Execute and deliver the Termination Certificate attached hereto as Schedule 2 (if applicable).

1.1.5. 电脑安全 在其任职期间，员工同意仅使用其被授予访问权限的公司的电脑资源，且只在授权范围内使用该等电脑资源（包括在办公场所内或办公场所外）。员工同意遵守关于电脑安全的公司政策和程序。

Computer Security. During her employment with the Company, the Employee agrees to use only those computer resources of the Company (both on and off the Company's premises) for which the Employee has been granted access to and then only to the extent authorized. The Employee agrees to comply with the Company's policies and procedures concerning computer security.

1.1.6. 通讯系统 员工理解公司有电子邮件系统、语音邮件系统、包括与英特网连接的电脑网络，以及其他为商业通讯之用途的相关设施。员工确认这些系统、网络和相关设施，以及所有电子或语音通讯和所有其间传输的数据或材料，属于公司财产，公司保留在通知或不通知的情况下，随时查看任何和一切电子邮件通讯、语音通讯、互联网浏览记录、以及保存或传输的信息和材料的权利。

Communications Systems. The Employee understands that the Company maintains an electronic mail system, a voice mail system, a computer network that includes access to the Internet, and related facilities for the purpose of business communications. The Employee acknowledges that these systems, network, and related facilities, as well as all electronic or voice communications and all data or materials transmitted thereon, are property of the Company, and the Company retains the right to review any and all electronic mail communications, voice communications, internet sites accessed, and data and materials stored or transmitted, with or without notice, at any time.

1.1.7. 第三方信息 员工认识到公司有可能已收到或者将会收到第三方的保密或专有信息，且公司将有责任对该等信息保密且仅为特定有限目的而使用该等信息。员工同意在受雇于公司期间和在此以后（无限期）对公司和该等第三方负有义务，对该等保密和专有信息严格保密，且不向任何个人或机构披露该等信息，且以公司与该第三方达成的协议所规定的方式和仅为经允许的有限目

的使用该等信息。上述第8.3.1条至第8.3.6条所载的义务同样适用于任何该等信息。

Third Party Information. The Employee recognizes that the Company may have received, and in the future may receive, from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. The Employee agrees that the Employee owes the Company and such third parties, during the Employee's employment by the Company and indefinitely thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person or firm and to use it in a manner consistent with, and for the limited purposes permitted by, the Company's agreement with such third party. The obligations set forth in Sections 8.3.1 through 8.3.6 above shall apply to any such information.

1.4. 合同基础 员工确认：(a) 使用、盗用或披露保密信息将违背信用且将会给公司造成不可弥补的损失，(b) 所有该等保密信息为公司的财产，且 (c) 保密信息的保密性是保护公司商誉以及保持公司竞争地位的关键，员工不得将保密信息向他人披露。员工进一步确认：员工对于本第8条约定的同意以及该等约定对员工的强制执行力是本合同的基础，如非该等约定及其强制执行力，公司不会 (i) 聘任员工，以及 (ii) 允许员工接触并使用保密信息。如果员工于在职期间违反第8.3条的，将构成对公司规章制度以及劳动纪律的严重违反，公司有权立即解除本合同，并不支付任何经济补偿。

Essence of Agreement. The Employee acknowledges (a) that the use, misappropriation or disclosure of Confidential Information would constitute a breach of trust and cause irreparable injury to the Company, (b) that all such Confidential Information is the property of the Company and (c) that it is essential to the protection of the Company's goodwill and to the maintenance of the Company's competitive position that the Confidential Information be kept secret and that the Confidential Information not be disclosed by the Employee to others or used by the Employee to the Employee's own advantage or the advantage of others. The Employee further acknowledges that the Employee's agreement to the provisions of this Section 8 and the enforceability of such provisions against the Employee are an essential element of this Contract and that, absent such provisions and the enforceability thereof, the Company would not (i) employ the Employee nor (ii) permit the Employee access and use of Confidential Information. The Employee's violation of any provisions of Section 8.3 constitutes material violation of the Company's rules and disciplines and the Company is entitled to immediately terminate this Contract without any compensation.

1.5. 先前的协议 本合同第8条项下的保密约定如和员工与公司在本合同签订前签署过的任何有关保密义务的协议（如有）有冲突的，应以保密要求更严格的约定为准。

Prior Agreement. In case there is conflict between the confidentiality agreement under Section 8 of this Contract and any agreements regarding confidentiality duty which the Employee signed with the Company prior to the execution of this Contract (if any), the agreement which sets out stricter standard shall prevail.

9. 知识产权

INTELLECTUAL PROPERTY RIGHTS

1.1. 在先信息员工特此陈述并保证：(a) 员工对本合同的履行以及作为公司员工所负有的职责不会违反与任何前雇主或其他第三方签订的任何保密、知识产权转让、竞业限制或其他协议，或与该等保密、知识产权转让、

竞业限制或其他协议相冲突；以及 (b) 员工目前不存在任何其他协议或职责将会与本合同的任何条款相冲突。员工将不会使用或向公司披露任何前雇主或员工对其负有保密义务的其他第三方的任何商业秘密或其他机密的技术或商业信息，除非员工获得该等前雇主或其他第三方的授权，或该信息非因员工的过错而可公开获得。此外，员工不会违反与前雇主或第三方的任何协议，将属于任何前雇主或其他第三方的任何未公开文件或任何财产携带至公司任何营业场地，或使用属于任何前雇主或其他第三方的任何未公开文件或任何财产。

Prior Information. The Employee hereby represents and warrants that (a) the Employee's performance under this Contract and her duties as an employee of the Company will not breach or be in conflict with any confidentiality, intellectual property assignment, non-competition or other agreement with any former employer or other third party and (b) there is no other agreement or duty on the Employee's part now in existence that would conflict with any provision contained herein. The Employee will not use or disclose to the Company any trade secret or other confidential technical or business information of any previous employer or other third party to whom the Employee has an obligation of secrecy unless the Employee is authorized to do so by such previous employer or other third party or the information has become publicly available through no fault of the Employee. In addition, the Employee will not bring onto any premises of the Company or use any unpublished documents or any property belonging to any former employer or other third party, in violation of any agreements with such former employer or third party.

1.2. 创意和发明 本合同的附件三描述了员工在与公司建立劳动关系前产生的，属于员工或者其前雇主所有的、与公司业务有关、但没有在本合同项下被转让给公司的所有发明、著作权、开发、改进和商业秘密（合称为"**在先发明**"）；或者，如果没有附上此等列表，员工则声明没有这样的在先发明。如果在公司任职期间，员工在公司任何产品、服务、流程、合成物、机器或其他财产中（包括保密信息）加入了属于员工所有或员工利益相关的任何发明、改进、开发、概念、发现、产品、版权材料、贸易或其他专有信息，公司特此被授予且应当拥有将所有该等项目作为与该等产品、服务、流程、合成物、或机器、或其他财产的一部分或相关联的内容，进行制作、修改、使用以及出卖非排他性的、免版税的、不可撤销的、永久的全球性授权。

Ideas and Inventions. Attached hereto as Schedule 3 is a list describing all inventions, original works of authorship, developments, improvements, and trade secrets which were made by the Employee prior to employment with the Company, which belong to the Employee or a former employer, which relate to the Company's business, and which are not assigned to the Company hereunder (collectively referred to as "**Prior Inventions**"); or, if no such list is attached, the Employee represents that there are no such Prior Inventions. If in the course of employment with the Company, the Employee incorporate any invention, improvement, development, concept, discovery, product, copyrightable material, trade or other proprietary information owned by the Employee or in which the Employee has an interest, into any product, service, process, composition, machine, or other property (including Confidential Information) of the Company, the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, worldwide license to make, modify, use, and sell such item as part of or in connection with such product, service, process, composition, or machine, or other property.

1.3. 对公司的披露和转让 员工确认，公司对员工的以下发明和知识产权拥有单独且排他的专有所有权：(a) 在受雇期间独自或与他人共同制造、构思、开发、创造或付诸实施的所有发明和知识产权，该等发明和知识产权 (i) 是通过使用任何公司拥有的、租赁的或承包的任何设备、设施、商业秘密、专有技术或其他保密信息而制造、构思、开发、创造或付诸实施的；(ii) 是通过员工为公司开展的任何工作而产生的；和/或 (iii) 与公司的业务、或实际的或预期的研究活动有关，以及 (b) 虽在员工与公司

建立雇佣关系前，但与公司业务有关的（包括与之相关的任何研究和开发项目）、员工已单独或共同构想、开发或付诸实施的（在先发明除外）且员工有权转让的所有发明和知识产权（统称“**公司知识产权**”）。员工将保持准确且完整的书面记录，并无需要求便及时以书面形式向公司披露所有公司知识产权。员工确认，该等公司知识产权被视为适用法律项下的职务成果且公司系该等公司知识产权的所有权利、所有权和利益在全球范围内的唯一且排他的所有权人，并且员工特此永久性地不可撤销地无偿转移和转让给公司或其指定人，所有包含在和对于所有该等公司知识产权的权利、所有权和利益，即使任何该等公司知识产权因任何原因在适用法律项下不属于职务成果。本第9.3条不应当适用于将员工完全使用其个人的时间且没有用公司器材、供应、设施、或保密信息、做出的知识产权转让给公司，除知识产权有以下情况外：(a) 在知识产权构思或付诸实施时，与公司业务或公司预期的研发活动有关；或 (b) 来自于员工为公司从事任何工作的结果。在本合同中，“**发明**”是指所有发明、发现、概念、信息、作品、材料、工艺、方法、数据、软件、程序、装置、设计等；“**知识产权**”是指所有专利、发明披露、发明注册、商标、服务商标、商号、商业外观、标识、域名、著作权、掩膜作品、商业秘密、专有技术以及任何司法管辖区的任何适用法律认可的所有其他知识产权和专有权，及上述内容的所有注册和注册申请，以及与上述内容相关的所有商誉。

Disclosure and Assignment to the Company. The Employee acknowledges that the Company will have sole and exclusive title and ownership rights in and to (a) all Inventions and Intellectual Property made, conceived, developed, created or reduced to practice by the Employee, either solely or jointly with others, during the Employee's employment that (i) are made, conceived, developed, created or reduced to practice using any equipment supplies, facilities, trade secrets, know-how or other Confidential Information that is owned, leased or contracted for by the Company, (ii) result from any work performed by the Employee for the Company and/or (iii) otherwise relate to the Company's business or actual or anticipated research activities, and (b) all Inventions and Intellectual Property which the Employee has solely or jointly conceived or developed or reduced to practice (other than the Prior Inventions) before the Employee's employment with the Company but relating to the Company's business (including any of its research and development projects) and have the right to assign ("**Company Intellectual Property**"). The Employee will maintain accurate and complete written records and promptly, without request, disclose promptly in writing to the Company all such Company Intellectual Property. The Employee acknowledges that such Company Intellectual Property are hereby deemed a "work made for hire" defined under applicable law and the Company shall be the sole and exclusive owner of all right, title and interest throughout the world in and to all such Company Intellectual Property therein, and the Employee hereby forever irrevocably transfers and assigns to the Company or its designee without additional consideration, even when any of such Company Intellectual Property does not constitute a "work made for hire" under applicable law for any reason. This Section 9.3 shall not apply to assign to the Company any of the Employee's rights in any intellectual property rights that he/she develops entirely on his/her own time without using the Company's equipment, supplies, facilities, or Confidential Information, except for intellectual property rights that either (a) relate, at the time that the intellectual property right is conceived or reduced to practice, to the Company's business or to anticipated research or development activities of the Company; or (b) result from any work performed by the Employee for the Company. For purposes of this Contract, "**Inventions**" means all inventions, discoveries, concepts, information, works, materials, processes, methods, data, software, programs, apparatus, designs and the like; and "**Intellectual Property**" means all patents, invention disclosures, invention registrations, trademarks, service marks, trade names, trade dress, logos, domain names, copyrights, mask works, trade secrets, know-how and all other intellectual property and proprietary rights recognized by any applicable law of any jurisdiction, and all registrations and applications for registration of, and all goodwill associated with, the foregoing.

1.4. 著作权 员工确认且同意所有写作或著作权，包括但不限于，商业策划文件、市场营销材料、操作手册、软件程序代码、图纸、流程图，和其在为公司工作期间制作的其他文档，均为职务作品且是公司财产，包括但不限于，这些著作的任何著作权，但在某种程度上该等由员工于其为公司工作时做出的写作，可能根据法律或其他规定，不是职务作品，员工特此永久性地不可撤销地转移并转让给公司该等作品的著作权的所有权，无论其是否出版。

Works of Authorship. The Employee acknowledges and agrees that all writings or works of authorship, including without limitation, business planning documents, marketing materials, operations manuals, software program code, drawings, procedural diagrams, and other documentation of any kind produced by her in the course of her work for the Company are works produced for hire and the property of the Company, including without limitation any copyrights on those writings; but to the extent any such writing produced by the Employee in the course of her work for the Company may not, by operation of law or otherwise, be a work made for hire, the Employee hereby forever irrevocably transfers and assigns to the Company the ownership of copyright in such works, whether published or unpublished.

1.5. 著作人身权 员工理解"**著作人身权**"条款指任何署名权或完整权，包括任何声明可获版权作品的著作权、反对对该等可获版权作品的修改、以及任何世界上任何国家的司法或法律中或任何条约中存在的任何类似权利，不论该等权利是否被称为或通常被称为"著作人身权"。员工特此永久性地豁免且同意绝不主张，即使是在其与公司的劳动关系解除后，任何其可能在任何根据本合同第9.4条规定转让给公司的可获版权作品中的任何著作人身权。

Moral Rights. The Employee understands that the term "moral rights" means any rights of paternity or integrity, including any right to claim authorship of a copyrightable work, to object to a modification of such copyrightable work, and any similar right existing under the judicial or statutory law of any country in the world or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right." The Employee forever hereby waives and agrees never to assert any moral rights she may have in any copyrightable work that is assigned to the Company as a result of Section 9.4 hereof, even after any termination of her employment with the Company.

1.6. 知识产权登记 员工同意协助公司或其指定人，由公司负担费用以任何合适的方式保证公司在一切国家的在公司知识产权中的权利，包括向公司披露所有相关信息和数据，签署公司为申请或获得该等权利并将向公司、公司继任者、受让人和被提名者转让并传递对该等公司知识产权的独家权利、所有权和利益，公司认为必要的所有申请、要求、誓言、转让、以及其他文书。员工同意其有签署或被促使签署的义务，当其有权这样做时，任何此类文书或文件应在本合同解除后继续有效。如果公司因为员工精神或身体原因或其他任何原因不能获得其签名以申请或寻求在任何国家对任何公司知识产权进行注册的任何申请，则员工特此不可撤销地指定且任命公司和其获正式授权的人员和代理人作为其实际代理人和律师，与员工本人执行有同等法律效力和效果地代表其行动并且签署和提交任何此等申请及完成所有其他法律允许的行动以促进信函出具及知识产权注册。

Patent and Copyright Registrations. The Employee agrees to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in the Company Intellectual Property in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments, and all other instruments which the

Company shall deem necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title, and interest in and to such Company Intellectual Property. The Employee further agrees that his/her obligation to execute or cause to be executed, when it is in her power to do so, any such instrument or papers shall continue after the termination of this Contract. If the Company is unable because of the Employee's mental or physical incapacity or for any other reason to secure her signature to apply for or to pursue any application in any country for the registration of any Company Intellectual Property, then the Employee hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as her agent and attorney in fact, to act for and on her behalf and to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters, IP Right registrations thereon with the same legal force and effect as if executed by the Employee.

1.7. 强制许可 员工确认中国专利管理部门有权根据中国专利法取得强制许可以使用任何职务发明。员工确认并声明，公司对于因该等强制许可所产生的全部许可费拥有独家且绝对的权利，员工在此放弃对该等许可费的所有权利（无论何种性质、现有的或者或有的、现在的或以后的）（如有）；同时，员工特此放弃其对前述许可费主张索赔的权利（如有，且不管该等权利的性质以及该等权利是否是真实的或偶然的，以及是当下的或潜在的）。

Compulsory License. The Employee understands that the PRC patent authorities have the authority to obtain a compulsory license to use any service Inventions pursuant to the PRC Patent Law. The Employee acknowledges and represents that the Company has an exclusive and absolute right in connection with any royalty arising from such compulsory license, and hereby waives all rights (of whatever nature, whether current or contingent, present or future), if any, in respect of such royalty and the Employee hereby waives her rights to claims in and to the foregoing royalty, if any, regardless of the nature of such rights and whether or not such rights are actual or accidental and are present or potential.

1.8. 奖励和报酬 员工理解，就其完成的且被中国知识产权局（"**SIPO**"）授予专利权的职务发明，在SIPO公布专利权公告之后，员工有权从公司处获得奖励和报酬。员工承认许多专利有可能从未被商业化使用或者成功地被商业化使用。基于该等事实，与其等待员工完成的且转让给公司的职务发明获得收益（如有，即来自职务发明的使用、许可或转让）之后取得奖励，员工同意并接受公司根据其奖励和报酬制度提供的固定的奖励和报酬，以及该等奖励和报酬是合理的，并构成了根据中国法律项下员工对员工人完成的职务发明有权获得的全部奖励和报酬，公司不再有义务向员工支付与之相关的任何形式的报酬。

Reward and Remuneration. The Employee understands that she may be entitled to reward and remuneration from the Company for service Inventions the Employee created that are granted patents by the State Intellectual Property Office of the PRC ("**SIPO**") after the publication of the patent grant by SIPO. The Employee acknowledges that many Inventions may never be commercialized or successfully commercialized. In light of that fact, rather than wait to be rewarded for service Inventions that the Employee has created and assigned to the Company for a portion from the proceeds or profits, if any, acquired from the exploitation, license, or transfer of the service Inventions, the Employee agrees to and accepts the set rewards and remunerations provided by the Company in accordance with its reward

and remuneration policies, and that such rewards and remunerations are reasonable and constitute all the rewards and remunerations the Employee is entitled to under the PRC law and that the Company shall not be obligated to pay any other form of compensation to the Employee in respect thereof. The Employee hereby irrevocably waives any claim against the Company for any other reward or remuneration for any service Inventions, regardless of whether the Company implements or licenses such service Inventions or whether the Company makes any profit or receives any royalty payment or license fees from such service Inventions. The Employee hereby waives to the fullest extent permitted by applicable laws any pre-emptive rights or rights of first refusal that the Employee may have to purchase the rights relating to any Inventions on assignment or other disposition of the same by the Company.

10. 不竞争、不招揽、不诋毁

NON-COMPETITION, NON-SOLICITATION AND NON-DISPARAGEMENT

考虑到本合同载明的相互承诺和义务以及其他善意和有价值的因素，员工特此同意遵守本第10条规定的限制。

In consideration of the mutual covenants and obligations set forth in this Contract and for other good and valuable consideration, the Employee hereby agrees to comply with the restrictions set forth in this Section 10.

1.1. 不竞争、不招揽

Non-Competition and Non-Solicitation

1.1.1. 员工特此承诺并同意在其任职期间任何时候，其或其配偶不应当直接或间接地参与同其任职期间公司或其关联公司曾经营业务或正在经营的业务、或于其劳动关系结束时公司及其关联公司积极计划经营的业务（合称"**业务**"）具有竞争关系的业务。如上第8.3.1条所述，在本合同解除或终止后的任何时间里，员工不应当利用公司保密信息或关于任何公司知识产权的信息、或其可能因劳动关系以任何方式获得的其他关于公司业务的保密事宜。

The Employee hereby covenants and agrees that at any time during her employment, she, or her spouse, shall not directly or indirectly engage in competition with the business that the Company or any of its Affiliates conducts or conducted at any time during her employment or which the Company or any of its Affiliates is actively engaged in planning to conduct at the time of the termination of her employment (collectively, the "**Business**"). As indicated above in Section 8.3.1, at any time after the termination of this Contract, the Employee shall not make use of the Company's Confidential Information or information concerning any Company Intellectual Property, or any other confidential matter relating to the Company's Business that she may in any way acquire by reason of her employment with the Company.

1.1.2. 在其因任何原因与公司结束劳动关系后紧接着的十二（12）个月内（"**竞业限制期**"）员工不应当直接或间接地、无论是否作为所有者、合伙人、投资人、顾问、代理人、员工、共同合资者或其他身份，在任何公司和其关联公司所在的，或者在其在职期间正积极地参与计划经营业务的国家，与业务相竞争（"**竞业限制义务**"）。但是，上述情况并不包括员工持有任何上市公司的百分之二（2%）或少于此等比例的证券权益的所有权。

For a period of twelve (12) months ("**Non-competition Period**") immediately following the termination of her employment with the Company for any reason, the Employee shall not, directly or indirectly, whether as owner, partner, investor, consultant, agent, employee, co-venturer or otherwise, compete with the Business within any country in which the Company or its Affiliates conduct Business or, at the time of her employment, is actively engaged in planning to conduct Business ("**Non-competition Obligations**"). The foregoing, however, shall not prevent the Employee's passive ownership of two percent (2%) or less of the equity securities of any publicly traded company.

1.1.3. 在员工同意于竞业限制期内履行其上述第10.1.2条所述之竞业限制义务的条件下，公司同意在竞业限制期内按月给予员工竞业限制补偿金，该等竞业限制补偿金每月的金额为员工月基本工资的30%，且不低于员工工作地最低工资（"**竞业限制经济补偿金**"）。员工同意按月向公司提交公司所需的一切证明材料（包括但不限于新雇主的在职证明、劳动合同、社会保险支付记录和劳动手册），以核实员工领取该等竞业限制补偿金的资格。在公司对该等证明材料满意的前提下，竞业限制补偿金将由公司在竞业限制期内按月支付给员工。

In consideration of the Employee agreeing to perform the Non-competition Obligations as outlined in Section 10.1.2 above during the Non-competition Period, the Company agrees to pay the Employee separate monetary compensation on a monthly basis during the Non-competition Period, of which the monthly amount is 30% of the Employee's monthly Base Salary but not lower than the local minimum wage of the place where the Employee works ("**Non-competition Compensation**"). The Employee agrees to submit to the Company on a monthly basis all certification materials (including but not limited to the incumbency certification, labor contract, social insurance payment record and labor handbook with the new employer) that are required by the Company to verify the Employee's qualification for receiving such non-competition compensation. On the condition that the Company is satisfied with the certification materials, the Company shall pay the non-competition compensation to the Employee on a monthly basis during the Non-competition Period.

1.1.4. 尽管存在第10.1.2条和10.1.3条之规定，公司和员工在此确认，公司仍有权在竞业限制期前的任何时候（包括本合同解除或终止的同时），书面通知员工来放弃要求员工履行其在本合同第10.1.2条项下的竞业限制义务的权利。在此情况下，公司无须向员工支付与竞业限制相关的任何经济补偿金。

Notwithstanding the provisions in Section 10.1.2 and 10.1.3, both Parties hereby confirm that the Company shall have the right to waive the Non-competition Obligations of the Employee under Section 10.1.2 of this Contract by giving the Employee a written notice at any time prior to the Non-competition Period (including at the time this Contract expires or is terminated). In this case, the Company should have no obligation to pay the Employee any compensation in relation to non-competition.

1.1.5. 员工如违反其在本合同下之竞业限制义务，公司有权要求员工支付违约金，该违约金等于员工离职前十二（12）个月内获得的税前工资总额，该税前工资总额包括但不限于员工的税前基本工资、第十三薪（如有）、任何奖金、津贴、佣金等，加上公司按照本合同第10.1.3条向员工实际支付的竞业限制经济补偿金总额。同时，本条约定并不妨碍公司（和/或其关联方）依据中国适用法律寻求其他救济的权利，包括但不限于实际履行竞业限制义务和禁令救济。

If the Employee breaches the Non-competition Obligations hereunder, the Company will be entitled to liquidated damages in the amount equal to the Employee's total gross salary (including without limitation the Base Salary, the thirteenth salary (if any) and any other bonus, allowance and commission) during the twelve (12) months before the termination of the Employee's employment with the Company plus the actual amount of Non-competition Compensation paid by the Company to the Employee pursuant to Section 10.1.3 hereof, without prejudice to the Company's right (and/or the rights of its Affiliates) to pursue any other remedies available under applicable PRC Law, including but not limited to actual performance of the Non-competition Obligations and other injunctive relief.

为免疑义，公司和员工在此确认，如公司决定执行合规协议中的第12.a条，则本合同第10.1.3条、10.1.4条和10.1.5条应对双方具有约束力。

For the avoidance of doubt, both Parties hereby confirm that Sections 10.1.3, 10.1.4 and 10.1.5 of this Contract shall be binding on both Parties if the Company decides to enforce Section 12.a of the Compliance Agreement.

1.1.6. 不招揽 在员工于公司任职期间和在其与公司不论以何种原因结束劳动关系后紧接着的二十四（24）个月内，除在其职责范围内被公司书面授权外，员工不能代表其个人或任何其他人：(a) 招揽、招聘或鼓励任何公司或其关联公司的管理人员、董事或雇员离开或终止与公司或关联公司的劳动关系；(b) 聘用或雇佣任何公司或其关联公司的管理人员、董事或雇员（或任何曾经在该等行为的六（6）个月内是公司或其关联公司的管理人员、董事或雇员的任何人）；或 (c) 引诱任何现有或潜在客户、供应商、卖方、被许可方、许可方、独立承包商或其他公司或其关联公司的业务关系，停止与公司或其关联公司业务往来、或者以对公司或关联公司不利的方式改变其业务关系。

Non-Solicitation. Both during the Employee's employment and for twenty-four (24) months immediately following the termination of her employment with the Company for any reason, the Employee will not, on behalf of herself or any other person, except as authorized by the Company in writing within the scope of her duties with the Company: (i) solicit, recruit, or encourage any of the Company's or its Affiliates' officers, directors or employees to leave or terminate their employment with the Company or such Affiliate; (ii) hire or employ any of the Company's or its Affiliates' officers, directors or employees (or any person who was an officer, director or employee of the Company or any of its Affiliates within six (6) months of such action); or (iii) induce any current or prospective customer, supplier, vendor, licensee, licensor, independent contractor or other business relation of the Company or any of its Affiliates to cease doing business with the Company or any of its Affiliates, or to modify its business relationship with the Company or any of its Affiliates in a manner adverse to the Company or any of its Affiliates.

1.2. 现在以及员工与公司的劳动关系终止后，员工不得直接或间接以任何方式贬低公司或就公司、其业务活动，或其任何董事、经理、官员、雇员、关联方、代理或代表向任何人或实体做负面、贬低或不实的陈述。

Presently, and after her employment relationship with the Company terminates or expires, the Employee shall not, directly or indirectly, disparage the Company in any way or make any negative, derogatory or untrue

statements about the Company, its business activities, or any of its directors, managers, officers, employees, affiliates, agents or representatives to any person or entity.

1.3. 如果员工因任何原因自公司离职，员工在此向公司同意并承诺，员工将通知新雇主员工在本合同项下的权利和义务。

If the Employee's employment with the Company is terminated for any reason, the Employee hereby consents to the Company that she shall notify the new employer about her rights and obligations under this Contract.

11. 员工陈述与保证

EMPLOYEE'S REPRESENTATIONS AND WARRANTIES

员工向公司陈述并保证：

The Employee represents and warrants to the Company that:

(a) 员工已经与前任雇主解除劳动关系，并且不存在任何的竞业限制义务。员工加入本公司时，已终止了所有其他的劳动关系以及其它相关竞业限制义务，并且其有充分能力签订本合同并完全履行其在本合同项下的各项义务；

The Employee has terminated all other employment relationships and other related contractual obligations prior to entering into an employment relationship with the Company. The Employee is not subject to any non-competition restraints and has full capacity to enter into this Contract and fully perform the obligations under this Contract;

(b) 员工签署并交付本合同以及履行本合同项下的任何交易将不会在任何方面违反其作为一方或对其具有约束力的任何协议、文件或文书的任何条件或条款。若员工因签订本合同而违反任何合同义务、法定义务或其他义务，导致公司任何费用支出和遭受损失，则员工应就该等一切费用和损失向公司承担赔偿责任；

Neither the execution and delivery of this Contract nor the carrying out of any of the transactions contemplated hereby will in any respect result in any violation of or be in conflict with any term or provision of any agreement, document or instrument to which the Employee is a party or by which she is bound. The Employee shall indemnify the Company for any and all expenses and damages that the Company incurs if, by entering into this Contract, the Employee breaches any contractual, statutory, or other obligations to which the Employee is subject to;

(c) 员工已经根据公司的要求，如实说明了与劳动合同和公司的聘用直接相关的基本情况；

The Employee has, in accordance with the requirements of the Company, fully disclosed all basic information in relation to this Contract and the employment relationship to be established with the Company;

(d) 员工向公司提供的所有信息、资料、证明等均属真实、有效；

All information, documents and certificates that she provided to the Company are accurate and valid;

(e) 员工具备本合同附件一所列的职责所要求的技能、经验和资质。员工应当以专业、娴熟的方式，按照类似服务的最佳行业标准，履行该等职责，并且员工应当倾注充分的资源以确保其职责得以及时可靠地履行；

The Employee has the required skill, experience and qualifications to perform her duties set forth in Schedule 1 hereof. The Employee shall perform such duties in a professional and workmanlike manner in accordance with best industry standards for similar services and the Employee shall devote sufficient resources to ensure that her duties are performed in a timely and reliable manner;

(f) 员工将按照所有适用法律法规履行其职责；

The Employee shall perform her duties in compliance with all applicable laws and regulations;

(g) 对于员工根据本合同第9.3条向公司转让的所有知识产权，员工应向公司转让良好有效的所有权，且该等公司知识产权不存在任何形式的负担或留置权；

The Employee shall assign to the Company good and valid title to all the Company Intellectual Property assigned to the Company pursuant to Section 9.3 hereof, free and clear of all encumbrances and liens of any kind;

(h) 员工根据本合同第9.3条向公司转让的所有公司知识产权为员工的原创作品（公共领域内或公司提供的材料除外），未且将不会违反或侵犯任何人士、商号、公司或其他实体的知识产权或任何其他权利。

All the Company Intellectual Property assigned by the Employee to the Company pursuant to Section 9.3 hereof are and shall be the Employee's original work (except for material in the public domain or provided by the Company) and do not and will not violate or infringe upon the intellectual property right or any other right whatsoever of any person, firm, corporation or other entity.

12. 变更、解除、终止

MODIFICATION AND TERMINATION

1.1. 变更

Modification

本合同经员工及经公司授权代表协商可以进行修改。公司也可根据经营状况、员工身体情况、员工工作能力等情况对本合同作相应书面变更。

This Contract may be amended by written agreement between the Employee and a duly authorized representative of the Company. In accordance with the business situation of the Company, the Employee's fitness and the Employee's performance, this Contract may also be amended in writing by the Company.

1.2. 非自愿解除

Involuntary Termination

1.1.1. 失能 如果员工死亡，则公司在本协议项下与员工的劳动关系将在员工死亡之日自动终止。如果员工因意外、疾病或其他原因丧失行为能力或残疾，以致其在连续九十（90）日或更长时间或任何六（6）个月中的九十（90）日在精神上或身体上无法履行本合同规定的服务（这种情况在本合同中称"**失能**"），无论是否提供合理的便利，公司可自行选择在向员工发出通知后立即解除员工在本合同项下的劳动关系。在失能的情况下，至公司按照上述规定解除员工的劳动关系之时，员工将有权按照本合同第4条所规定的标准以及方式获得补偿。根据本合同第12.2条规定发生的解除以下称为"**非自愿解除**"。

Disability. If the Employee dies, then the Employee's employment by the Company hereunder shall automatically terminate on the date of the Employee's death. If the Employee is incapacitated or disabled by accident, sickness or otherwise so as to render her mentally or physically incapable of performing the services required to be performed by her under this Contract, either with or without reasonable accommodation, for a period of ninety (90) consecutive days or longer, or for ninety (90) days during any six (6) month period (such condition being herein referred to as "**Disability**"), the Company, at its option, may terminate the Employee's employment under this Contract immediately upon giving her notice to that effect. In the case of a Disability, until the Company shall have terminated the Employee's employment in accordance with the foregoing, the Employee will be entitled to receive compensation, at the rate and in the manner provided in Section 4. Termination pursuant to this Section 12.2 is hereinafter referred to as an "**Involuntary Termination**".

1.1.2. 替代 Lianbio（公司的关联方）董事会（"**董事会**"）可以在员工劳动关系期间出现失能情况的任何时候任命另一名员工以代替员工开展工作。尽管有此类任命，员工仍应根据本合同第4条的规定继续领取员工的基本工资和福利，直至员工有资格根据公司的失能收入保险（如有）获得失能收入或直至员工劳动关系的解除或终止，以先发生的情形为准。

Substitution. The board of directors of LianBio, an affiliate of the Company (the "**Board**") may designate another employee to act in the Employee's place during any period of Disability suffered by the Employee during the Employment Period. Notwithstanding any such designation, the Employee shall continue to receive the Employee's Base Salary and benefits in accordance with Section 4 of this Contract until the Employee becomes eligible for disability income under the Company's disability income insurance (if any) or until the termination of the Employee's employment, whichever shall first occur.

1.1.3. 失能收入的支付 在根据公司的失能收入保险（如有）领取失能收入时，员工无权根据第4.1条领取任何基本工资，但应继续按照第4.6条领取所有其他补偿和福利，直至员工劳动关系解除或终止。

Disability Income Payments. While receiving disability income payments under the Company's disability income insurance (if any), the Employee shall not be entitled to receive any Base Salary under Section 4.1, but shall continue to receive all other compensation and benefits in accordance with Section 4.6 until the date of the Employee's termination of employment.

1.1.4. 失能验证 如果出现任何问题，关于员工是否在任何期间因任何疾病、受伤、事故或生理或心理的状况而无法履行在本合同项下几乎所有的职责和责任，员工可以，并且在公司要求时应当，接受由公司选定的医生进行体检，员工或其监护人应对由该等医生判断员工是否失能没有合理的反对意见；并且，就本合同而言，这种判断结论对此问题具有决定性意义。如果出现此类问题且员工未能接受此类体检，则公司对该问题的认定结果对员工具有约束力。

Verification of Disability. If any question shall arise as to whether during any period the Employee is disabled through any illness, injury, accident or condition of either a physical or psychological nature so as to be unable to perform substantially all of the Employee's duties and responsibilities hereunder, the Employee may,

and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Employee or the Employee's guardian has no reasonable objection to determine whether the Employee is so disabled and such determination shall for the purposes of this Contract be conclusive of the issue. If such question shall arise and the Employee shall fail to submit to such medical examination, the Company's determination of the issue shall be binding on the Employee.

1.3. 因过错解除 公司在董事会的建议下，可在劳动关系期限内的任何时间因员工过错而向员工发出解除通知以解除员工的劳动关系（该解除以下称为"**因过错解除**"），在此等解除通知发出后劳动关系的解除立即生效。就本合同而言，"**因过错**"是指以下任何一种原因：(i) 屡次醉酒或使用非法药物，对员工在公司中履行义务和职责造成不利影响；(ii) 员工被判犯有重罪，或任何涉及欺诈或虚假陈述或违反适用的证券法律的罪行；(iii) 员工对公司或公司的任何关联公司的业务和事务严重管理不当，有相当的可能性给公司或公司的任何关联公司造成重大损失；(iv) 严重违反本合同的任何重要条款，而该严重违约行为在员工收到关于违约行为的书面通知后三十（30）天内没有得到纠正（如果违约行为能够纠正的话）；(v) 严重违反公司的规章制度；以及 (vi) 由董事会任命的独立事实调查人对员工的任何故意不当行为或不诚实行为做出结论性的认定，该行为对公司或公司任何关联公司的利益和福祉造成严重损害，包括但不限于对其业务或声誉的损害。

Termination for Cause. The Company, on recommendation from the Board, may terminate the employment of the Employee hereunder at any time during the Employment Period for Cause (such termination being hereinafter referred to as a "**Termination for Cause**") by giving the Employee notice of such termination, upon the giving of which such termination shall take effect immediately. For the purposes of this Contract, "**Cause**" means any one of the following grounds: (i) repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the Employee's obligations and duties in the Company; (ii) the Employee's conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws; (iii) gross mismanagement by the Employee of the business and affairs of the Company or any affiliate of the Company which is reasonably likely to result in a material loss to the Company or any affiliate of the Company; (iv) material violation of any material terms of this Contract, which material violation has not been cured (if it is capable of being cured) within thirty (30) days after the Employee receives written notice of such violation; (v) serious violation of the Company's rules and policies; or (vi) a conclusive finding by an independent fact finder appointed by the Board for any willful misconduct or dishonesty by the Employee which is materially detrimental to the interests and well-being of the Company or any affiliate of the Company, including, without limitation, harm to its business or reputation.

1.4. 无理由解除 公司在董事会的建议下，可在劳动关系期限内的任何时间向员工提前六十（60）天发出书面解除通知或支付相应补偿后无理由解除与员工的劳动关系（该解除以下称为"**无理由解除**"）。

Termination without Cause. The Company, on recommendation from the Board, may terminate the employment of the Employee hereunder at any time during the Employment Period without Cause (such termination being hereinafter called a "**Termination without Cause**") by giving the Employee sixty (60) days' prior written notice of such termination or pay in lieu of such notice (or any portion thereof).

1.5. 员工要求解除

Termination by the Employee

1.1.1. 无正当理由 在本合同中“**自愿解除**”是指非因非自愿解除、因过错解除、无理由解除、因正当理由解除（定义见下文）或不续约终止（定义见下文）而导致员工在本合同下劳动关系的任何解除。自愿解除将被视为在书面通知三十（30）日后生效。

Without Good Reason. Any termination of the employment of the Employee hereunder other than as a result of an Involuntary Termination, a Termination for Cause, a Termination without Cause, a Termination for Good Reason (as defined below) or a Non-Renewal Termination (as defined below) will be referred to hereinafter as a “**Voluntary Termination**”. A Voluntary Termination will be deemed to be effective thirty (30) days after written notice hereof.

1.1.2. 因正当理由 员工可在任何时候以正当理由解除其在本合同下的劳动关系，但前提是：(i) 员工在该状况最初存在的三十（30）天内向公司提供书面通知，合理详细地说明引起正当理由的状况的性质；(ii) 在该通知发出后的三十（30）天内，该状况仍未被公司纠正，以及 (iii) 员工在该纠正期结束后的三十（30）天内解除其劳动关系（如果有的话）（该解除以下称为“**因正当理由解除**”）。就本合同目的而言，“正当理由”是指 (a) 员工在本合同下的职责或责任的任何重大减少（涉及因过错解除或符合第12.2.2条的每一种情形除外）或向员工分配的职责与责任与员工当时的职位严重不符；或 (b) 公司存在对本合同的任何重大违约行为。

With Good Reason. The Employee may terminate the employment relationship of such Employee hereunder at any time for Good Reason, provided that (i) the Employee provides written notice to the Company, setting forth in reasonable detail the nature of the condition giving rise to Good Reason, within thirty (30) days of the initial existence of such condition, (ii) the condition remains uncured by the Company for a period of thirty (30) days following such notice and (iii) the Employee terminates her employment, if at all, not later than thirty (30) days after the expiration of such cure period (such termination being hereinafter referred to as a “**Termination for Good Reason**”). For purposes of this Contract, the term “**Good Reason**” shall mean (a) any material diminution of the Employee’s duties or responsibilities hereunder (except in each case in connection with the Termination for Cause or pursuant to Section 12.2.2) or the assignment to the Employee of duties or responsibilities that are materially inconsistent with the Employee’s then current position; or (b) any material breach of the Contract by the Company.

1.6. 合同解除或终止后的义务

Termination Obligations

1.1.1. 在员工离职前应将工作有序移交给公司指定的其他雇员，完成公司要求的所有交接程序，并交还所有属于公司的任何财产，包括但不限于：

Upon termination of his/her employment, the Employee shall transfer his/her work to other employees designated by the Company and complete other hand-over procedures as required by the Company. The Employee shall return all properties of the Company, which include but is not limited to:

(a) 公司的所有设备、记录、数据、笔记、报告、提案、名单、往来信函、规格说明、图纸、蓝图、草图、资料、设施、其他文件或财物、以及以上各项的复制品；

all devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, and other documents or property, and all reproductions of any aforementioned items;

(b) 员工保管的所有公司钥匙和门禁卡；以及

all keys and access cards of the Company in the Employee's custody; and

(c) 根据公司规章制度及各种政策应移交的其他项目。

all other items that are required to be returned according to the Company's regulations and policies.

员工在完成移交手续后，公司应书面确认移交手续已完成。若员工未按要求完成移交手续，且公司因此遭受损失的，公司有权要求员工进行赔偿。

If the employee fails to complete the hand-over procedures as required and the Company suffers a loss as a result, the Company shall have the right to require the Employee to indemnify the Company for such loss.

1.1.2. 除法定情形外，如员工因任何原因解除劳动合同，应偿还公司录用员工时代员工垫付的任何费用（包括但不限于向员工原雇主交纳的违约金、为员工垫付的培训费用，以及其他双方约定为员工垫付的费用）。若劳动合同期间公司为员工提供了专项培训费用，对其进行专业技术培训的，公司可以和员工签署相关协议对员工的服务期进行约定。如果员工解除劳动合同违反了该协议，员工应按双方的约定赔偿公司相应违约金。

If the Employee terminates this Contract for any reason other than reasons specified by the applicable laws and regulations, the Employee shall repay any and all expenses and costs to the Company which the Company has paid on behalf of the Employee during his/her employment (including but not limited to, compensation paid to the previous employer of the Employee, training expenses paid for the Employee and other expenses agreed to by the Parties). If the Company provides special funding for the professional technical training of the Employee, the Company may enter into an agreement with the Employee specifying a required term of service, in such case, the Employee shall pay the Company liquidated damages as mandated by the agreement if his/her termination of this Contract breaches the terms of such agreement.

13. 解除或终止劳动关系的后果

EFFECT OF TERMINATION ON SERVICES

1.1. 员工不续约、自愿解除或员工因过错被解除 如因员工出具不续约通知（下称"**员工不续约**"）而导致初始期限或任何续约期限不能自动续约，或因自愿解除或员工因过错被解除在本合同下的劳动关系，员工或其受益人或继承人在本合同下对公司、其关联公司或其子公司均无任何进一步的权利或索赔，但可获得 (i) 第4.1条规定的基本工资的未支付部分，按比例计算到该解除日期；以及(ii)适用法律规定的任何其他福利（第 (i)项及第 (ii) 项以下合称为"**应付福利**"）。

Non-Renewal by the Employee, Voluntary Termination or a Termination for Cause. In the event that the Initial Term or any Renewal Term is not automatically renewed as a result of the Employee providing a Non-Renewal Notice (hereinafter a "**Non-Renewal by the Employee**"), or upon the

termination of the Employee's employment hereunder pursuant to a Voluntary Termination or a Termination for Cause, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates, or its subsidiaries under this Contract except to receive (i) the unpaid portion of the Base Salary provided for in Section 4.1, computed on a pro rata basis to the date of such termination; and (ii) any other benefits as required by applicable law (collectively, clauses (i) and (ii) are hereinafter referred to as the "**Accrued Benefits**").

1.2. 非自愿解除 在员工根据非自愿解除而解除劳动关系时，员工或其受益人或继承人都不会根据本合同对公司、其关联公司或其附属公司有任何进一步的权利或索赔，除了收到 (i) 应付福利；以及 (ii) 相当于十二（12）个月的基本工资总额以及附带福利（为避免疑义，该等附带福利不包括员工调动福利（定义见2022年10月1日生效的公司和员工之间的《劳动合同附录》），但应包括因员工同意于该解除日期后六十（60）天内迁回美国而产生的合理的归国机票费用、家庭用品国际运输和归国津贴（这些费用应在员工同意迁回美国后根据《高管国际调动/派遣政策》支付）），其应根据公司的正常薪资和/或报销（如适用）政策按本合同第4.1条规定的相同标准和方式从该解除之日起支付，加上适用法律明确规定的任何额外补偿（合称为"**经济补偿金**"）。

Involuntary Termination. Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Contract except to receive: (i) the Accrued Benefits; and (ii) an aggregate amount equal to the Base Salary and fringe benefits (which, for the avoidance of doubt, shall exclude the Employee's Relocation Benefits (as defined in the Addendum to Employment Contract, effective as of October 1, 2022, by and between the Company and the Employee), other than reasonable repatriation air ticket cost, international shipment of household goods and repatriation allowance, which are payable upon the Employee's consent to relocate back to the United States within sixty (60) days of the date of such termination and in accordance with the Executive International Relocation/Assignment Policy) for twelve (12) months, payable from the date of such termination in accordance with the Company's normal payroll and/or reimbursement policies (as applicable) and at the same rate and in the same manner as set forth in Section 4.1 hereof, plus any additional compensation as may be expressly required under applicable law (collectively, the "**Severance Payment**").

1.3. 公司不续约 如果初始期限或任何续约期限因公司出具不续约通知而没有自动续约（以下简称"公司不续约"，与员工不续约合称为"不续约终止"），员工或其受益人或继承人都不会根据本合同对公司、其关联公司或其子公司有任何进一步的权利或索赔，但可以获得 (i) 应付福利；以及 (ii) 经济补偿金。

Non-Renewal by the Company. In the event that the Initial Term or any Renewal Term is not automatically renewed as a result of the Company providing a Non-Renewal Notice (hereinafter a "**Non-Renewal by the Company**", and together with the Non-Renewal by the Employee, collectively referred to as the "**Non-Renewal Termination(s)**"), neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Contract except to receive: (i) the Accrued Benefits; and (ii) the Severance Payment.

1.4. 其他解除 在根据本合同的规定因无理由解除或因正当理由解除劳动关系时，员工或其受益人或继承人都不会在本合同下对公司、其关联方或其子公司有任何进一步的权利或索赔，但可以收到 (i) 应付福利；以及 (ii) 经济补偿金。

Other Terminations. Upon the termination of the Employee's employment hereunder pursuant to a Termination without Cause or a Termination for Good Reason, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Contract except to receive: (i) the Accrued Benefits; and (ii) the Severance Payment.

1.5. 控制权变更解除 在控制权变更后十二（12）个月内根据无理由解除或因正当理由解除劳动关系后，员工或其受益人或继承人都不会在本合同下对公司、其关联方或其子公司有任何进一步的权利或索赔，但可以收到 (i) 应付福利；(ii) 经济补偿金；(iii) 从该等解除日后十二（12）个月内产生的员工调动福利（定义见2022年10月1日生效的公司和员工之间的《劳动合同附录》），该等福利应根据《劳动合同附录》的条款和条件进行支付；以及 (iv) 公司或其关联公司授予员工的任何当时未归属的股票期权或其他基于股权的激励措施百分之百（100%）的加速归属。

Change in Control Termination. Upon the termination of the Employee's employment hereunder pursuant to a Termination without Cause or a Termination for Good Reason within twelve (12) months following a Change in Control, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Contract except to receive: (i) the Accrued Benefits; (ii) the Severance Payment; (iii) the Employee's Relocation Benefits (as defined in the Addendum to Employment Contract, effective as of October 1, 2022, by and between the Company and the Employee) that incurred within twelve (12) months following the date of such termination, payable in accordance with the terms and conditions of the Addendum to Employment Contract; and (iv) one hundred percent (100%) accelerated vesting of any then outstanding unvested stock options or other equity-based incentives granted to the Employee by the Company or its Affiliates.

为了本合同之目的，"控制权变更"是指发生了以下任一情况：(i) 任何一个个人，或一个以上的个人作为一个团体（"**个人**"）获得LianBio股票的所有权，并且与该个人持有的股票一起构成LianBio股票总投票权的50%以上，但因董事会批准的LianBio非公开融资而导致的LianBio股票所有权的任何变化将不被视为控制权变更；或 (ii) 出售LianBio的全部或几乎全部资产。

For purposes of this Contract, "**Change in Control**" means the occurrence of any of the following: (i) any one person, or more than one person acting as a group ("**Person**"), acquires ownership of the stock of LianBio that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of LianBio, except that any change in the ownership of the stock of LianBio as a result of a private financing of LianBio that is approved by the Board will not be considered a Change in Control; or (ii) the sale of all or substantially all assets of LianBio.

就这一定义而言，如果个人是与LianBio进行收购、兼并、购买股票或类似商业交易的公司的所有者，则他们将被认为是作为一个团体而行事。此外，为避免疑问，在以下情况下，交易将不构成控制权变更：(i) 其唯一目的是将LianBio重新注册在原注册地以外的司法管辖区，或 (ii) 其唯一目的是创建一个控股公司，该公司将由紧接该交易之前持有LianBio股票的人以基本相同的比例而拥有。关于任何被认为是第409A条（定义见下文）规定的非合格递延薪酬的款项，在适用范围内，在控制权变更时应予以支付，以避免根据第409A条征收额外的税款、利息或罚款，除非该控制权变更构成Treasury Regulations第1.409A-3(i)(5)条意义上的"控制权变更事件"，否则将不支付任何金额。

For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with LianBio. Further and for the avoidance of doubt, a

transaction will not constitute a Change in Control if: (i) its sole purpose is to re-domicile LianBio in a jurisdiction other than its original jurisdiction of incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held LianBio's securities immediately before such transaction. With regard to any payment considered to be nonqualified deferred compensation under Section 409A (as defined below), to the extent applicable, that is payable upon a Change in Control, to avoid the imposition of an additional tax, interest or penalty under Section 409A, no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

1.6. 免责 双方承认并同意，因员工被公司无理由解除本合同或公司违反本合同而给员工造成的损失应是极难或无法确定或证明的，并同意将经济补偿金视为至解除合同之日公司发生任何违反本合同约定行为的违约金。员工同意，除了本合同条款或任何适用的福利计划明确规定的员工可能有权获得的其他款项和福利外，该违约金应代替员工因解除劳动关系或任何此类违反本合同的行为而可能提出的所有其他索赔，并且作为领取经济补偿金的条件，员工将以公司合理满意的形式签署一份索赔免责书（"**免责书**"）。免责书（如有）必须在员工解除劳动关系后的第60个日历日之前生效。员工有权获得的任何经济补偿金的第一笔款项将在解除日期后六十（60）个日历日后的公司下一个正常发薪日进行支付；但此等第一笔款项的支付应追溯到员工劳动关系解除日期的下一日。

Release. The parties acknowledge and agree that damages which will result to the Employee for Termination without Cause by the Company or other breach of this Contract by the Company shall be extremely difficult or impossible to establish or prove, and agree that the Severance Payment shall constitute liquidated damages for any breach of this Contract by the Company through the date of termination. The Employee agrees that, except for such other payments and benefits to which the Employee may be entitled as expressly provided by the terms of this Contract or any applicable benefit plan, such liquidated damages shall be in lieu of all other claims that the Employee may make by reason of termination of her employment or any such breach of this Contract and that, as a condition to receiving the Severance Payment, the Employee will execute a release of claims in a form reasonably satisfactory to the Company (the "**Release**"). The Release must become effective, if at all, by the sixtieth (60th) calendar day following the date the Employee's employment is terminated. The first payment of any Severance Payments to which the Employee is entitled will be made on the Company's next regular payday following the expiration of sixty (60) calendar days from the date of termination; but that first payment shall be retroactive to the day following the date the Employee's employment terminates.

14. 劳动争议处理

DISPUTE RESOLUTION

双方应首先尝试通过协商解决因本合同发生或与本合同有关的任何争议；如果双方协商不成，任何一方可以自劳动争议发生之日起一（1）年内向公司注册所在地劳动争议仲裁委员会申请仲裁。对裁决不服的，相关一方可以向有管辖权的法院提起诉讼。

The Parties shall first attempt to settle any dispute arising out of or relating to this Contract through negotiation. In the event of the failure of the Parties to settle a dispute through such negotiation, any Party may submit the dispute to the local Labor Dispute Arbitration Committee in the locality where the Company is registered for arbitration within one (1) year of the date that the labor dispute arises. The relevant Party may file a lawsuit with an appropriate court if it is dissatisfied with the arbitration award.

15. 其他约定

MISCELLANEOUS

1.1. 本合同的各个方面均适用中华人民共和国法律并依据其进行解释。

This Contract is governed by and shall be construed in all respects in accordance with PRC Law.

1.2. 本合同未尽事宜，或与中国法律法规规定相悖的协议事宜，按有关规定执行。

In the event that this Contract does not cover a relevant issue, the applicable law or regulation shall apply. Where an existing provision contradicts or violates PRC Law, the PRC Law shall prevail.

1.3. 本合同第8条、第9条、第10条、第12.6条、第14条和第15条在本合同终止后继续有效。

The provisions set forth in Sections 8, 9, 10, 12.6, 14 and 15 of this Contract shall survive the termination of this Contract.

1.4. 关于本合同第8条、第9条、第10条所述事项，公司有权要求员工另行签署《员工知识产权合规协议》及《竞业限制协议》；若《员工知识产权合规协议》或《竞业限制协议》的条款与本合同的条款有任何不一致的，以向公司提供更有利保护的条款为准。

The Company has the right to ask the Employee to sign an "Employee IP Compliance Agreement" and a "Non-Competition Agreement" separately, with respect to the matters stated in Section 8, Section 9 and Section 10 hereof. In the event of any discrepancy between the provisions of this Contract and the provisions of the Employee IP Compliance Agreement or the Non-Competition Agreement, the provisions which provide better protection to the Company shall prevail.

1.5. 员工承诺所提供自身资料和各类证明确实无误，在本合同页首所载住址发生变化时，将于十（10）日内通知公司，否则，公司按原通讯方式向员工送达文件，仍将视为已送达。

The Employee warrants that any personal information or certificates provided to the Company are true and accurate. The Employee shall inform the Company of any changes made to her residential address within ten (10) days from the date that the change occurs. Otherwise, any documents intended for the Employee that is delivered by the Company to the original residential address of the Employee shall be deemed to be served.

1.6. 所有合同附件的条款均应被视为本合同的一部分且对双方当事人具有法律约束力。

Any schedules attached to this Contract are deemed to be incorporated into this Contract and binding on both Parties.

1.7. 如本合同有任何条款或附件被认定为无效、非法或不可执行，其他条款的有效性和执行性不得以任何方式受到影响。

If any provision of this Contract or its schedules shall be determined invalid, illegal, or unenforceable under the law, the validity and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

1.8. 本合同自双方签字或盖章之日起生效。本合同以中、英文同时书就，并签署原件两（2）份，每一方各持原件一（1）份。两种语言具有同等效力，若存在差异，以中文文本为准。

The Contract shall become effective upon the execution of the Contract by the Parties. This Contract is written in both Chinese and English and executed in two (2) original copies, with each Party holding one (1) original copy. Both language versions are deemed to have the same effect. Should any discrepancies arise, the Chinese version shall prevail.

1.9. 本合同是双方就本合同标的事项订立的最终、完整和唯一的协议，并取代和合并了双方在此之前就本合同标的事项的所有讨论、提案、谈判、沟通及协议（无论口头或是书面）。

This Contract sets forth the entire agreement and understanding between the Company and the Employee relating to the subject matter herein and merges all prior discussions, proposals, negotiations, communications and agreements, whether written or oral, between the Parties.

16. 付款时间及第409A条

TIMING OF PAYMENTS AND SECTION 409A.

1.1. 尽管本合同有相反的规定，如果在员工劳动关系解除或终止时，员工是“特定员工”（定义见下文），由于劳动关系的解除或终止根据本合同应在解除或终止日期后的六（6）个月内支付的任何和所有款项，但就本条款而言，应在该六（6）个月期满后的下一个工作日支付，或者于更早的时间如员工死亡时支付，但以下情况除外：(A) 就金额而言不构成Treasury regulation第1.409A-1(b)条所指的递延薪酬（包括但不限于由于根据第1.409A-1(b)(9)(iii)条规定的安全港，由公司以合理的善意酌情决定）；(B) 根据Treasury regulation第1.409A-1(a)(5)条符合例外福利条件的福利；或 (C) 不受不时修订的1986 年Internal Revenue Code第409A条（“**第409A条**”）要求约束的其他款项或福利。

Notwithstanding anything to the contrary in this Contract, if at the time the Employee’s employment terminates, the Employee is a “specified employee,” as defined below, any and all amounts payable under this Contract on account of such separation from service that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six (6)-month period or, if earlier, upon the Employee’s death; except (A) to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A-1(b) (including without limitation by reason of the safe harbor set forth in Section 1.409A-1(b)(9)(iii), as determined by the Company in its reasonable good faith discretion); (B) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (C) other amounts or benefits that are not subject to the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (“**Section 409A**”).

1.2. 就本合同而言，在遵守第409A条所需的范围内，所有涉及“劳动关系解除或终止”和相关短语均应解释为要求“离职”（定义见Treasury regulations第1.409A-1(h)条，在其中包含的推定生效后），“特定员工”一词是指公司根据Treasury regulation第1.409A-1(i)条确定为特定员工的个人。

For purposes of this Contract, to the extent required to comply with Section 409A, all references to “termination of employment” and correlative phrases shall be construed to require a “separation from service” (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term “specified employee” means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

1.3. 任何会构成第409A条规定的非合格递延薪酬的费用报销应遵守以下附加规则：(i) 任何此类费用的报销不得影响员工在任何其他应税年度报销任何此类费用的权利；(ii) 费用应及时报销，但不得迟于发生费用的日历年的下一个日历年的年底；以及 (iii) 报销的权利不得被清算或交换为任何其他利益。

Any reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement of any such expense shall affect the Employee's right to reimbursement of any such expense in any other taxable year; (ii) reimbursement of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for any other benefit.

1.4. 在任何情况下，公司均不因本合同项下的任何付款或利益未能或据称未能符合或被豁免第409A条的要求而承担任何责任。

In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Contract to comply with, or be exempt from, the requirements of Section 409A.

[以下无正文，为签字页 / Remainder of page intentionally left blank, signature pages follow]

有鉴于此，本合同双方已于文首载明的日期签署或促使其有效授权代表签署本合同。

In WITNESS WHEREOF, the Parties hereto has executed or caused its duly authorized representative to execute this Contract as of the date first above written.

公司 / COMPANY:

上海联拓生物科技有限公司（公章）

Shanghai LianBio Development Co., Ltd. (Chop)

姓名/ Name：王轶喆/Yizhe Wang

职务/ Title：法定代表人/Legal Representative

签字/ Signature：_/s/ Yizhe Wang_____

[劳动合同签字页/Signature Page to Employment Contract]

有鉴于此，本合同双方已于文首载明的日期签署或促使其有效授权代表签署本合同。

In WITNESS WHEREOF, the Parties hereto has executed or caused its duly authorized representative to execute this Contract as of the date first above written.

员工 / Employee：Yi Larson

签字/ Signature：_/s/ Yi Larson_____

[劳动合同签字页/Signature Page to Employment Contract]

[劳动合同签字页/Signature Page to Employment Contract]

附件一

Schedule 1

职位描述

JOB DESCRIPTION

员工在本合同项下的义务主要为提供以下服务（该服务应当按照最高的专业标准予以履行）：履行与本公司类似的生物制药企业的首席财务官的惯常职责并提供相关服务，以及履行本公司首席执行官合理分配给她的其他职责。

The general scope of the Employee's obligations hereunder shall be to provide the following services (all of which shall be performed in accordance with the highest professional standards): the Employee will perform such duties and services as are customary for the position of CFO in similarly situated enterprises in the biopharmaceutical industry and such other duties as may be reasonably assigned to her from time to time by the Chief Executive Officer of the Company.

附件二

Schedule 2

离职确认书

TERMINATION CERTIFICATE

特此证明本人不再拥有，并且本人按照本人与上海联拓生物科技有限公司（“**公司**”）间的劳动合同（“**劳动合同**”）的第8、9和12条的规定，向公司交还所有保密信息（如劳动合同第8.1条中所定义）和其他所有公司的文件、材料和财产（包括上述的副本）。

This is to certify that I do not have in my possession, and that I have returned to Shanghai LianBio Development Co., Ltd. (the “**Company**”) in compliance with Sections 8, 9 and 12 of the Employment Contract between me and the Company (the “**Employment Contract**”), all Confidential Information (as that term defined in Section 8.1 of the Employment Contract) of the Company and all other documents, materials, and property of the Company (including any copies of the foregoing).

本人进一步确认本人已遵守所有本人所签署的劳动合同的约定，包括向公司报告包含在劳动合同里任何本人（单独或与他人共同）构思或创作的公司知识产权（如劳动合同第9.3条定义）。本人确认和同意本人没有在先发明（如劳动合同第9.2条定义）或原创作品著作权；除了由本人在签署劳动合同时于劳动合同附件三中已列出的在先发明或原创作品著作权（如有）。

I further certify that I have complied with all the terms of the Employment Contract signed by me, including the reporting of any Company Intellectual Property (as defined in Section 9.3 of the Employment Contract), conceived or made by me (solely or jointly with others) covered by the Employment Contract. I acknowledge and agree that I have no Prior Inventions (as defined in Section 9.2 of the Employment Contract) or original works of authorship other than those, if any, identified by me on Schedule 3 to the Employment Contract at the time that I signed the Employment Contract.

姓名/ Print Name：_____

签字/ Signature：_____

解除日/ Termination Date：_____

附件三

Schedule 3

在先发明和有著作权的原创作品名单

LIST OF PRIOR INVENTIONS

AND ORIGINAL WORKS OF AUTHORSHIP

编号 / No.	所有权 / Title	日期 / Date	识别码或简要说明 / Identifying Number or Brief Description
1.			
1.			
1.			
1.			
1.			
1.			
1.			

□无在先发明或有著作权的原创作品/ No Prior Inventions or original works of authorship

□附上额外页/ Additional Sheets Attached

员工姓名/ Name of Employee：

员工签名/ Signature of Employee：

日期/ Date：

劳动合同附录

ADDENDUM TO EMPLOYMENT CONTRACT

本劳动合同附录（本"**附录**"）旨在就上海联拓生物科技有限公司（"**公司**"）和 Yi Larson（"**员工**"）之间于2022年10月1日生效的劳动合同（"**合同**"）进行补充。本附录于合同生效之日同日生效。本附录中使用的所有被定义的术语，如本文未另行定义，应具有合同中所赋的含义。

The purpose of this Addendum to Employment Contract (the "**Addendum**") is to supplement the Employment Contract (the "**Contract**"), effective as of October 1, 2022, by and between Shanghai LianBio Development Co., Ltd., (the "**Company**") and Yi Larson (the "**Employee**"). This Addendum shall take effect on the same date of the Contract. All defined terms used in this Addendum that are not otherwise defined herein shall have the meaning ascribed to them in the Contract.

签署方特此同意如下：

The undersigned parties hereby agree as follows:

1. **调动福利**。

Relocation Benefits.

在员工与公司之间存在有效且可执行的劳动合同的前提下，员工从美国到中国的调动将于2022年10月1日开始，预计将于2026年9月30日结束。但是，公司并不保证调动期长短，因业务状况和/或签证需要，公司可能会缩短或延长员工的调动期限。为免疑义，公司决定缩短员工的调动时间不应构成合同第12.5条或其他条款规定的正当理由事件。一旦员工被调回美国，员工将与LianBio美国公司签订一份由LianBo美国公司提供的劳动合同，该合同将完全取代本合同和附录。

除合同第4条规定的员工工资和福利待遇外，员工还将有资格获得有效的且可由公司独自决定不时修改的高管国际调动/派遣政策下的津贴、费用报销、福利以及服务（"**高管国际调动/派遣福利政策**"），附件A（"**Yi Larson的调动薪酬福利清单**"）以及下文提及的税负平衡和税务申报服务（合称"**调动福利**"）。

为免疑义，Yi Larson的调动薪酬福利清单将在2026年9月30日或之前保持不变，除非合同没有续签或者员工或公司根据合同条款和条件解除合同。但公司可在2026年9月30日后自行决定修改和/或撤销Yi Larson的调动薪酬福利清单的部分或全部内容以及税负平衡和税务申报服务，并于书面通知员工九十（90）日后生效。2026年9月30日之后，对Yi Larson的调动薪酬福利清单以及税负平衡和税务申报服务的任何调整、削减和取消，均不构成合同第12.5条或其他规定的正当理由。2026年9月30日之前，对Yi Larson的调动薪酬福利清单以及税负平衡和税务申报服务的任何调整、削减和取消，均构成合同第12.5条或其他条款规定的正当理由事件。

The relocation of the Employee from the United States to China will begin on October 1, 2022 and it is anticipated that it will end on September 30, 2026, provided for the existence of a valid and enforceable employment contract between the Employee and the Company. The Company does not guarantee the length of the relocation, however, as business conditions and /or visa requirements may require the Company to reduce or extend the duration of the Employee's relocation. For the avoidance of doubt, the Company's decision to reduce the duration of the Employee's relocation shall not constitute an event of Good Reason for purposes of Section 12.5 of the Contract or otherwise. Once the Employee is repatriated to the United States, the Employee will enter into an employment agreement with LianBio US in the form provided by LianBio US, which shall replace in its entirety the Contract and the Addendum.

In addition to the Employee's compensation and benefits as specified in Section 4 of the Contract, the Employee will be eligible to receive the allowances, reimbursements, benefits and services outlined in the Executive International Relocation/Assignment Policy (the "**Executive International Relocation/Assignment Benefit Policy**"), as in effect, and as may be modified by the Company in its sole and exclusive discretion, from time to time, and Appendix A (the "**Relocation Compensation and Benefit List for Yi Larson**"), as well as the tax equalization and tax preparation service referenced below (collectively, the "**Relocation Benefits**").

For the avoidance of doubt, the Relocation Compensation and Benefit List for Yi Larson shall not be modified and/or revoked on or before September 30, 2026, unless the Contract is not renewed or terminated by the Employee or the Company in accordance with its terms and conditions. The Company may, at its sole and exclusive discretion, modify and/or revoke all or a portion of the Relocation Compensation and Benefit List for Yi Larson, and the tax equalization and tax preparation service, after September 30, 2026, which shall become effective after giving ninety (90) days of prior written notice to the Employee. Any such modification, reduction or revocation of the Relocation Compensation and Benefit List for Yi Larson, and the tax equalization and tax preparation service, after September 30, 2026 shall not constitute an event of Good Reason for purposes of Section 12.5 of the Contract or otherwise. Any such modification, reduction or revocation of the Relocation Compensation and Benefit List for Yi Larson, and the tax equalization and tax preparation service, before September 30, 2026 shall constitute an event of Good Reason for purposes of Section 12.5 of the Contract or otherwise.

2. 税负平衡。

Tax Equalization.

员工负责其在调动前所在国家的假设税。假设税是指，在员工在没有调动的情况下，对于从公司赚取的收入包括基本工资、年终奖和股票期权行权/受限股票单位或其他基于股权的奖励的归属和/或结算产生的收益而本应在原籍国支付的国家和州/市/地方（或省、州）的所得税和社会税（如适用）。假设税按每个支付周期从员工薪酬中扣除。

The Employee is responsible for home country hypothetical tax. Hypothetical tax is the national and state/city/local (or provincial, cantonal) income and social tax, if applicable, on Company-earned income, including base salary, annual bonus, and gains from the exercise of stock options/vesting and/or settlement of restricted stock units or other equity-based awards that the Employee would have paid in the home country had there been no relocation. Hypothetical tax is deducted from the Employee's compensation on a per-pay period basis.

公司将负责支付因员工调动而产生的与LianBio支付的员工在职收入相关的实际中国和调动前所在国家的税费。一旦完成所有纳税申报表，员工通过扣除支付的假设税额和公司支付的实际税额将在公司指定的税务供应商进行的年度税负平衡核对过程中进行核对。如果税负核对显示假设扣除额（以及任何实际支付的税款减去收到的任何退款）超过最终的假设税款，则公司将退还员工超出的金额。相反，员工必须向公司支付因最终假设税的差额而所欠公司的金额。

The Company will be responsible for paying actual China and home country taxes resulting from the relocation in relation with the Employee's employment income paid by LianBio. Hypothetical tax amounts paid by the Employee through deductions and actual tax amounts paid by the Company will be reconciled during the annual tax equalization reconciliation process conducted by the Company-designated tax provider once all tax returns are completed. If the tax reconciliation shows that the hypothetical deductions (as well as any actual taxes paid less any refunds received) exceed the final hypothetical tax, then the Company will refund the Employee the excess amount. Conversely, the Employee must repay the Company any funds owed for any shortfall in payment of her final hypothetical tax.

员工有责任确保及时申报所有要求的纳税申报表。如果公司的税务服务供应商未被及时提供所需的税务信息，或者员工未遵守税务服务供应商的税务申报指示，则因未能遵守前述要求而产生的任何罚款和利息将由员工承担。

It is the responsibility of the Employee to ensure that all required tax returns are filed on a timely basis. If the Company's tax firm is not provided with the required tax information on a timely basis or the Employee does not follow the tax firm's tax filing instructions, any penalties and interest resulting from failure to comply will remain the responsibility of the Employee.

预估的假设税包括美国联邦所得税部分和员工在进行调动之前所居住州的州所得税部分。如果应在员工调动前所在国家缴纳加州税款，员工有责任承担与其基本工资、年终奖和股票期权行权/受限股票单位或其他基于股权的奖励的归属和/或结算产生的收益相关的州所得税。具体而言，就州税之目的，员工和公司同意不将加利福尼亚州视为其居住州，但前提是，员工为加利福尼亚州税收之目的被视为非居民。如果在员工的原籍国

实际应缴纳加利福尼亚州税款，员工应自行承担就其基本工资、年终奖及股票期权行权/受限股票单位或其他基于股权的奖励的归属和/或结算产生的收益而需缴纳的州所得税。如果员工为加利福尼亚州税收之目的被视为非居民，员工应承担其返回调动前所在国家时所在州的假设税。

Estimated hypothetical tax includes a U.S. federal income tax component and a resident state income tax component for the state in which the Employee would be resident prior to undertaking the relocation. In the event California taxes are due in the Employee's home country, it will be the Employee's responsibility to cover state income tax due in connection with her base salary, annual bonus, and gains from the exercise of stock options/vesting and/or settlement of restricted stock units and other equity-based awards. Specifically, for the purposes of state tax, the Employee and the Company agree to not consider California as the state of residency, provided Employee is considered a nonresident for California taxes purposes. In the event that actual California taxes are due in the Employee's home country, it will be Employee's responsibility to cover state income tax due on the Employee's base salary, annual bonus and gains from the exercise of stock options/vesting and/or settlement of restricted stock units and other equity-based awards. In the event that the Employee is considered nonresident for California tax purposes, the Employee will be held to the hypothetical tax of the state that the Employee would be resident of on repatriation to home country.

3. 税务申报服务。

Tax Preparation Service.

公司将通过指定的税务服务供应商（该等指定的税务服务供应商将由公司自主决定）为员工提供税务服务，以便为员工，包括其未工作的配偶/伴侣准备和提交每一调动年度的中国和调动前所在国家的个人所得税申报表，包括归国当年，以及归国后仍有剩余与调动相关收入和/或有效的重大外国税收抵免的年度（具体由公司的税务服务供应商确定但不包括与员工的个人收入、配偶收入或员工从其拥有的公司实体（如公司和有限责任合伙）获得的非员工工资的所有商业收入的附加表格。公司的税务服务供应商将与员工就其纳税申报信息的具体内容保持专业关系。

The Company will provide the Employee with tax services via a designated tax service provider (such designated tax service provider to be determined in the sole discretion of the Company) to prepare and file China and home country individual income tax returns for the Employee, inclusive of her on-working spouse/partner, while exclusive of additional forms related to personal income, spousal income or all business income derived from all corporate entities (such as corporations and LLPs) that is not the Employee's salary, for each year of relocation, including the year in which repatriation occurs, and any year following repatriation if there is still residual relocation-related income and/or significant foreign tax credits in effect, as determined by the Company's tax service provider. The Company's tax service provider will maintain a professional relationship with the Employee with respect to the details of her tax return information.

如果员工聘用其他税务服务供应商，员工应自行承担所有相关风险和费用。公司提供的税务服务范围仅限于纳税申报表所列的与调动相关的应税项目。公司鼓励员工会见其私人财务顾问。

If the Employee engages another tax service provider, the Employee shall bear all associated risks and expenses. Tax service coverage provided by the Company is limited to relocation related items taxable in the tax return. The Employee is encouraged to meet with her personal financial advisor.

[以下无正文，为签字页 / Remainder of page intentionally left blank, signature pages follow]

有鉴于此，本附录双方于文首载明的日期签署或促使其有效授权代表签署本附录。

In WITNESS WHEREOF, the Parties hereto has executed or caused its duly authorized representative to execute this Addendum as of the date first above written.

公司/COMPANY:

上海联拓生物科技有限公司（公章）

Shanghai LianBio Development Co., Ltd. (Chop)

姓名/Name: 王轶喆/Yizhe Wang

职务/Title: 法定代表人/Legal Representative

签字/Signature: _/s/ Yizhe Wang_____

[劳动合同附录签字页/Signature Page to Addendum to Employment Contract]

有鉴于此，本附录双方于文首载明的日期签署或促使其有效授权代表签署本附录。

In WITNESS WHEREOF, the Parties hereto has executed or caused its duly authorized representative to execute this Addendum as of the date first above written.

员工/Employee: Yi Larson

签　　字　　/Signature:　　_/s/ Yi Larson_____

[劳动合同附录签字页/Signature Page to Addendum to Employment Contract]

附件A
Appendix A

Yi Larson的调动薪酬福利清单
Relocation Compensation and Benefit List for Yi Larson

合同生效后，Yi Larson的常规薪酬（包括基本工资和酌情年终奖）将继续根据LianBio美方的薪酬调整指引执行。LianBio LLC根据LianBio 2021股权激励计划授予Larson女士的股权奖励将继续由 LianBio, LLC进行管理。

Upon the effective date of the Contract, Yi Larson's regular compensation (including base salary and discretionary annual bonus) will continue to be subject to LianBio's US-side salary adjustment guideline. The equity awards granted by LianBio, LLC to Ms. Larson will continue to be administered by LianBio, LLC under the LianBio 2021 Equity Incentive Plan.

根据高管国际调动/派遣政策，自2022年10月1日，Larson女士将有资格获得下文表一所列的国际调动福利，以及公司向其中国员工普遍提供的其他社会保险和补充福利，包括但不限于商业保险、法定年休假以及社会保险。其在美国方面的福利，包括社会保险和公司补充福利（包括401K计划、美国医疗保险、休假等）将停止。为免疑义，以下各项调动福利始终受限于公司的审查和批准，且可由公司依据附录第一条进行修改或撤销。除另有说明外，公司将仅报销和/或向员工（或第三方供应商，如注明）支付所发生的实际费用，且不超过注明的金额。

Pursuant to the Executive International Relocation/Assignment Policy, effective October 1, 2022, Ms. Larson will be eligible to receive the international relocation benefits listed in Table 1 below, as well as other social security and supplementary benefits that are provided by the Company to its Chinese employees generally, including but not limited to commercial insurance, Statutory annual leave, and social insurance. Her US-side benefits, including social security insurance and company supplementary benefits (including 401K, US healthcare insurance, leave, etc.) will cease. For the avoidance of doubt, each of the relocation benefits set forth below remain at all times subject to the Company's review and approval and can be modified or revoked by the Company pursuant to Section 1 of the Addendum. Except where noted, the Company will only reimburse and/or pay the Employee (or the third party provider, as noted) for actual expenses incurred, up to a maximum amount as noted.

基本工资，奖金和津贴的发放将由上海联拓生物科技有限公司和LianBio LLC根据公司商定的发薪币种共同管理。在第一年，根据Larson女士的选择，100%的税后年度基本工资和酌情发放的年终奖将以美元形式发放，但是生活费津贴，调动/归国津贴，以及配偶津贴将以人民币形式发放。公司将于每年发薪币种调整的窗口期通知Larson女士。

Base salary, bonus and allowances payment will be jointly administrated by Shanghai LianBio Development Co., Ltd. and LianBio LLC based on currency fluctuation agreed by the companies. For the initial year, as opted by Ms. Larson, **100%** of the after-tax annual base salary and discretionary annual bonus will be paid in **USD**, while cost of living allowance, relocation/repatriation allowance, and spouse allowance will be paid in **RMB**. Company will notify Ms. Larson of the currency fluctuation adjustment open window each following year.

表1 调动福利

Table 1 Relocation Benefits

1. 抵达中国后将提供的调动/派遣定期支持:
Relocation/Assignment recurring support to be provided upon arrival in China:

项目 **Items**	**费用要求** **Spending Requirement**	**支付周期** **Payment Frequency**	**支付方式** **Payment Method**
子女教育 Children education	1. 对于所有符合条件的子女，每学年（发票开具日）的总额最高不超过人民币1,000,000元（即与子女教育相关的所有金额不超过人民币1,000,000元/学年），最多不超过三名子女。 Up to a maximum aggregate of RMB 1,000,000/academic year (invoice issue date) for all eligible children (i.e., all amounts relating to Children Education shall not exceed RMB1,000,000 /academic year), up to a maximum of three children. 2. [***]	[***]	[***]
住房支持 Housing support	实际每月住房开支，但不超过人民币70,000元/月，不包括水电费 Actual monthly housing rental expenditure up to RMB 70,000/month cap, excluding utilities	[***]	[***]
公司用车 Company car	每月最高人民币30,000元/月，包含发生的超时用车费用及其他费用，如套餐津贴、停车费、清洁费、燃料费、通行费等（具体的车辆使用指导见附表2）。 Up to RMB 30,000/month capped inclusive of car usage overtime costs incurred and other costs such as fixed meal allowance, parking fee, cleaning, fuel, tolls, etc. (detail car usage guidance as attached table 2). [***]	[***]	[***]
保险 Insurance	[***]	[***]	[***]
语言培训 Language training	五位家庭成员的中文语言课程费用报销总计（即并非每人）： Reimbursement of Chinese language classes/lessons for five family members in the aggregate (i.e., not per person): 2022日历年度（发票开具日）人民币80,000元封顶 RMB 80,000 capped in 2022 calendar year (invoice issue date) 2023&2024日历年度（发票开具日）人民币40,000元封顶 RMB 40,000 capped in 2023&2024 calendar year (invoice issue date)	[***]	[***]

2. 在合同生效之日起提供的调动/派遣定期支持:
Relocation/Assignment recurring support to be provided upon effective date of the employment contract:

项目 **Items**	**费用要求** **Spending Requirement**	**支付周期** **Payment Frequency**	**支付方式** **Payment Method**
生活费津贴 Cost of living allowance	年基本工资的10%，根据公司独自决定，根据中国的合同生效及合同结束时间进行折算 10% of Annual Base Salary, prorated upon commencement of effectiveness of China assignment and terminating upon cessation of China assignment as determined in the sole discretion of the Company	[***]	[***]
探亲假津贴（每年往返*五人） Home leave air ticket cost (round-trip per year * 5 persons)	[***]	[***]	[***]

3. 调动/归国一次性支持
Relocation/Repatriation One-Off Support:

项目 Items	费用要求 Spending Requirement	支付方式 Payment Method	开始时间 Commence Timing
签证申请/延期费（首次派遣） Visa application/extension fee (initiate assignment)	[***]	[***]	[***]
调动/归国机票（首次派遣） Relocation and repatriation air ticket cost (initiate assignment)	[***]		
调动/归国家庭用品国际运输（首次派遣） Relocation and repatriation international shipment of household goods (initiate assignment)	[***]		
调动后的临时居住（强制隔离后） Temporary living at relocation (after mandatory quarantine)	仅限租赁费用。不超过人民币50,000元/月，且不超过2个月，不包括任何强制隔离公司另行单独承担强制隔离费用 Rental fee only. Based on expenditure within RMB 50,000/month cap, 2 months excluding any quarantine. Company covers mandatory quarantine cost separately		
落地安排服务（当地导向） Accommodation service (local orientation)	按实际支出，不超过人民币25,000元。 Upon actual expenditure within budget RMB 25,000		
调动津贴 Relocation allowance	人民币50,000元固定金额 RMB 50,000 Fixed Amount	[***]	[***]
归国津贴 Repatriation allowance	人民币35,000元固定金额 RMB 35,000 Fixed Amount		
配偶津贴 Spousal allowance	人民币50,000元固定金额 RMB 50,000 Fixed Amount		

表2车辆使用指导

Table 2 Car Usage Guidance

[***]

附件A /Appendix A

Exhibit 10.49
Execution Version

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

COMMERCIALIZATION AGREEMENT

WITH RESPECT TO SISUNATOVIR

BY AND BETWEEN

LIANBIO DEVELOPMENT (HK) LIMITED

LIANBIO RESPIRATORY LIMITED

REVIRAL LTD

AND

PFIZER INC.

TABLE OF CONTENTS

COMMERCIALIZATION AGREEMENT

This COMMERCIALIZATION AGREEMENT (the "Agreement") is entered into as of December 16, 2022 (the "Effective Date"), by and between:

(1) **LianBio Development (HK) Limited**, a limited liability company organized under the laws of Hong Kong, having an address at RM 1901, 19/F Lee Garden One 33 Hysan Avenue, Causeway Bay HK ("LianBio Development");

(2) **LianBio Respiratory Limited**, a company limited by shares organized and existing under the laws of Hong Kong, having an address at Room 1902, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong ("LianBio Respiratory", together with LianBio Development, referred to collectively as the "LianBio Entities" and individually a "LianBio Entity");

(3) **ReViral Ltd.**, a corporation organized under the laws of England & Wales with principal offices at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, United Kingdom ("ReViral"), for the sole purposes as described in Section 8.8; and

(4) **Pfizer Inc.**, a Delaware corporation, having an address of 235 East 42nd Street, New York, New York 10017 (together with ReViral, "Pfizer").

LianBio Entities, ReViral and Pfizer each may be referred to herein individually as a "Party" or collectively as the "Parties". All attached appendices and exhibits are a part of this Agreement.

RECITALS

WHEREAS, LianBio (an exempted company organized under the laws of the Cayman Islands, the parent company of LianBio Development) and Pfizer Inc. entered into a Strategic Collaboration Agreement dated November 17, 2020 (the "Strategic Collaboration Agreement"), pursuant to which LianBio and Pfizer Inc. reached a strategic collaborative arrangement in the in-license, develop and commercialization of any pharmaceutical or biological product in any therapeutic area that LianBio acquires the right to develop and commercialize in the PRC, Hong Kong, Macau and Taiwan; and LianBio, LianBio Development and Pfizer Inc. entered into an Assignment and Assumption Agreement dated December 15, 2021, pursuant to which LianBio has assigned and transferred all its rights and obligations under the Strategic Collaboration Agreement to LianBio Development.

WHEREAS, LianBio Respiratory (which, as of the Effective Date, is a subsidiary wholly indirectly owned by LianBio) and ReViral (which, as of the Effective Date, is a subsidiary wholly owned by Pfizer Inc.) entered into a Co-Development and License Agreement dated March 1, 2021 (the "ReViral License Agreement"), pursuant to which ReViral granted to LianBio Respiratory certain rights in the PRC, Hong Kong, Macau and Singapore with respect to the Compound and Licensed Product (each as defined in the ReViral License Agreement).

WHEREAS, the Parties now agree that (i) Pfizer will exercise its opt-in right under the Strategic Collaboration Agreement with respect to the Relevant Product (as defined in Section 1.1 below) which will become the first Opted-In Product (as defined in the Strategic Collaboration Agreement) and Parties will enter into this Agreement as a Commercialization Agreement (as defined in the Strategic Collaboration Agreement) with respect to the first Opted-In Product under the Strategic Collaboration Agreement, and (ii) the Parties will enter into this Agreement to supersede the ReViral License Agreement in its entirety, with all licenses and rights granted by ReViral and/or Pfizer to LianBio Respiratory under the ReViral License Agreement reverting to Pfizer.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

1.1 For purposes of this Agreement, unless otherwise indicated in this Agreement, the following capitalized terms used herein will have the following meanings:

"Accounting Standards" means, for the purposes of Article 4, generally accepted accounting principles ("GAAP") as practiced in the United States followed by Pfizer and its Affiliates, currently used at the relevant time and consistently applied by them; or in the case of a Licensee (if applicable), the GAAP or International Financial Reporting Standards consistently applied by the Licensee.

"Affiliate" means, with respect to any Person, any Person controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For purposes of this definition, "control" means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Laws; provided, however, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Affiliates of a Party shall exclude Persons who are financial investors of such Party or under common control of such financial investors other than such Party and its subsidiary entities.

"Agreement" shall have the meaning ascribed to it in the Recitals.

"Annual Net Sales" means, during the Net Sales Sharing Term, the aggregate annual Net Sales of the Relevant Product in any Pfizer Year in the Territory; provided that the calculation of the Annual Net Sales shall be subject to Section 4.6 below.

"Anti-Corruption Laws" means any applicable international, national, state, and local laws, statutes, rules, and regulations regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to Public Officials or private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including but not limited to the United States Foreign Corrupt Practices Act, 15 U.S.C. §78-dd-1, et seq., the Criminal Law and Anti-Unfair Competition Law of the PRC, the Prevention of Bribery Ordinance of Hong Kong, and laws implementing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions; each as may be amended or supplemented from time to time.

"Business Day" means any day, other than a Saturday or a Sunday, on which the banks in New York and Hong Kong are open for business.

"Change of Control" shall mean, with respect to a Party, the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other similar transaction, as a result of which any Person gains control of such Party (where control has the meaning given to it in the definition of Affiliate).

"Challenge Action" shall have the meaning ascribed to it in Section 4.12.2.

"Combination Product" means, during the Net Sales Sharing Term, any Relevant Product that is sold in any Region of the Territory [***]. For the avoidance of doubt, Combination Product does not include [***].

"Competing Product" means [***].

"Commercial Milestone Event" shall have the meaning ascribed to it in Section 4.2.

"Commercially Reasonable Efforts" means [***].

"Confidential Information" shall have the meaning ascribed to it in Section 7.1.1.

"Cover", "Covering" or "Covered" means, with respect to a particular subject matter at issue and a relevant Patent or individual claim in such Patent, as applicable, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent or the individual claim of such Patent.

"Determined Compound" means [***].

"Dispute" shall have the meaning ascribed to it in Section 8.2.

"Distributor" means any Third Party that is appointed to distribute and sell Relevant Product and purchases its requirements of Relevant Product for resale from Pfizer or any of its Affiliates or Licensees, or from any contract manufacturing organization that manufactures Relevant Product on behalf of any of the foregoing; provided, however, that such Third Party does not pay upfront payments, milestone payments, royalties, commissions, or any other risk sharing payments to Pfizer or any of its Affiliates or Licensees with respect to its distribution and sale of such Relevant Product.

"Dollars" or "US$" means United States dollars.

"Effective Date" shall have the meaning ascribed to it in the Recitals.

"Excluded Region" [***].

"First Commercial Sale" shall mean, the first sale in the Territory, by Pfizer, its Affiliates or Licensees to an end user or prescriber (or to a Distributor for resale) for use or consumption of the Relevant Product in any Region within the Territory [***]; provided that such first sale occurs after the Regulatory Approval of the Relevant Product in that Region has been granted by the Regulatory Authority in that Region. For the avoidance of doubt, any supply of Relevant Products for [***] is not a First Commercial Sale.

"First PRC Regulatory Approval" means the obtaining by Pfizer or its Affiliate or Licensees of the first Regulatory Approval in the PRC of any pharmaceutical product containing [***] that is granted by the National Medical Products Administration (formerly the China Food and Drug Administration) of the PRC (the "NMPA").

"Government" or "Governmental Authority" means (i) any multinational, federal, national, state, provincial, local, regional or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government, (ii) any enterprise or instrumentality performing a government function; or (iii) any political party.

"HKIAC" shall have the meaning ascribed to it in Section 8.2.

"Law" or "Laws" means any applicable United States federal, state, or local law, or foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution, or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination, or award entered by or with any Governmental Authority, or any license, franchise, permit, or similar right granted under any of the foregoing, or any similar provision having the force or effect of law. For the avoidance of doubt, any specific references to any Applicable Law or any portion thereof shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, order, writ, judgment, injunction, decree, stipulation, ruling, or determination thereto.

"LianBio Development" shall have the meaning ascribed to it in the Recitals.

"LianBio Entities" or "LianBio Entity" shall have the meaning ascribed to it in the Recitals.

"LianBio Respiratory" shall have the meaning ascribed to it in the Recitals.

"Licensee(s)" means any Person other than an Affiliate of Pfizer to whom Pfizer has granted a license or sublicense under the Licensed IPR (as defined in the ReViral License Agreement), but not solely a trademark license, to Develop and Commercialize (both terms as defined in the ReViral

License Agreement) [***]. For the avoidance of doubt, Licensee shall not in any event include any Distributor.

"Monotherapy" means [***].

"Net Sales" means, during the Net Sales Sharing Term, with respect to the Relevant Product, the gross amount invoiced by Pfizer and its Affiliates and Licensees (each of the foregoing, a "Seller") to independent, unrelated persons (including Distributors) ("Buyers") in bona fide arm's length transactions with respect to the Relevant Product, less the following deductions and offsets [***]:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***]; and

(g) [***].

[***].

Subject to the above, Net Sales shall be calculated in accordance with [***]. Transfers or sales among Pfizer and its Affiliates and Licensees will be disregarded for purposes of calculating Net Sales.

With respect to Net Sales not denominated in Dollars, Net Sales shall be converted from the applicable foreign currency into Dollars in accordance with [***].

In the event that the Relevant Product is sold in any Region as part of a Combination Product, then [***].

"Net Sales Sharing Term" shall mean [***].

"Party" or "Parties" shall have the meaning ascribed to it in the Recitals.

"Patents" shall mean:

(a) all national, regional and international patents and patent applications, including provisional patent applications; and

(b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications; and

(c) any and all patents that have issued or in the future issue from the foregoing patent applications in paragraphs (a) and (b) including author certificates, inventor certificates, utility models, petty patents and design patents and certificates of invention.

"Person" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

"Pfizer Quarter" means [***].

"Pfizer Year" means [***].

"PRC" means the People's Republic of China, which for the sole purposes of this Agreement, excludes Hong Kong, Macau and Taiwan.

"Pfizer" shall have the meaning ascribed to it in the Recitals.

"Public Official" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

"Regulatory Approval" means the final or conditional approval of the applicable Regulatory Authority necessary for the marketing and sale of the Relevant Product in the Territory.

"Regulatory Authority" means any multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, manufacture, marketing or sale of the Relevant Product in the Territory, including the NMPA.

"Regulatory Exclusivity" shall mean, during the Net Sales Sharing Term, with respect to the Relevant Product in any Region in the Territory, [***], in each case, in accordance with applicable Laws in such Region (other than, for the avoidance of doubt, any Patent protection).

"Regulatory Milestone Event" shall have the meaning ascribed to it in Section 4.1.

"Regulatory Milestone Payment" shall have the meaning ascribed to it in Section 4.1.

"Relevant Compound" means: [***].

"Relevant Product" means any pharmaceutical product containing the Relevant Compound [***].

"Relevant Factors" means [***].

"Relevant Objective" shall have the meaning ascribed to it in Section 2.6.

"ReViral" shall have the meaning ascribed to it in the Recitals.

"ReViral License Agreement" shall have the meaning ascribed to it in the Recitals.

"RSV" means respiratory syncytial virus.

"RV521" means Sisunatovir (RV521), Pfizer's proprietary compound, having the chemical structure described on Exhibit A of the ReViral License Agreement.

"RV956" means RV-00014956, a proprietary compound of Pfizer (as listed on Exhibit B of the ReViral License Agreement other than RV521).

"Strategic Collaboration Agreement" shall have the meaning ascribed to it in the Recitals.

"Territory" means the PRC, Hong Kong, Macau and Singapore, where each of the PRC, Hong Kong, Macau and Singapore is individually referred to as a "Region".

"Third Party" means any Person other than a Party or any of its Affiliates.

"United States" or "U.S." or "US" means the United States and its territories, possessions and commonwealths.

"Valid Claim" means (a) a claim of any issued and unexpired Patent whose validity, enforceability, or patentability has not been rendered invalid by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, Governmental Authority, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim in a Patent application that has not been pending more than [***] from [***]. For clarity, (A) any claim in a Patent application, for which more than [***] have lapsed from [***], shall not be considered a Valid Claim, and (B) a holding, finding, or decision being final and unappealable or not appealed within the time allowed for appeal means a holding, finding, or decision from which no appeal can be or has been taken.

Article 2
FIRST OPTED-IN PRODUCT

1.1 **Definitions used in Article 2**. For the sole purposes of this Article 2, capitalized terms used in this Article 2 which are not defined in this Agreement shall have the meanings given to them in the Strategic Collaboration Agreement.

1.2 **Pfizer's Exercise of First Opt-In**. The Parties agree that, as of the Effective Date,

1.1.1 LianBio Development shall be deemed to have provided the Opt-In Notice with respect to the Relevant Product to Pfizer pursuant to Section 2.2.1 of the Strategic Collaboration Agreement;

1.1.2 Pfizer shall be deemed to have provided the Opt-In Confirmation to LianBio Development with respect to the Relevant Product pursuant to Section 2.2.2 of the Strategic Collaboration Agreement; and

1.1.3 the Relevant Product shall become the first Opted-In Product, subject to the terms and conditions of this Agreement.

1.3 **Waiver of LianBio's Development Obligation with respect to the Relevant Product.** Notwithstanding the Relevant Product being the first Opted-In Product, from the Effective Date, Pfizer hereby waives any obligation of LianBio and LianBio Entities to Develop (and, for the avoidance of doubt, any obligation to Commercialize as well) the Relevant Product under the Strategic Collaboration Agreement, including but not limited to the obligations under Section 2.4 (*Development of Opt-In Product*) and Section 3.5 (*Commercialization Agreement*) of the Strategic Collaboration Agreement.

1.4 **Release of Upfront Payment; No Reimbursement Obligations with respect to Relevant Product.** Notwithstanding any provision to the contrary in the Strategic Collaboration Agreement, with effect from the Effective Date:

1.1.1 in consideration of Pfizer's exercise of the opt-in right with respect to the Relevant Product, the Upfront Payment (in the amount of Twenty Million U.S. Dollars ($20,000,000) that has already been paid by Pfizer and received by LianBio Development prior to the Effective Date shall, with no further action required from either Party, become unrestricted and LianBio Development shall thereafter be free to use the entirety of the Upfront Payment as it chooses;

1.1.2 without prejudice to Section 2.4.1 above, neither LianBio Development nor any of its Affiliates shall have any right to invoice, or require Pfizer or any of its Affiliates to reimburse, pay or otherwise bear, any cost (including any Eligible Costs) in relation to the Relevant Product under or in connection with the Strategic Collaboration Agreement (including Section 2.5.1 of the Strategic Collaboration Agreement), whether actual, contingent or otherwise; and

1.1.3 for clarity, Pfizer shall be released from any obligation or liability, whether for the Relevant Product as the first Opted-In Product or any subsequent Opted-In Products, with respect to the First Opt-In Contingent Payment Cap (i.e. US$20,000,000) under Section 2.5.1(c) of the Strategic Collaboration Agreement.

1.5 **Development and Commercialization of Relevant Product.** Notwithstanding any provision to the contrary in the Strategic Collaboration Agreement, with effect from the Effective Date:

1.1.1 Pfizer shall have all rights, with no further action required from LianBio Development or any of its Affiliates, to Develop and Commercialize the Relevant Product in the Territory, it being further specified that, for clarity, with effect from the Effective Date, neither LianBio Development nor any of its Affiliates shall have any right to Develop or Commercialize the Relevant Product anywhere in the world; nor shall Pfizer's right to Develop and Commercialize the Relevant Product in the Territory, in such manner as may be deemed appropriate by Pfizer at its sole discretion (including, for the avoidance of doubt, through any licensee of Pfizer), be subject to any right of LianBio Development under the Strategic Collaboration Agreement or otherwise; and

1.1.2 Pfizer will, through the Joint Collaboration Committee under the Strategic Collaboration Agreement, and, if the Joint Collaboration Committee no longer exists, directly to LianBio Development, provide LianBio Development with:

(a) an annual update on the status of the Development of the Relevant Product in the Territory to be provided within [***] after the end of each Pfizer Year, and interim updates on any material change to the Development of the Relevant Product or plans therefor in the Territory that delays or reasonably would be expected to delay the timing for Regulatory Approval in the PRC [***] to be provided reasonably promptly, but in any event no later than [***], after the occurrence of such change;

(b) notification with respect to the following: [***]; and

(c) during the Net Sales Sharing Term, a non-binding annual Net Sales forecast of the Relevant Product in the Territory,

in each case of (a) to (c), solely for LianBio Development's information purposes; *provided that* all information provided pursuant to sub-paragraphs (a) to (c) will constitute Pfizer's Confidential Information under Article 7 below and LianBio Development shall abide by its obligations under Article 7 below with respect to such information.

Furthermore, Pfizer shall no longer have any obligation to provide LianBio Development with any information or data under this Section 2.5.2 in the event that [***].

1.6 **Development Diligence with respect to RV521**. Pfizer will use Commercially Reasonable Efforts to [***] ("Relevant Objective"). [***]. Notwithstanding any provision of this Agreement to the contrary, Pfizer will be relieved of and considered to have satisfied in full its obligations under this Section 2.6 to the extent that [***].

1.7 **Other Supplements to the Strategic Collaboration Agreement with respect to Relevant Product.** Notwithstanding any provision to the contrary in the Strategic Collaboration Agreement and notwithstanding the Relevant Product being the first Opted-In Product:

1.1.1 Section 2.6 (*Joint Steering Committee*) (for clarity, the "Joint Collaboration Committee" under Article 5 shall continue to apply), Section 2.7 (*Pfizer Services*), Article 3 (*Right of First Negotiation*), Article 6 (*Intellectual Property*) and Article 8 (*Indemnification*) of the Strategic Collaboration Agreement shall not apply to the Relevant Product (and, without prejudice to Section 2.5.1 and Section 2.7.2, each of LianBio Development and Pfizer shall be deemed to have, with effect from the Effective Date, irrevocably waived its respective rights with respect to the Relevant Product under such provisions of the Strategic Collaboration Agreement as referred to in the foregoing sentence of this Section 2.7.1); and

1.1.2 the following shall apply:

(a) any and all intellectual property rights developed or generated by Pfizer, any of its Affiliates or any of their employees, independent contractors or agents in relation to the Relevant Compound or Relevant Product, whether in or out of the Territory and whether before, at or after the Effective Date, under the Strategic Collaboration Agreement, this Agreement or otherwise will be solely owned by Pfizer and Pfizer will not have any obligation under the Strategic Collaboration Agreement or this Agreement to assign any right or interest or grant any license to LianBio Development or any of its Affiliates with respect to any of such intellectual property rights; and LianBio Development (for itself and on behalf of its Affiliates) hereby irrevocably waive any claim to any right or interest in any intellectual property rights or information or data in relation to the Relevant Compound or Relevant Product arising under or from any activities under the Strategic Collaboration Agreement or this Agreement; and

(b) from the Effective Date, neither LianBio, LianBio Development nor Pfizer shall have any obligation or liability to each other with respect to the Relevant Product (as the first Opted-In Product) under the Strategic Collaboration Agreement; and, for the further avoidance of doubt, if the Strategic Collaboration Agreement is terminated pursuant to Section 9.2.1 or Section 9.2.2 of the Strategic Collaboration Agreement, Pfizer shall have no obligation or liability to LianBio Development under Section 9.3 of the Strategic Collaboration Agreement with respect to the Relevant Product.

1.8 **Subsequent Opted-In Products.** LianBio Development's obligation under the Strategic Collaboration Agreement to conduct Sourcing Activities shall be unaffected by this Agreement. For the avoidance of doubt, the next Product for which Pfizer exercises its Opt-In Right under the Strategic Collaboration Agreement after the Relevant Product (if any) shall be the second Opted-In Product, and:

1.1.1 if Pfizer exercises its opt-in right with respect to the second Opted-In Product, Section 2.5.2 (*Second Opted-In Product*) of the Strategic Collaboration Agreement, including the Second Opt-In Payment (i.e. [***]) and the Second Opt-In Contingent Payment Cap (i.e. [***]), shall apply with respect to such product; and

1.1.2 with respect to any Opted-In Product after the second Opted-In Product until the [***] Opted-In Product, Section 2.5.3 of the Strategic Collaboration Agreement shall apply;

provided that, notwithstanding any provision to the contrary in the Strategic Collaboration Agreement or this Agreement, with effect from the Effective Date, the Aggregate Contingent Payment Cap shall only comprise the Second Opt-in Contingent Payment Cap (i.e. [***]).

Article 3
SUPERSESSION OF REVIRAL LICENSE AGREEMENT

1.1 **Supersession of ReViral License Agreement**. With effect from the Effective Date, this Agreement shall unconditionally and irrevocably supersede the ReViral License Agreement in its entirety. Without prejudicing the generality of the foregoing sentence, with effect from the Effective Date:

1.1.1 all the licenses and rights granted by ReViral and/or Pfizer to LianBio Respiratory under the ReViral License Agreement shall unconditionally and irrevocably revert to Pfizer;

1.1.2 neither LianBio Respiratory nor any of its Affiliates shall have or retain any right under the ReViral License Agreement, including, for the avoidance of doubt, any right with respect to any Compound or Licensed Product (each as defined under the ReViral License Agreement);

1.1.3 the obligations of each of LianBio Respiratory, ReViral and/or Pfizer to the other party(ies) under the ReViral License Agreement are forever waived, satisfied and extinguished, and none of them shall have any further obligation or liability to each other under the ReViral License Agreement, including (for the avoidance of doubt and notwithstanding any provision to the contrary in the ReViral License Agreement) any obligation under Sections 14.6, 14.7 and 14.8 and any

provision in the ReViral License Agreement referred to in the last sentence of Section 14.9 of the ReViral License Agreement; provided that:

(a) each of LianBio Respiratory, ReViral and Pfizer shall continue to abide by its obligations under Section 11 (*Confidentiality*) of the ReViral License Agreement, for a period of [***] after the Effective Date;

(b) promptly after the Effective Date, LianBio Respiratory shall destroy all Confidential Information (as defined in the ReViral License Agreement) in its possession as of the Effective Date (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the LianBio Respiratory to confirm compliance with the non-use and non-disclosure provisions of the ReViral License Agreement). Notwithstanding the foregoing, LianBio Respiratory shall not be required to destroy and any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received such Confidential Information under the ReViral License Agreement; and

(c) without prejudice to Section 5.2.2, in the event that there is any Licensee IPR (as defined in the ReViral License Agreement), LianBio Respiratory hereby unconditionally and irrevocably grants to Pfizer a fully paid, royalty free, perpetual, exclusive and sublicensable (through multiple tiers) license under the Licensee IPR for any purposes anywhere in the world.

Article 4
FINANCIAL TERMS

1.1 **Regulatory Milestone**. Pfizer shall make a one-time milestone payment of [***] to LianBio Development (the "Regulatory Milestone Payment") upon and only after the First PRC Regulatory Approval (the "Regulatory Milestone Event") to the extent that the First PRC Regulatory Approval occurs prior to the end of the Net Sales Sharing Term.

1.2 **Commercial Milestones**. Pfizer shall pay to LianBio Development the one-time milestone payments set forth in the table below upon and only after the Annual Net Sales first meets or exceeds the indicated Dollar value in a Pfizer Year (each a "Commercial Milestone Event") to the extent the relevant Commercial Milestone Event occurs prior to the end of the Net Sales Sharing Term.

Annual Net Sales	**Payment Amount**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

1.3 **Achievement of Milestones**. Each Regulatory Milestone and each Commercial Milestone (collectively, "Milestones") shall be payable a maximum of one time regardless of the number of times such Milestone is achieved under this Agreement or the number of Relevant Products developed or commercialized hereunder or the number of dosage forms or formulations of the Relevant Product developed or commercialized hereunder. All milestone payments made to LianBio Development pursuant to Sections 4.1 and 4.2 shall be non-refundable and shall not be creditable against any other amount due to LianBio Development pursuant to this Agreement. The maximum amount payable by Pfizer to LianBio Development under Sections 4.1 and 4.2 is one hundred thirty-five million U.S. Dollars (US$135,000,000). WITHOUT LIMITING THE FOREGOING, THE PARTIES AGREE THAT THE REGULATORY MILESTONE EVENT AND COMMERCIALIZATION MILESTONE EVENTS SET FORTH IN THIS AGREEMENT ARE MERELY INTENDED TO DEFINE THE REGULATORY MILESTONE PAYMENT AND COMMERCIALIZATION MILESTONE PAYMENTS IF SUCH REGULATORY MILESTONE EVENT AND COMMERCIALIZATION MILESTONE EVENTS ARE ACHIEVED. NONE OF

THE PARTIES MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT PFIZER WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE THE RELEVANT PRODUCT IN THE TERRITORY OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF THE RELEVANT PRODUCT WILL BE ACHIEVED [***].

1.4 **Reporting and Timing of Milestone Payments**. Pfizer shall report the occurrence of each milestone event under Sections 4.1 within [***] of its occurrence and any milestone event under Section 4.2 at the same time as Pfizer provides the report set forth in Section 4.5.2. Promptly following the delivery of any such report, LianBio Development shall invoice Pfizer for any applicable milestone payments due to LianBio Development in accordance with Sections 4.1 and 4.2, and Pfizer shall pay such amounts to LianBio Development in Dollars within [***] following Pfizer's receipt of such invoice.

1.5 **Net Sales Sharing**.

1.1.1 During the Net Sales Sharing Term, Pfizer shall, for each Pfizer Year and in accordance with Section 4.5.2, make the following payment ("Net Sales Sharing Amount") to LianBio Development:

Net Sales Sharing Amount = **A** + **B** + **C** + **D** where:

A equals [***];

B equals [***];

C equals [***];

D equals [***].

1.1.2 During the Net Sales Sharing Term, within [***] of the end of each Pfizer Quarter, Pfizer shall send to LianBio Development a written report setting out, (i) the amount of the aggregate Net Sales in the Territory during such Pfizer Quarter expressed in Dollars (which shall be converted from local currency in the respective Region of the Territory into Dollars in accordance with Section 4.8), subject to, for the avoidance of doubt, Section 4.6 below and (ii) the amount of the Net Sales Sharing Amount due to LianBio Development in relation to such Pfizer Quarter, it being understood that, notwithstanding the calculation of the Net Sales in the Territory and payment of the Net Sales Sharing Amount on a Pfizer Quarterly basis, the Net Sales Sharing Amount for each Pfizer Year shall be subject to annual true-up following the year-end in accordance with the Accounting Standards. Upon receipt of such report, LianBio Development shall invoice Pfizer for the Net Sales Sharing Amount due and Pfizer shall pay the same to LianBio Development in Dollars within [***] of Pfizer's receipt of such invoice.

1.1.3 Pfizer shall, and shall cause its Affiliates to keep complete and accurate books and records pertaining to the Net Sales of the Relevant Product in the Territory, in reasonable detail to calculate all amounts payable by Pfizer hereunder. At the request of LianBio Development, Pfizer shall permit an independent public accounting firm of internationally recognized standing designated by LianBio Development and reasonably acceptable to Pfizer, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to this Section 4.5.3 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (i) be conducted for any Pfizer Quarter more than [***] after the end of such quarter, (ii) be conducted more than once in any [***] period or (iii) be repeated for any Pfizer Quarter. The accounting firm shall disclose to LianBio Development only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. The cost of such audit shall be borne by [***].

1.6 **Lack of Patent Coverage and Regulatory Exclusivity**. Notwithstanding any contrary provision hereunder, for the purposes of this Article 4 (*Financial Terms*), on a Region-by-Region basis, if during any Pfizer Quarter within the Net Sales Sharing Term, there is [***], then in calculating the Annual Net Sales of the Relevant Product in the Territory (whether for the purposes of Section 4.2 or Section 4.5), [***] Net Sales of the Relevant Product in that [***] during that Pfizer Quarter shall be counted in the calculation.

1.7 **Mode of Payment**. All payments to LianBio Development under this Article 4 shall be made by deposit of Dollars by wire transfer in immediately available funds in the requisite amount to such bank account in Hong Kong as LianBio Development may from time to time designate by notice to Pfizer.

1.8 **Currency Conversion**. Wherever it is necessary to convert currencies other than the Dollar, such conversion shall be made by Pfizer into Dollars using [***] and [***].

1.9 **Withholding Taxes.** Where any sum due to be paid to LianBio Development under this Article 4 is subject to any withholding or similar tax, Pfizer and LianBio Development shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, [***].

1.10 **Other Taxes**. It is understood and agreed between the Parties that any payments made and other consideration provided under this Agreement are [***]. Where taxes are properly chargeable on a payment made or consideration provided under this Agreement, [***] will pay the amount of taxes in accordance with the laws and regulations of the country in which the taxes are chargeable.

1.11 **No Other Compensation.** Each Party hereby agrees that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party(ies) in connection with the transactions contemplated herein.

1.12 **Termination of [***]**. Pfizer has the right, by providing [***] written notice to LianBio Development, to terminate [***], in the event:

1.1.1 [***]; or

1.1.2 [***].

Article 5
REPRESENTATIONS AND WARRANTIES; COVENANTS AND UNDERTAKINGS

1.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other, as of the Effective Date, that:

1.1.1 it is a corporation duly incorporated and validly existing under the laws of the jurisdiction of its incorporation;

1.1.2 it is duly authorized and empowered (and has obtained all necessary authorizations and approvals by the shareholders, board of directors and/or similar organizations of any Affiliate(s) to whose control (as defined in Section 1.1) it is subject) to execute, deliver and perform this Agreement and that such action does not conflict with or violate any provision of law, regulation, policy, contract, deed of trust or other instrument to which it is a party or by which it is bound and that this Agreement constitutes a valid and binding obligation of it enforceable in accordance with its terms.

1.2 LianBio Entity Representations and Warranties. Each LianBio Entity (on behalf of itself and each of its Affiliates) hereby represents and warrants to Pfizer, as of the Effective Date, that:

1.1.1 [***] with respect to the Relevant Product, any Compound or Licensed Product anywhere in the world, [***] the Relevant Product, the Compound or Licensed Product performed by LianBio Respiratory or its Affiliates or any Person engaged by them or acting on their behalf (where, for the purposes of this Section 5.2.1, Compound, Licensed Product, Development and Commercialization shall have the meanings given to them in the ReViral License Agreement);

1.1.2 neither LianBio Respiratory nor its Affiliates [***] with respect to the Relevant Product, Compound or Licensed Product anywhere in the world which resulted in any [***], and to its knowledge, [***];

1.1.3 neither LianBio Respiratory nor its Affiliates has ever [***];

1.1.4 to its knowledge, there has not been any breach by LianBio Respiratory of the ReViral License Agreement, and no notice of breach has been received by LianBio Respiratory from ReViral alleging any such breach;

1.1.5 the execution and delivery of this Agreement and the consummation of the transactions contemplated hereunder will not result in a breach of or conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which any LianBio Entity or any of its Affiliates is a party or by which such LianBio Entity or any of its Affiliates is bound, nor violate any Laws of any Governmental Authority having jurisdiction over such LianBio Entity or any of its Affiliates;

1.1.6 such LianBio Entity and its Affiliates and any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents (collectively, "Representatives", for the sole purposes of this Section 5.2.6) have at all times complied in all material respects with all applicable Anti-Corruption Laws in performing its or their obligations under the ReViral License Agreement. Each LianBio Entity further represents that neither it, nor any of its Affiliates, nor any of its or their respective Representatives have, in such capacity, directly or indirectly made, given, paid, agreed, offered or promised to give any gift, contribution, payment, bribe, kickback, anything of value or similar benefit to any person or entity, including any (i) elected or appointed Public Official or person acting for or on behalf of a Public Official, (ii) employee or person acting for or on behalf of a Public Official, agency, or enterprise performing a governmental function, (iii) political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, (iv) employees or persons acting for or on behalf of international public organizations, or (v) any other person to the extent that it would result in a violation of Anti-Corruption Laws; in each case in order to gain an improper business advantage and have not accepted such payment.

1.3 LianBio Entity Covenants and Undertakings. Each LianBio Entity (on behalf of itself and each of its Affiliates) hereby covenants and undertakes to Pfizer that, within [***] after the Effective Date, neither it nor any of its Affiliates shall, [***].

Article 6
LIMITATION OF LIABILITY

1.1 **Limitation of Liability**. None of the Parties shall be liable to the others for any special, consequential, incidental, punitive, or indirect damages arising from or relating to this Agreement, regardless of any notice of the possibility of such damages. Notwithstanding the foregoing, nothing in this Section 6.1 is intended to or shall limit or restrict damages available for a Party's breach of confidentiality obligations in Article 7, gross negligence, willful misconduct or fraud.

Article 7
CONFIDENTIALITY; NON-USE

1.1 **Confidential Information**.

1.1.1 Confidentiality Obligation. All information disclosed by one Party to the other Parties pursuant to this Agreement shall be the "Confidential Information" of the disclosing Party for all purposes hereunder. Notwithstanding the foregoing, upon and following the Effective Date, all information with respect to the Relevant Product and the Compound (as such term is defined in the ReViral License Agreement) including all information, data, and documentation generated in connection with the performance of activities pursuant to this Agreement), whether disclosed by Pfizer or any of its Affiliates or representatives or otherwise, shall be deemed to be the Confidential Information of Pfizer and not of any LianBio Entity. Unless otherwise permitted by this Article 7, each Party agrees to, and will cause its Affiliates and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Parties.

1.1.2 Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Parties' Confidential Information only to the receiving Party's

officers, directors, employees, consultants, advisors, current and prospective investors, contractors and subcontractors ("Representatives", for the sole purposes of this Section 7.1), and to the Representatives of the receiving Party's Affiliates, in each case, on a need to know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 7.1; provided, however, that each Party will remain responsible for any failure by its Affiliates or its or their Representatives to treat such Confidential Information as required under this Section 7.1 as if such Affiliates and Representatives were parties directly bound to the requirements of this Section 7.1.

1.1.3 Confidentiality Limitation. Notwithstanding anything to the contrary herein, each Party ("First Party") may use and disclose the other Party's Confidential Information as required by any competent court or other governmental body or as otherwise required by applicable Laws; provided that, notice is promptly given to the other Parties and the First Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information. Confidential Information that is required to be disclosed pursuant to the foregoing sentence will remain otherwise subject to the provisions of this Section 7.1. If any Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States, then such Party will, within a reasonable time prior to any such filing, provide the other Parties with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Parties with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use commercially reasonable efforts to have terms identified by such other Parties afforded confidential treatment by the applicable Regulatory Authority.

1.2 **Terms of the Agreement**. The terms of this Agreement will be the Confidential Information of all the Parties. Except as provided in Section 7.1, none of the Parties nor its Affiliates may disclose the existence or the terms of this Agreement.

1.3 **Publicity; Use of Names**.

1.1.1 Press Release. The Parties have mutually agreed on a joint press release announcing this Agreement to be issued by the Parties on such date and time as may be mutually agreed by the Parties. Other than the press release as described in the foregoing sentence, the Parties agree that the portions of any other news release or other public announcement of a Party or any of its Affiliates relating to this Agreement or the performance hereunder that would disclose any Confidential Information of the other Parties will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed).

1.1.2 Use of Names. Each Party and its Affiliates will retain all right, title and interest in and to its and their respective house marks, corporate names and corporate logos. Except with the prior express written permission of the other Party, none of the Parties will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Law.

Article 8
MISCELLANEOUS

1.1 **Governing Law; Jurisdiction and Venue**. This Agreement shall be governed by and construed and enforced in accordance with the laws of State of New York, United States, without reference to conflicts of laws principles.

1.2 **Dispute Resolution**. Each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof (each, a "Dispute") will be referred to and finally resolved exclusively by arbitration administered by Hong Kong International Arbitration Centre ("HKIAC") in Hong Kong, which will be conducted in accordance with the then effective HKIAC Administered Arbitration Rules. The Dispute shall be resolved by an arbitral tribunal composed of three (3) arbitrators, all of whom will have previous judicial experience and significant experience in the biopharmaceutical industry, with

each Party appointing one (1) arbitrator and the third arbitrator to be selected by mutual agreement of the two (2) arbitrators appointed by the Parties. If the two initial arbitrators are unable to select a third arbitrator within [***], the third arbitrator will be appointed in accordance with HKIAC rules. The foregoing arbitration proceedings may be commenced by either Party by notice to the other Party. All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be determined by the arbitrators, or, in the absence of such determination, each Party will pay its own expenses. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrators will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 8.2). The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 8.2 may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, none of the Parties nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Parties.

1.3 **Assignment and Successors**.

1.1.1 This Agreement shall not be assignable nor the rights hereunder be transferable in any way by either Party except by prior written consent of the other Parties, not to be unreasonably withheld, conditioned or delayed; provided, however, that:

(a) a Party may assign this Agreement (together with transfer of its rights and obligations hereunder) in whole or in part to its Affiliate without the non-assigning Parties' consent (where such Affiliate will assume all assigned rights and obligations from such assigning Party) on the condition that such assigning Party shall remain liable hereunder for the prompt performance of the obligations of the Affiliate assignee under this Agreement;

(b) this Agreement may be assigned by a Party (together with transfer of all of its rights and obligations hereunder) without the non-assigning Parties' consent to a Third Party in connection with a sale or transfer of all or substantially all of such assigning Party's and/or its Affiliates' business or assets to which this Agreement relates to such Third Party or in connection with a merger or consolidation transaction involving such assigning Party and such Third Party, provided, in each case, always that at the time of such assignment such Third Party gives a written deed of undertaking to the non-assigning Parties agreeing to abide by all the outstanding obligations of such assigning Party under this Agreement.

1.1.2 This Agreement shall be binding upon, and shall inure to the benefit of, all permitted assigns. Any assignment or attempted assignment by either Party in violation of the terms of Section 8.3 will be null, void and of no legal effect.

1.4 **Notices**. Any notice or request required or permitted to be given under or in connection with this Agreement will be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to LianBio Entities:	LianBio c/o International Corporation Services Ltd. 2nd Floor, Harbour Place, 103 South Church Street, P.O. Box 472 George Town, Grand Cayman KY1-1106 Cayman Islands Attention: [***]
With copies to:	Ropes & Gray LLP 36F Park Place 1601 Nanjing Road West Shanghai, China 200040 Attention: [***] Fax: [***] Email: [***]
If to Pfizer:	Pfizer Inc. 235 East 42nd Street New York, NY 10017 USA Attention: [***] Email: [***] and Pfizer Investment Co., Ltd. 41/F, CITIC Square 1168 Nan Jing Road (W) Shanghai, P.R. China 200041 Attention: [***] Email: [***]

or to such other address for such Party as it will have specified by like notice to the other Party; provided that notices of a change of address will be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery will be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery will be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery will be deemed to be [***] after such notice or request was deposited with the U.S. Postal Service.

1.5 **Entire Agreement**. This Agreement, together with the Appendices and Exhibits hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersedes and terminates all prior agreements and understanding between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

1.6 **Performance by Affiliates**. Pfizer may use one (1) or more of its Affiliates to perform its obligations and duties hereunder and such Pfizer Affiliates are expressly granted certain rights herein; *provided that* each such Affiliate shall be bound by the corresponding obligations of Pfizer and, subject to an assignment to such Affiliate pursuant to Section 8.3, Pfizer shall remain liable hereunder for the prompt performance of the payment obligations under Article 4.

1.7 **Relationship with Strategic Collaboration Agreement**. Other than for those provisions of the Strategic Collaboration Agreement that are amended by this Agreement, the Strategic Collaboration Agreement shall remain unchanged and in full force and effect; *provided that*

if there is any discrepancy between this Agreement and the Strategic Collaboration Agreement, this Agreement shall prevail.

1.8 **ReViral as a Signing Party**. The Parties hereby acknowledge and agree that ReViral is a signing party to this Agreement for the sole purposes of [***].

1.9 **Other**. Section 11.5 (*Force Majeure*), Section 11.7 (*Waiver*), Section 11.8 (*Severability*), Section 11.10 (*Independent Contractors*), Section 11.11 (*Interpretation*), Section 11.12 (*Further Actions*), Section 11.13 (*Construction of Agreement*), and 11.14 (*Counterparts*), of the Strategic Collaboration Agreement are incorporated herein by reference and shall apply to this Agreement *mutatis mutandis*.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

LIANBIO DEVELOPMENT (HK) LIMITED

By: /s/ Yizhe Wang
Name: Yizhe Wang
Title: Director

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

LIANBIO RESPIRATORY LIMITED

By: /s/ Yizhe Wang
Name: Yizhe Wang
Title: Director

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

REVIRAL LTD.

By: /s/James Pearson
Name: James Pearson
Title: Authorized Signatory

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

PFIZER INC.

By: /s/ Jean-Christophe Pointeau
Name: Jean-Christophe Pointeau
Title: Authorized Signatory

Exhibit 10.50

December 9, 2022

Via PDF Email ([***])

Debra Yu
[***]

Dear Debra:

As we discussed, LianBio, LLC, a limited liability company organized under the laws of the State of Delaware (the "Company"), has accepted your resignation and your employment with the Company shall terminate, effective as of January 1, 2023 (the "Resignation Date"). The purpose of this letter (the "Agreement") is to confirm the terms concerning your resignation. Capitalized terms not defined herein shall have the respective meanings ascribed to them in the Amended and Restated Executive Employment Agreement between you and the Company, dated September 14, 2021 (the "Employment Agreement").

1. **Notice Period and Resignation from the Board and Company Positions.**

(a) Effective as of December 9, 2022, (the "Notice Date"), you will be placed on a paid leave of absence that will continue through the Resignation Date. The period beginning on the Notice Date and concluding on the Resignation Date is hereinafter referred to as the "Notice Period". During the Notice Period, the Company will continue to pay you your base salary at the same rate and in the same manner in effect as of the date hereof, and to participate in all employee benefit plans of the Company accordance with the terms of those plans (to the extent applicable), except that you will not incur any business expenses during the Notice Period without the advance approval of the board of directors of the Company (the "Board"). During the Notice Period, you will not be expected to report to the Company's offices, will not be required or permitted to perform any duties for the Company, and will have no authority to make any commitments or representations on behalf of the Company, in each case unless expressly requested by the Board, or its expressly-authorized designee, and you agree to refer any inquiries or other communications you may receive concerning the Company or its business to the Board or its expressly-authorized designee.

(b) As of the Resignation Date, you will be deemed to have resigned from any and all positions, offices, or memberships that you held with the Company or on any boards of directors or other governing boards of the Company or those Affiliates, including but not limited to the general managers, authorized signatories, legal representatives and other similar positions of any direct or indirect subsidiary of the Company, the Board, and any and all memberships you held on any of the committees of any such boards, without any further action required therefor (collectively, the "Resignations"). The Company, on its own behalf and on behalf of its Affiliates,

hereby accepts the Resignations as of the Resignation Date, and you agree to sign and return such documents confirming the Resignations as the Company or any of its Affiliates may reasonably require.

2. **Final Compensation, Expense Reimbursement and Benefits.** On the next regular payday following the Resignation Date, you will receive: (a) pay for all work you performed for the Company through the Resignation Date, to the extent not previously paid in accordance with Section 13.1 of the Employment Agreement; and (b) reimbursement for any business expenses you have incurred through the Notice Date and have submitted to the Company on or prior to the Resignation Date in accordance with all applicable policies. You will receive the payments described in this Section 2 regardless of whether or not you sign this Agreement. Except for any right you may have to continue your participation and that of your eligible dependents in the Company's group medical, dental, and vision plans under the federal law known as "COBRA" or similar applicable state law (together, "COBRA") and except as provided in Section 3(b) below, your participation in all employee benefit plans of the Company will end as of the Resignation Date, in accordance with the terms of those plans. You will receive information about your COBRA continuation rights under separate cover.

3. **Severance Benefits.** In consideration of your acceptance of this Agreement and subject to your meeting in full your obligations hereunder, and in full consideration of any rights you may have under the Employment Agreement, the Company will provide you with the following:

(a) Severance Payments and 2022 Lump Sum Payment: The Company will pay you (i) an amount equal to your base salary for a period of twelve (12) months following the Resignation Date (the "Severance Payments") plus (ii) an additional lump sum payment equivalent to fourteen
(14) months of your base salary (the "2022 Lump Sum Payment"). The Severance Payments will be made in the form of salary continuation and will begin on the next regular Company payday which is at least five (5) business days following the later of the Resignation Date or the date this Agreement is received by the Company. The first payment will be retroactive to the day following the Resignation Date. The 2022 Lump Sum Payment will be paid in a lump sum on or before March 31, 2023.

(b) COBRA: If you timely elect to continue your participation and that of your eligible dependents in the Company's group medical, dental and/or vision plans pursuant to COBRA, the Company will reimburse you monthly in a taxable cash payment equal to the lower of (i) 90% of the monthly premiums for such coverage paid by the Company on your behalf and that of your eligible dependents immediately prior to the Resignation Date and (ii) $2,000 per month, for your COBRA continuation coverage, subject to your submission of supporting documentation evidencing your payment of COBRA premiums, until the earlier of (i) the twelve (12)-month anniversary of the Resignation Date, (ii) the date you and your dependents cease to be eligible for such COBRA coverage under applicable law or plan terms and (iii) the date on which you obtain health coverage from another employer.

(c) Stock Options.

(i) During your employment with the Company, you were granted options (the "Options") to acquire (i) 1,999,947 ordinary shares of the Company ("Shares") pursuant to an Employee Share Option Agreement by and between you and the Company effective as of January 1, 2020 (the "2020 Option Award"), which 2020 Option Award is subject to the Company's 2019 Equity Incentive Plan (the "2019 Plan"), (ii) 747,227 Shares pursuant to an Employee Share Option Agreement by and between you and the Company effective as of October 31, 2021 (the "First 2021 Option Award"), which First 2021 Option Award is subject to the Company's 2021 Equity Incentive Plan (the "2021 Plan"), and (iii) 85,490 Shares pursuant to an Employee Share Option Agreement by and between you and the Company effective as of December 31, 2021 (the "Second 2021 Option Award"), which Second 2021 Option Award is subject to a performance-based vesting condition and granted pursuant to the 2021 Plan (the Second 2021 Option Award together with the 2020 Option Award and the First 2021 Option Award, the "Option Awards"). You have also been granted performance-based restricted share units (the "RSUs" and together with the Option Awards, the "Outstanding Equity") in respect of 17,098 Shares pursuant to a Restricted Share Unit Agreement by and between you and the Company effective as of December 31, 2021 (the "2021 RSU Award"), which 2021 RSU Award is subject to the 2021 Plan. As of the Resignation Date, (i) options to purchase 1,000,000 Shares under the 2020 Option Award have been exercised, and the remaining options to purchase 999,947 Shares under the 2020 Option Award will be vested but unexercised (the "2020 Vested Options"); (ii) options to purchase 217,941 Shares under the First 2021 Option Award will be vested but unexercised (the "2021 Vested Options", and together with the 2020 Vested Options, the "Vested Options") and the remaining options to purchase 529,286 Shares under the First 2021 Option Award will be unvested (the "Unvested Options"); (iii) options to purchase 85,490 Shares under the Second 2021 Option Award are unearned and unvested; and
(iv) the RSUs in respect of 17,098 Shares under the 2021 RSU Award are unvested and unearned.

(ii) The Outstanding Equity will be treated as follows: the Company agrees to keep the Second 2021 Option Award and the RSUs outstanding and eligible for vesting until their original performance measurement dates, and to the extent that it becomes vested, the Second 2021 Option Award must be exercised no later than the tenth (10th) anniversary of the grant date applicable to the Second 2021 Option Award. The Company also agrees to extend the exercise period for the Vested Options, such that the Vested Options must be exercised not later than the tenth (10th) anniversary of the grant date applicable to the Vested Options, and, to the extent not exercised during such period, the Vested Options shall immediately and automatically terminate and be cancelled upon expiration of such period with no consideration due to you. The Unvested Options shall immediately and automatically terminate and be cancelled as of the Resignation Date for no consideration and any portion of the Second 2021 Option Award or the RSUs that does not become earned as of its original performance measurement date shall immediately and automatically terminate and be cancelled as of such date for no consideration. You acknowledge and agree that, if any portion of the Vested Options was granted as an incentive stock option under the U.S. Internal Revenue Code of 1986, as amended, as a result of the provisions of this Agreement, it shall cease to be so, and the Company shall have no liability with respect to the foregoing. You further acknowledge and agree that as of the Resignation Date, other than as set forth in this Section 3(c), you shall have no further rights or entitlements with respect to the Outstanding Equity.

4. **Acknowledgement of Full Payment and Withholding.**

(a) You acknowledge and agree that the payments provided under Sections 2 and 3 of this Agreement are in complete satisfaction of any and all compensation or benefits due to you from the Company, whether for services provided to the Company under the Employment Agreement or otherwise, through the Resignation Date and that, except as expressly provided under this Agreement, no further compensation or benefits are owed or will be provided to you by the Company.

(b) All payments made by the Company under this Agreement shall be reduced by any tax or other amounts required to be withheld by the Company under applicable law and all other lawful deductions authorized by you.

5. **Continuing Obligations, Confidentiality and Non-Disparagement.**

(a) Subject to Section 7(c) of this Agreement, you acknowledge that you continue to be bound by your obligations under the (i) Compliance Agreement between you and the Company dated as of September 19, 2019 (the "Compliance Agreement"), other than the post-employment non- competition obligations set forth in Section 3(a) of the Compliance Agreement, which the Company agrees to waive in consideration of your acceptance of this Agreement, (ii) the Option Awards, as well as (iii) any other obligations or provisions under the Employment Agreement that survive the termination of your employment by necessary implication or the terms thereof (collectively, the "Continuing Obligations"). For the avoidance of doubt, you will not be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (y) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (z) in a complaint or other document filed under seal in a lawsuit or other proceeding; provided, however, that notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means.

(b) Subject to Section 7(c) of this Agreement, you agree that you will not disclose this Agreement or any of its terms or provisions, directly or by implication, except to members of your immediate family and/or to your legal and tax advisors on the condition that they agree and undertake not to further disclose this Agreement or any of its terms or provisions to others.

(c) Subject to Section 7(c) of this Agreement, you agree that you will not disparage or criticize any of the Released Parties (as defined below), the Company, its Affiliates, their business, their management or their products or services, and that you will not otherwise do or say anything that could disrupt the good morale of employees of the Company or any of its Affiliates or harm the interests or reputation of the Company or any of its Affiliates. Further, you and the Company agree that the Press Release and the draft of the Company's 8-K form, all attached as Exhibit A hereto, shall serve as the talking points for anyone inquiring about your resignation, and that you will not deviate therefrom when discussing same. The Company agrees that you may publicly use "Founding President" and "Founding CBO" with respect to your past role at the Company.

(d) You agree to cooperate with the Company and its Affiliates hereafter with respect to all matters arising during or related to your employment, including but not limited to

all matters in connection with any governmental investigation, internal investigation, litigation or regulatory or other proceeding which may have arisen or which may arise following the signing of this Agreement. The Company will reimburse your out-of-pocket expenses incurred in complying with Company requests hereunder, provided such expenses are authorized by the Company in advance.

6. **Return of Property.**

(a) Company Documents and Other Property. In signing this Agreement and in accordance with Section 1(c)(4) of the Compliance Agreement, you represent and warrant that you have returned to the Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business of the Company and its Affiliates (whether present or otherwise), and all chops, seals, certificates, bank USB-keys (with their passwords), office keys, access cards, credit cards, computer hardware and software, telephones and telephone-related equipment and all other property of the Company or any of its Affiliates in your possession or control, and that you have signed and delivered to the Company the Termination Certificate attached to the Compliance Agreement as Exhibit A. Further, you represent and warrant that you have not retained any copy or derivation of any documents, materials or information (whether in hardcopy, on electronic media or otherwise) of the Company or any of its Affiliates, except that, for the avoidance of doubt, you may retain copies of your Employment Agreement, the Compliance Agreement and this Agreement. Recognizing that your active employment with the Company has ended as of the Notice Date, you agree that you have not, since the Notice Date, for any purpose, other than for performance of this Agreement, attempted to access or use any computer or computer network or system of the Company or any of its Affiliates, including without limitation the electronic mail system, and you agree that you will not do so. You acknowledge that you have disclosed to the Company any and all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, all information which you have password-protected on any computer equipment, network or system of the Company or any of its Affiliates.

(b) Your Personal Property. To the extent the Company finds your personal property on or before the Resignation Date, your personal property will be carefully packed and shipped to your home. The Company and you agree that you shall promptly schedule a time to meet, on or before the Resignation Date, with the Company's information technology team to transfer your personal files to your personal computer.

7. **General Release and Waiver of Claims.**

(a) In exchange for the severance pay and benefits provided to you under this Agreement, to which you would not otherwise be entitled, and other good and valuable consideration, the receipt and sufficiency of which you hereby acknowledge, on your own behalf and that of your heirs, executors, administrators, beneficiaries, personal representatives, successors and assigns, and all others connected with or claiming through you, you agree that this Agreement shall be in complete and final settlement of any and all causes of action, suits, rights and claims, demands, damages and compensation, whether at law or in equity, whether now known or unknown, suspected or unsuspected, accrued or unaccrued, contingent or otherwise, which you have had in the past, now have, or might now have, against the Company or any of its Affiliates of

any nature whatsoever, including but not limited to those in any way related to, connected with or arising out of your employment, its termination, or your other associations with the Company or any of its Affiliates, or pursuant to Title VII of the Civil Rights Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, the Employee Retirement Income Security Act, the wage and hour, wage payment and fair employment practices laws and statutes (each as amended from time to time) of the state or states in which you have provided services to the Company or any of its Affiliates, and/or any other federal, state, local or foreign law, regulation or other requirement (collectively, the "Claims"), and you hereby release and forever discharge the Company, its Affiliates and all of their respective past, present and future directors, shareholders, officers, members, managers, general and limited partners, employees, employee benefit plans, administrators, trustees, agents, representatives, predecessors, successors and assigns, and all others connected with any of them, both individually and in their official capacities (collectively, the "Released Parties"), from, and you hereby waive, any and all such Claims. For the avoidance of doubt, nothing in this Agreement releases your right to enforce the terms of the Agreement.

(b) Nothing contained in this Agreement shall be construed to prohibit you from filing a charge with or participating in any investigation or proceeding conducted by the federal Equal Employment Opportunity Commission or a comparable state or local agency, provided, however, that you hereby agree to waive your right to recover monetary damages or other individual relief in any such charge, investigation or proceeding or any related complaint or lawsuit filed by you or by anyone else on your behalf. Nothing in this Agreement limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to such governmental agency or entity.

(c) This Agreement, including the general release and waiver of claims set forth in Section 7(a) creates legally binding obligations and the Company and its Affiliates therefore advise you to consult an attorney before signing this Agreement. In signing this Agreement, you give the Company and its Affiliates assurance that you have signed it voluntarily and with a full understanding of its terms; that you have had sufficient opportunity of not less than twenty-one (21) days, before signing this Agreement, to consider its terms and to consult with an attorney, and to consult with any other of those persons to whom reference is made in Section 5(b) above, if you wished to do so; and that you have not relied on any promises or representations, express or implied, that are not set forth expressly in this Agreement.

8. **Miscellaneous.**

(a) This Agreement constitutes the entire agreement between you and the Company and supersedes all prior and contemporaneous communications, agreements and understandings, whether written or oral, with respect to your employment, its termination and all related matters, including but not limited to the Employment Agreement, and excluding only the Continuing Obligations, all of which shall remain in full force and effect in accordance with their terms.

(b) This Agreement may not be modified or amended, and no breach shall be deemed to be waived, unless agreed to in writing by you and the Board or its expressly authorized

designee. The captions and headings in this Agreement are for convenience only, and in no way define or describe the scope or content of any provision of this Agreement.

(c) The obligation of the Company to make payments or provide benefits to you or on your behalf under this Agreement, and your right to retain the same, is expressly conditioned upon your continued full performance of your obligations under this Agreement (including the Continuing Obligations).

(d) This is a New Jersey contract and shall be governed and construed in accordance with the laws of the State of New Jersey, without regard to any conflict of laws principles that would result in the application of the laws of another jurisdiction. You agree to submit to the exclusive jurisdiction of the courts of the State of New Jersey in connection with any dispute arising out of this Agreement.

[Remainder of page intentionally left blank]

If the terms of this Agreement are acceptable to you, please sign, date and return it to me within twenty-one (21) days of the date that you receive it. You may revoke this Agreement at any time during the seven (7)-day period immediately following the date of your signing by notifying me in writing of your revocation within that period, and this Agreement shall not become effective or enforceable until that seven (7)-day revocation period has expired. If you do not revoke this Agreement, then, on the eighth (8th) day following the date that you signed it (the "Effective Date"), this Agreement shall take effect as a legally binding agreement between you and the Company on the basis set forth above. You agree that if there have been any changes to a prior version of this Agreement (whether material or immaterial), the 21-day consideration period will not be reset. The enclosed copy of this letter, which you should also sign and date, is for your records.

Sincerely,
LIANBIO

By: /s/ Yizhe Wang
Name: Yizhe Wang
Title: Chief Executive Officer

Accepted and agreed:

Signature: /s/ Debra Yu
Debra Yu

Date: December 13, 2022

[*Signature Page to the Separation Agreement*]

Exhibit A

Exhibit 10.51

December 12, 2022

Debra Yu
[***]

Dear Debra:

This letter (this "Agreement") confirms the terms of your engagement to provide consulting services to LianBio, an exempted company organized under the laws of the Cayman Islands (the "Company").

1. **Services.** Effective as of January 1, 2023, you will provide certain consulting services to the Company. Such consulting services will include, without limitation, consultation with respect to the Company's corporate strategy and business development activities, as well as other assistance, in each case, as may be requested by Yizhe Wang, the Chief Executive Officer of the Company (the "CEO") from time to time. You agree to devote as much business time as is necessary to properly perform any services requested hereunder. This Agreement and your engagement hereunder will continue until terminated in accordance with the provisions of Section 7 hereof.

2. **Relationship of Parties**. You and the Company expressly agree that, in providing services to the Company under this Agreement, you will be an independent contractor and will not be an employee or agent of the Company or any of its affiliates. You agree that you will not render any services to the Company or its affiliates under this Agreement or make any commitments on behalf of the Company or any of its affiliates without the express, advance written consent of the CEO. You further agree that you will provide services hereunder independently and will not receive training or direction from the Company or any of its affiliates, other than as to the goals to be achieved through the provision of such services. You are free to accept engagements from others during the term of this Agreement, as long as those engagements do not interfere with you providing services under this Agreement or otherwise violate any of your obligations hereunder or under any other agreement between you and the Company, including the separation agreement dated December 9, 2022 by and between you and the Company (the "Separation Agreement").

3. **Consulting Fees**. In exchange for all of the services that you provide to the Company under this Agreement, during the term of this Agreement, the Company will pay you consulting fees in the amount of $900 per hour, with such fees to be paid within thirty (30) days following the Company's receipt of an invoice from you detailing the amount of business time spent performing the consulting services, with such invoices to be provided by you on a monthly basis.

4. **Taxes and Benefits**. You acknowledge and agree that, as an independent contractor, you will be solely responsible for the withholding and payment of all federal, state and local income taxes, Social Security and Medicare taxes, and any and all other legally- required payments on sums paid to you hereunder. The Company will provide you with an IRS

Form 1099 evidencing all consulting fees paid by it to you in connection with your engagement hereunder. You further acknowledge and agree that, except as otherwise expressly provided in the Separation Agreement, neither you nor any individual claiming through you will be eligible to (a) participate in any Company or Company affiliate bonus, incentive or other compensation plan, program or arrangement of any kind, whether payable in cash or equity, or (b) participate in or receive benefits under any of the employee benefit plans, programs and arrangements maintained by the Company or any of its affiliates (all of the foregoing benefit and compensation plans, programs and arrangements, hereinafter, the "Plans"). Except as otherwise expressly provided in the Separation Agreement, you hereby waive any and all rights to participate in, or receive benefits under, any of the Plans, and you agree not to make any claim under any of the Plans. You further agree to indemnify and hold harmless the Company, its investors, or any of their respective affiliates, the Plans, and all those connected with them from any and all liabilities
(i) arising out of any claims under any of the Plans by you or by anyone claiming through you in violation of this Section 4 or
(ii) otherwise incurred as a result of your failure to meet your obligations under this Section 4.

5. **Confidential Information.** You agree that, during your engagement hereunder and thereafter, you will not use or disclose to any third party any Confidential Information, except as required for the proper performance of this engagement. For purposes of this Agreement, "Confidential Information" means (a) any and all information of the Company or any of its affiliates that is not generally known to the public and (b) any and all information received by the Company or any of its affiliates from customers or other third parties with any understanding, express or implied, that the information would not be disclosed. For the avoidance of doubt, (i) nothing contained in this Agreement limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to the governmental agency or entity and (ii) you cannot be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (y) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (z) in a complaint or other document filed under seal in a lawsuit or other proceeding; provided, however, that notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means.

6. **Assignment of Rights to Intellectual Property.** You will promptly and fully disclose all Intellectual Property to the Company. You hereby assign and agree to assign to the Company (or as otherwise directed by the Company) your full right, title and interest in and to all Intellectual Property. You agree to execute any and all applications for domestic and foreign patents, copyrights or other proprietary rights and to do such other acts (including without limitation the execution and delivery of further instruments of assignment or confirmation and the provision of good faith testimony by declaration, affidavit or in-person) requested by the Company to assign the Intellectual Property to the Company (or as otherwise directed by the Company) and to permit the Company to secure, prosecute and enforce any patents, copyrights or other proprietary rights to the Intellectual Property. You will not charge the Company for time spent in complying with these obligations. For purposes of this Agreement, "Intellectual

Property" means inventions, discoveries, developments, methods, processes, compositions, works, concepts and ideas (whether or not patentable or copyrightable or constituting trade secrets) (collectively, "Inventions") conceived, made, created, developed or reduced to practice by you (whether alone or with others, whether or not during normal business hours or on or off Company premises) during your engagement with the Company that relate either to the business of the Company or to any prospective activity of the Company or any of its affiliates or that result from any services performed by you for the Company or any of its affiliates or that make use of Confidential Information or any of the equipment or facilities of the Company or any of its affiliates. Notwithstanding the foregoing, Intellectual Property shall not apply to any Invention that you develop entirely on my own time, without using the equipment, supplies, facilities or trade secret information of the Company or any of its affiliates, unless such Invention
(a) relates to the business of the Company or any of its affiliates for whom you are performing services or to the actual or demonstrably anticipated research or development of the Company or any of its affiliates for whom you are performing services or (b) results from any work performed by you for the Company or any of its affiliates.

7. **Termination.** The term of this Agreement and your engagement hereunder will continue until June 30, 2023. Notwithstanding the foregoing, either party may terminate this Agreement and your engagement hereunder at any time upon two (2) weeks' prior written notice. Upon termination of this Agreement, the Company shall have no further obligation to you, other than for payment for requested services provided by you through the date of termination in accordance with Section 3 above and solely to the extent not already paid. Your obligations under Sections 4 through 6 of this Agreement will survive the termination of this Agreement and your engagement hereunder, however occurring.

8. **Miscellaneous.** This Agreement contains the entire agreement between you and the Company, and replaces all prior agreements, whether written or oral, with respect to the services to be provided by you to the Company and all related matters. For the avoidance of doubt, all of the obligations in this Agreement shall be in addition to and not in lieu of, any of your obligations in the Separation Agreement, all of which shall remain in full force and effect. This Agreement may not be amended and no breach will be deemed waived unless agreed to in a signed writing by you and the CEO. The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement. This is a New Jersey contract and shall be governed and construed in accordance with the laws of the State of New Jersey, without regard to any conflict of laws principles that would result in the application of the laws of another jurisdiction. You agree to submit to the exclusive jurisdiction of the courts of the State of New Jersey in connection with any dispute arising out of this Agreement.

[*Remainder of page intentionally left blank.*]

If the terms of this Agreement are acceptable to you, please sign, date and return it to me by December 13, 2022, at which time this Agreement will take effect as a legally binding agreement between you and the Company on the basis set forth above. The enclosed copy of this Agreement, which you should also sign and date, is for your records.

Sincerely, LIANBIO

By: /s/ Yizhe Wang
Yizhe Wang
Chief Executive Officer

Accepted and agreed:

By: /s/ Debra Yu

Debra Yu

Date: December 13, 2022

Exhibit 10.52

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

FIRST AMENDMENT TO
LICENSE AND COLLABORATION AGREEMENT

THIS FIRST AMENDMENT TO THE LICENSE AND COLLABORATION AGREEMENT (this "Amendment") is made as of February 28, 2023 (the "Amendment Effective Date") by and between LianBio Respiratory Limited ("Lian") and Landos BioPharma, Inc. ("Landos").

Lian and Landos are parties to the License and Collaboration Agreement dated as of May 14, 2021 (the "Original License Agreement"; as amended by this Amendment, the "License Agreement").

The Parties desire to amend the Original License Agreement: (i) to acknowledge the transfer by Landos (the "Landos Transfer") of ownership of certain of the Licensed Technology (as defined therein) relating to its proprietary compound known as BT-11 ("BT-11") to NImmun Biopharma, Inc. ("Newco"), (ii) to provide that the License Agreement no longer covers the licensing of such Licensed Technology relating to BT-11 and (iii) to include additional, mutually agreed-upon amendments to the Original License Agreement and clarify the Parties' ongoing rights and obligations with respect thereto.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Definitions. Unless otherwise indicated herein, words and terms that are defined in the License Agreement shall have the same meaning where used in this Amendment.

Acknowledgement and Consent of Transfer of Certain Licensed Technology related to BT-11. Lian and Landos each hereby acknowledges and confirms that, simultaneously herewith, Landos has transferred and assigned to Newco all of its right, title and interest in and to the Licensed Technology specifically relating to BT-11, and exclusively licensed to Newco all of its right, title and interest in and to certain other Licensed Technology relating to BT-11, together including all intellectual property rights Controlled by Landos as of such date that are necessary or reasonably useful for the Development, Manufacture, or Commercialization of BT-11 (or products containing BT-11) (collectively, "BT-11 Products") (such Licensed Technology, the "Transferred BT-11 Technology") and that Lian and Newco separately have entered into a new License and Collaboration Agreement relating to such Transferred BT-11 Technology.

2. Amendment to License Agreement.

(a) Section 1.29 of the Original License Agreement is revised to replace the word "compounds" with the word "compound" and to delete the words "BT-11 and" on line 1 thereof.

(b) Section 3.3(a) of the Original License Agreement is deleted in its entirety and replaced with the following:

Global Phase III Trial Participation. In the event that Landos decides to conduct a Global Phase III Trial for a Licensed Product, Lian will participate in the first such Global Phase III Trial by including Clinical Trial sites for such Global Phase III Trial in the Territory, subject to [***]. In the event that Lian participates in such Global Trial, subject to this Section 3.3(a) (Global Phase III Trial Participation) and Section 3.3(c) (Study Design and Protocol), such activities to be conducted by Lian in support of such Global Phase III Trial will be included in the Global Development Plan, and Lian will support Landos on such global development for such Global Trial by (i) including Clinical Trial sites in the Territory [***], (ii) being responsible for any costs and expenses incurred by or on behalf of Lian for its participation in

such Global Trial conducted in the Territory, and (iii) using Commercially Reasonable Efforts to enroll patients in the Territory equal to a minimum of [***] of the total patients in such Global Phase III Trial (the "Patient Commitment"). In the event that Lian participates in such a Global Phase III Trial and fails to enroll sufficient patients in the Territory to meet the Patient Commitment (the "Patient Shortfall"), and Landos instead enrolls patients in such Global Phase III Trial in lieu of Lian in order to meet the Patient Commitment, then Lian will reimburse Landos for the number of patients representing the Patient Shortfall that Landos so enrolls in such Global Phase III Trial (up to the Patient Commitment) based on the Average Cost Per Patient in the Territory. If Lian does not participate in a Global Phase III Trial for either of Crohn's disease or ulcerative colitis, then Lian will conduct a Clinical Trial in the Territory intended to support the Regulatory Approval for the use of the Licensed Product in the applicable disease in the Territory, and such Clinical Trial will be included in the Territory-Specific Development Plan. Additionally, in such event, Lian shall use good faith efforts to design the protocol for such Clinical Trial in a manner that would permit Landos to use clinical data generated from such Clinical Trial to support the Regulatory Approval for the use of the Licensed Product in the applicable disease in the U.S.

(c) The chart in Section 6.1 of the Original License Agreement is deleted and replaced with the following:

Development Milestone Event	**Development Milestone Payment (in Dollars)**
1. [***]	[***]
2. [***]	[***]
Total	[***]

(d) The Parties hereby acknowledge that, notwithstanding any provision to the contrary set forth in the Agreement or this Amendment, as between the Parties, (a) Landos will remain responsible for all indemnification obligations under Section 10.1 of the Original License Agreement with respect to BT-11 Products to the extent such obligations, or the circumstances related to the relevant claims, arise prior to the Amendment Effective Date and (b) Lian will remain responsible for all indemnification obligations under Section 10.2 of the Original License Agreement with respect to BT-11 Products to the extent such obligations, or the circumstances related to the relevant claims, arise prior to the Amendment Effective Date.

(e) Section 12.3(d) of the Original License Agreement is hereby amended by deleting such section in its entirety and replacing it with the following:

> Termination by Lian for Convenience. Lian may, upon [***] days' prior written notice to Landos, terminate this Agreement in its entirety, for convenience, without cause and for any or no reason.

(f) Section 14.3 of the Original License Agreement is hereby amended by deleting the address for notices to Landos and replacing it with the following:

If to Landos:

Landos Biopharma Inc.
PO Box 11239
Blacksburg, VA 24062
Attention: [***]
Email: [***]

and deleting the address for copies of notices to Lian and replacing it with the following:

With copies to:
Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Attention: [***]
Email: [***]

(g) Schedule 1.29 of the Original License Agreement is deleted and replaced with Schedule 1.29 annexed hereto.

(h) Schedule 1.76 of the Original License Agreement is deleted and replaced with Schedule 1.76 annexed hereto.

3. Continued Validity of License Agreement. Except as specifically amended hereby, the Original License Agreement shall continue in full force and effect as originally constituted and is ratified and reaffirmed by the Parties hereto. The Parties confirm that any breach of this Amendment shall constitute a breach of the License Agreement, and shall entitle the non-breaching Party to all rights and remedies set forth in the License Agreement.

4. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[*Remainder of page intentionally left blank*]

[*Signature Page of First Amendment to License and Collaboration Agreement*]

IN WITNESS WHEREOF, the undersigned parties have executed this Amendment as of the date first written above.

LANDOS BIOPHARMA, INC.

/s/ Gregory Oakes
Name: Gregory Oakes
Title: Chief Executive Officer

LIANBIO RESPIRATORY LIMITED

/s/ Yizhe Wang
Name: Yizhe Wang
Title: Director

SCHEDULE 1.29
(REVISED)

Licensed Compound

[***]

SCHEDULE 1.76

LICENSED PATENTS

Patent Rights licensed by Landos

[***]

Exhibit 10.53

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), entered into as of February 28, 2023 (the "Effective Date"), is entered into by and between LianBio Development (HK) Limited, a company limited by shares organized and existing under the laws of Hong Kong Special Administrative Region of the People's Republic of China ("Lian"), and NImmune Biopharma, Inc., a company organized and existing under the laws of the State of Delaware ("Licensor").

INTRODUCTION

WHEREAS, LianBio Respiratory Limited ("Lian Respiratory") entered into that certain License and Collaboration Agreement, dated as of May 14, 2021, with Landos BioPharma, Inc. ("Landos") (the "Original License Agreement"; such date, the "Original Agreement Effective Date"), pursuant to which, among other things, Landos granted a license to Lian Respiratory under the Licensed Technology relating to its proprietary Compound known as BT-11 ("BT-11") for the Development, Manufacture and Commercialization of Licensed Products containing BT-11 in the Field in the Territory (with each capitalized term as defined in the Original License Agreement);

WHEREAS, simultaneously herewith, Landos has (a) transferred and assigned to certain of its former stockholders (the "Selling Entities") all of Landos' rights, title and interests in and to the intellectual property rights specifically relating to the Compound, including the Patent Rights, Trademarks and copyrights specifically related thereto and (b) granted to the Selling Entities a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, exclusive (even with respect to Landos), freely sublicensable and transferable license under all of Landos' rights, title and interests in and to certain Licensed Technology, including all other intellectual property rights Controlled by Landos as of such date that are necessary or reasonably useful for the Development, Manufacture, or Commercialization of BT-11 (such transferred Licensed Technology, Joint Know-How, and Joint Patent Rights being sometimes referred to herein as the "Transferred BT-11 Technology");

WHEREAS, the Selling Entities subsequently have transferred to Licensor all of their rights, title and interests in and to the intellectual property rights relating to BT-11 that were acquired by the Selling Entities from Landos, including the Transferred BT-11 Technology, in consideration for the issuance by Licensor of shares of its capital stock to the Selling Entities;

WHEREAS, Lian Respiratory and Landos have, simultaneously herewith, amended the Original License Agreement to reflect that Landos is no longer the licensor to Lian Respiratory of the Transferred BT-11 Technology; and

WHEREAS, Lian wishes to obtain from Licensor and Licensor wishes to grant to Lian certain rights and licenses under intellectual property owned or controlled by Licensor to Develop, Manufacture, and Commercialize Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions set forth herein.

NOW, THEREFORE, the Parties hereby agree as follows:

Article 1 DEFINITIONS

Unless the context clearly indicates otherwise, the following terms used in this Agreement will have the meanings set forth in this Article 1 (Definitions):

1.1 "Accounting Standards" means, with respect to a Person, generally accepted accounting principles ("GAAP") as practiced in the United States or applicable international standards followed by such Person.

1.2 "Acquired Party" has the meaning set forth in Section 2.9(c) (Business Combinations).

1.3 "Acquirer" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.4 "Action" means any claim, action, cause of action, or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.5 "Active Ingredient" means those active materials that provide pharmacological activity in a pharmaceutical or biologic product [***].

1.6 "Additional Product" means any pharmaceutical compound or product, other than a Compound or Licensed Product, that has the same mechanism of action as any Compound and is being Developed by Licensor for use outside the Territory.

1.7 "Additional Product License" has the meaning set forth in Section 2.10 (Right of Negotiation).

1.8 "Adverse Event" or "AE" means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.9 "Affiliate" means, with respect to any Person, any entity controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For purposes of this definition, "control" means (i) direct or indirect ownership of more than 50% of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Laws; provided, however, that such ownership interest provides actual control over such Person), (ii) status as a general partner in any partnership, or (iii) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Affiliates of a Party exclude Persons who are financial investors of such Party or under common control of such financial investors other than such Party and its subsidiary entities.

1.10 "Agreement" has the meaning set forth in the Preamble.

1.11 "Alliance Manager" has the meaning set forth in Section 5.7(a) (Appointment).

1.12 "Anti-Corruption Laws" means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including, to the extent applicable, the *Corruption of Foreign Public Officials Act (CFPOA)*, the *US Foreign Corrupt Practices Act (FCPA)*, the *UK Bribery Act 2010*, and similar laws governing corruption and bribery, whether public, commercial or both.

1.13 "Average Cost Per Patient" means the [***] cost in the Territory for a particular Global Phase III Trial, as reasonably estimated by Lian or its then-current CRO at the time of commencement of such Global Phase III Trial.

1.14 "Breaching Party" has the meaning set forth in Section 12.3(a) (Termination of Material Breach).

1.15 "Business Day" means any day, other than a Saturday or a Sunday, on which the banks in New York, Beijing, Hong Kong, and Cayman Islands are open for business.

1.16 "Calendar Quarter" means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year.

1.17 "Calendar Year" means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2023, and for each Calendar Year thereafter each 12-month period commencing on January 1, and ending on December 31, except that the last Calendar Year will commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.18 "CDE" means the Center for Drug Evaluation of the NMPA.

1.19 "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party (including the issuance or sale of securities for financing purposes) or changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

1.20 "Clinical Trial" means a trial in which human subjects or patients are dosed with a drug, whether approved or investigational.

1.21 "Clinical Supply Agreement" has the meaning set forth in Section 4.1 (Supply Agreement).

1.22 "CMC" means the Chemistry, Manufacturing, and Controls portion of any Regulatory Filing.

1.23 "CMC Data" means any data included in the CMC portion of a Regulatory Filing or in any supporting development reports thereto, in each case, with respect to any Licensed Product in any country in the world.

1.24 "Combination Product" means a Licensed Product that (a) contains or comprises both (i) the Compound and (ii) at least one additional Active Ingredient other than a Compound, whether packaged together or in a single finished dosage form, (b) sold for a single invoice price together with any (i) delivery device or component therefor, (ii) companion diagnostic related to any Licensed Product, or (iii) product, process, service, or therapy other than the Licensed Product (such additional Active Ingredient and each of (i) – (iii), an "Other Component") or (c) that is defined as a "combination product" by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent.

1.25 "Commercial Supply Agreement" has the meaning set forth in Section 4.1 (Supply Agreement).

1.26 "Commercialization" means any and all activities related to the pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing and exporting for sale, having imported and exported for sale, distribution, having distributed, customer service and support, and post-marketing safety surveillance and reporting of a product (including the Licensed Product), but not including Development activities or Manufacturing. "Commercializing" or "Commercialize" will be construed accordingly.

1.27 "Commercially Reasonable Efforts" means, [***].

1.28 "Competitive Product" means [***].

1.29 "Compound" means (a) Licensor's proprietary compound known as BT-11, the chemical structure of which is set forth on Schedule 1.29 (Licensed Compound), and (b) any [***].

1.30 "Confidential Information" means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party or any of its Affiliates in connection with this Agreement or disclosed in connection with the Term Sheet, and (b) the terms and conditions of this Agreement; provided, however, that Confidential Information will not include information that:

(i) is published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no breach of this Agreement on the part of the receiving Party;

(ii) is in the receiving Party's possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information;

(iii) is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party; or

(iv) is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information.

The Parties acknowledge and agree that any information that (A) constituted confidential or proprietary information of Landos pursuant to the Original License Agreement and was provided or disclosed to Lian or its Affiliates in connection therewith and (b) was subsequently transferred and assigned to Licensor pursuant to that certain asset purchase and redemption agreement entered into between Landos and Licensor as of the date hereof (such information, "Transferred BT-11 Information") shall, as between the Parties, and notwithstanding any provision to the contrary in this Agreement, constitute Confidential Information of Licensor hereunder. For clarity, the terms and conditions of this Agreement (and not the Original License Agreement) shall govern with respect to the confidentiality, use and disposition of any Transferred BT-11 Information by or on behalf of Lian or its Affiliates at all times after the Effective Date.

1.31 "Contract Manufacturing Organization" or "CMO" means any Third Party contract manufacturing organization.

1.32 "Control" or "Controlled" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Filings, intangible Know-How, or other Intellectual Property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Filings, intangible Know-How, or other Intellectual Property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right that are owned or in-licensed by an Acquirer except (i) with respect to any such Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right arising from active participation by employees or consultants of the Acquirer in the Development, Manufacture, or Commercialization of Licensed Products in the Field after such Change of Control, or (ii) to the extent that any such Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right are included in or used in furtherance of the Development, Manufacture, or Commercialization of Licensed Products in the Field by the Acquirer after such Change of Control.

1.33 "Cover," "Covering," or "Covered" means, when referring to the Licensed Product: (a) with respect to an issued Patent Right, that, in the absence of a license granted to a Person under an issued claim included in such Patent Right, the manufacture, use, sale, offer for sale or import by such Person of a specified activity with respect to such Licensed Product would infringe such claim, or (b) with respect to an application for Patent Rights, that, in the absence of a license granted to a Person under a claim included in such application, the manufacture, use, sale, offer for sale or import by such Person of such Licensed Product would infringe such claim if such patent application were to issue as a patent.

1.34 "CRO" means a Third Party contract research organization.

1.35 "Development" means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but excluding activities directed to Manufacturing or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biologic product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic product in such region). "Develop," "Developing," and "Developed" will be construed accordingly.

1.36 "Development Milestone Event" has the meaning set forth in Section 6.1(b) (Development Milestone Payment).

1.37 "Development Milestone Payment" has the meaning set forth in Section 6.1(b) (Development Milestone Payment).

1.38 "Development Plan" means the Territory-Specific Development Plan and the Global Development Plan, collectively.

1.39 "Dollars" or "US$" means United States dollars.

1.40 "Effective Date" has the meaning set forth in the Preamble.

1.41 "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.42 "Field" means all uses or indications.

1.43 "First Commercial Sale" means with respect to the Licensed Product in any Region in the Territory, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such Region after the Marketing Authorization for such Licensed Product has been obtained in such Region and where the sale results in a recordable Net Sale. First Commercial Sale excludes transfers of Licensed Product to Third Parties as *bona fide* samples, for the performance of Clinical Trials or other Development purposes, or for any expanded access program, or any compassionate sales or use program in accordance with applicable Law.

1.44 "Force Majeure" has the meaning set forth in Section 14.9 (Force Majeure).

1.45 "Fully Burdened Manufacturing Cost" means, with respect to any Licensed Product (or the Compound contained therein) supplied by or on behalf of Licensor to Lian:

(a) if such Licensed Product (or the Compound contained therein) (or any precursor or intermediate thereof) is Manufactured by a CMO, the actual CMO costs of such Manufacturing incurred by or on behalf of Licensor, including [***] or

(b) if such Licensed Product (or the Compound contained therein) (or any precursor or intermediate thereof) is manufactured by Licensor or its Affiliate, the actual, fully burdened cost of such manufacturing, including [***].

1.46 "GCP" or "Good Clinical Practice" means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) as set forth in the PRC Good Clinical Practice for Pharmaceuticals effective as of September 1, 2003 and its subsequent amendments, (d) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (e) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.47 "Generic Product" means, with respect to a particular Licensed Product in a Region, any product that (a) has Regulatory Approval for use in such Region pursuant to a regulatory process governing approval of generic or interchangeable pharmaceutical products based on the then-current standards for Regulatory Approval in such Region, where such Regulatory Approval relied on or incorporated clinical data generated by either Party to this Agreement or their Affiliates or Sublicensees, or was obtained using an abbreviated, expedited or similar process, (b) during the Royalty Term is not owned or licensed by Lian under this Agreement; and (c) is sold in the same Region as the relevant Licensed Product by a Third Party that is not a Sublicensee or Affiliate of Lian and that did not purchase such product in a chain of distribution that included Lian or its Affiliates or its or their Sublicensees.

1.48 "Global Development Plan" has the meaning set forth in Section 3.2(b) (Global Development Plan).

1.49 "Global Phase III Trial" means a global registrational Phase III Trial that is included under the Global Development Plan.

1.50 "Global Trial" has the meaning set forth in Section 3.3(a) (Global Phase III Trial Participation).

1.51 "GLP" or "Good Laboratory Practice" means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the PRC Good Clinical Practice effective as of September 1, 2003, or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and such standards of good laboratory practice as are required by the equivalent applicable Laws in the relevant Region and other organizations and governmental agencies in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

1.52 "GMP" or "Good Manufacturing Practice" means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 201, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the Eudralex guidelines, (c) Pharmaceutical Good Manufacturing Practice of the PRC effective as of March

1, 2011 and its appendices, (d) the principles detailed in the applicable ICH guidelines, (e) the conduct of an inspection by a Qualified Person (as defined therein) and the execution by such Qualified Person of an appropriate certification of inspection and (f) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time.

1.53 "Governmental Authority" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative, or taxing authority or functions of any nature pertaining to government.

1.54 "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.55 "Indemnified Party" means a Person entitled to indemnification under Article 10 (Indemnification; Damages).

1.56 "Indemnifying Party" means a Party from whom indemnification is sought under Article 10 (Indemnification; Damages).

1.57 "Indication" means each separate and distinct disease, disorder, illness, health condition, or interruption, cessation or disruption of a bodily function, system, tissue type or organ, for which a separate Regulatory Approval Application is required to be filed to obtain Regulatory Approval.

1.58 "Infringement" has the meaning set forth in Section 7.3 (Third Party Infringement).

1.59 "Infringement Action" has the meaning set forth in Section 7.3(b) (Lian First Right).

1.60 "Infringement Claim" has the meaning set forth in Section 7.4 (Claimed Infringement).

1.61 "Intellectual Property" means all Patent Rights, rights to Inventions, copyrights, design rights, trademarks, trade secrets, Know-How, materials, and all other intellectual property rights (whether registered or unregistered), and all applications and rights to apply for any of the foregoing anywhere in the world.

1.62 "Invention" has the meaning set forth in Section 7.1(a) (Assignment Obligation).

1.63 "Joint Know-How" means Know-How developed or invented jointly by a Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, on the other hand, in the performance of activities under this Agreement during the Term.

1.64 "Joint Patent Right" means any Patent Right claiming any Invention conceived jointly by employees, contractors, or agents of Lian or its Affiliates, on the one hand, and employees, contractors, or agents of Licensor or its Affiliates, on the other hand.

1.65 "JSC" has the meaning set forth in Section 5.1 (Formation; Purposes and Principles).

1.66 "Know-How" means all proprietary chemical and biological materials and other tangible materials, inventions, practices, methods, protocols, formulae, knowledge, know-how, trade secrets, processes, procedures, assays, skills, experience, techniques, information, data and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical test data and analytical and quality control data, whether patentable or otherwise.

1.67 "Landos" has the meaning set forth in the Recitals.

1.68 "Law" or "Laws" means all laws, statutes, rules, codes, regulations, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.69 "Lian" has the meaning set forth in the Preamble.

1.70 "Lian Indemnified Party" has the meaning set forth in Section 10.1 (Indemnification by Licensor).

1.71 "Lian Technology" means the Patent Rights and Know-How Controlled by Lian, its Affiliates or Sublicensees as of the effective date of termination of this Agreement, that (a) Cover any Inventions and (b) are used or applied as of the date of such termination in the Development, Manufacture or Commercialization of the Compound or Licensed Products in the Field.

1.72 "Lian Trademark" has the meaning set forth in Section 4.4(c) (Trademarks).

1.73 "Licensed Know-How" means any and all Know-How owned or Controlled by Licensor or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development, Manufacture, or Commercialization of any Compound or Licensed Product in the Territory, but excluding any Joint Know-How.

1.74 "Licensed Mark(s)" means any Trademark(s) that Licensor or its Affiliates registers with a Governmental Authority in any Region in the Territory to be used in connection with the Commercialization of a Licensed Product.

1.75 "Licensed Patent Rights" means any and all Patent Rights that are owned or Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time during the Term that (a) Cover the Licensed Know-How or (b) are otherwise necessary or reasonably useful for the Development, Manufacture, or Commercialization of any Compound or Licensed Product in the Field in the Territory. The Licensed Patent Rights as of the Effective Date are listed in Schedule 1.76 (Licensed Patents). The Licensed Patent Rights (i) include any Patent Rights claiming Product Inventions that are Controlled by Licensor or its Affiliates, and (ii) exclude any Joint Patent Rights.

1.76 "Licensed Product" means any product containing the Compound in any formulation or dosage form, or as part of any combination that has been or is being Developed by Licensor outside the Territory. For clarity, no rights or licenses are granted under this Agreement by Licensor to Lian with respect to any Active Ingredient Controlled by Licensor or its Affiliates included in a combination product that is not a Compound.

1.77 "Licensed Technology" means collectively Licensed Patent Rights, Licensed Know-How and Licensor or its Affiliates' interests in the Joint Know-How and Joint Patent Rights.

1.78 "Licensor" has the meaning set forth in the Preamble.

1.79 "Licensor Indemnified Party" has the meaning set forth in Section 10.2 (Indemnification by Lian).

1.80 "Losses" means damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys' and experts' fees and expenses), in each case, resulting from an Action.

1.81 "Manufacture" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development or Commercialization. "Manufacturing" or "Manufactured" will be construed accordingly.

1.82 "Marketing Authorization" means the grant of all necessary final or conditional permits, registrations, authorizations, licenses, and approvals (or waivers) required for the Commercialization of the Licensed Product for use in the Field and in the Territory, including any Regulatory Approval for sale or marketing, and, where applicable, Pricing and Reimbursement Approvals.

1.83 "Milestone Payments" means Development Milestone Payments and Sales Milestone Payments.

1.84 "Negotiation Period" has the meaning set forth in Section 2.10 (Right of Negotiation).

1.85 "Net Sales" means the net sales recorded by Lian or any of its Affiliates or Sublicensees (for the purpose of this definition, "Sublicensees" will not include any distributors or wholesalers) (each of the foregoing Persons, a "Selling Party") for any Licensed Product sold to Third Parties other than Sublicensees, less the following deductions calculated in accordance with the Accounting Standards, consistently applied throughout the Territory by the relevant Selling Party to the extent allocated to such Licensed Product and actually taken, paid, accrued, allowed, included, or allocated, based on good faith estimates, in the gross sales price with respect to such sales, as set forth below:

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

Net Sales will be calculated only once for the first *bona fide* arm's length sale of the Licensed Product to a Third Party that is not a Selling Party. Net Sales does not include (a) any sale of such Licensed Product to or between Lian, its Affiliates or its or their Sublicensees for further sale by such entity (but includes the subsequent sale by such entity to a Third Party that is not a Selling Party), (b) samples of Licensed Product used to promote additional Net Sales, in amounts consistent with normal business practices of a Selling Party, or (c) any use of such Licensed Product as *bona fide* samples, as donations, for Clinical Trials or other Development purposes, or for any expanded access program or compassionate sales or use program in accordance with applicable Law (provided, that, in each case such sales are at or below cost).

In the event that a Licensed Product is sold as a Combination Product, Net Sales, for the purposes of determining royalty payments on the Combination Product, shall mean the gross amount collected for the Combination Product less the deductions set forth in clauses (a) - (f) above, multiplied by a proration factor that is determined as follows:

(i) If all Other Components of the Combination Product were sold separately during the same or immediately preceding Calendar Quarter, the proration factor shall be determined by the formula [A / (A+B)], where A is the average gross sales price of all Licensed Product components containing only the Compound as its Active Ingredient during such period when sold separately from the other component(s), and B is the average gross sales price of the Other Components during such period when sold separately from the Compound (as applicable);

(ii) If the Licensed Product components containing only the Compound as its Active Ingredient are sold separately from the Other Components, but the Other Components in such Combination Product are not sold separately, then the proration factor shall be determined by the formula [A / C], where A is the average gross sales price of all Licensed Product components containing only the Compound as its Active Ingredient during such period when sold separately from the Other Components, and C is the average gross sales price of the Combination Product during such period;

(iii) If the Licensed Product components containing only the Compound as its Active Ingredient are not sold separately from the Other Components, but the Other Components in such Combination Product are sold separately, then the proration factor shall be determined by the formula [(C- B) / C], where B is the average gross sales price of the Other Components included in such Combination Product if sold separately from the other component(s), and C is the average gross sales price of the Combination Product during such period; or

(iv) If neither the Compound nor the Other Components included in the Combination Product were sold or provided separately during the relevant period, then the proration factor shall be [***].

1.86 "NMPA" means the National Medical Product Administrations of the PRC, or its successor.

1.87 "Non-Breaching Party" has the meaning set forth in Section 12.3(a) (Termination by Material Breach).

1.88 "Offer" has the meaning set forth in Section 2.10 (Right of Negotiation).

1.89 "Offer Period" has the meaning set forth in Section 2.10 (Right of Negotiation).

1.90 "Original License Agreement" has the meaning set forth in the Recitals.

1.91 "Original License Agreement Effective Date" has the meaning set forth in the Recitals.

1.92 "Other Component" has the meaning set forth in Section 1.24 (Combination Product).

1.93 "Party" means either Licensor or Lian; "Parties" means Licensor and Lian, collectively.

1.94 "Party Vote" has the meaning set forth in Section 5.5 (Decision-Making; Escalation to Senior Officers).

1.95 "Patent Challenge" has the meaning set forth in Section 12.3(b) (Termination for Patent Challenge).

1.96 "Patent Rights" means the rights and interests in and to (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, and (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.97 "Patient Commitment" has the meaning set forth in Section 3.3(a) (Global Phase III Trial Participation).

1.98 "Patient Shortfall" has the meaning set forth in Section 3.3(a) (Global Phase III Trial Participation).

1.99 "Person" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.100 "Pharmacovigilance Agreement" has the meaning set forth in Section 3.9 (Pharmacovigilance).

1.101 "Phase III Trial" means a Clinical Trial of an investigational product in subjects that incorporates accepted endpoints for confirmation of statistical significance of efficacy and

safety with the aim to generate data and results that can be submitted to obtain Regulatory Approval as described in 21 C.F.R. 312.21(c), or a comparable Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.

1.102 "PRC" means the People's Republic of China, which for the purposes of this Agreement, excludes Hong Kong, Macau and Taiwan.

1.103 "Pricing and Reimbursement Approval" means, with respect to the Licensed Product, the governmental approval, agreement, determination or decision establishing the price or level of reimbursement for such Licensed Product in a given Region in the Territory in such jurisdiction in the Field in the Territory.

1.104 "Prior Product Inventions" means any and all inventions, Know-How, developments, or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by Lian (including its Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) prior to the Effective Date in the performance of its obligations or exercise of its rights under the Original License Agreement and Controlled by Lian as of the Effective Date that relate to the Compound.

1.105 "Product Inventions" means any Inventions that are necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Compound or Licensed Products in the Field.

1.106 "Prosecution" or "Prosecute" means, with respect to a particular Patent Right, all activities associated with the preparation, filing, defense, prosecution and maintenance of such Patent Right, as well as supplemental examinations, re-examinations, reissues, applications for patent term adjustments and extensions, supplementary protection certificates and the like with respect to such Patent Right, together with the conduct of interferences, derivation proceedings, *inter partes* review, post-grant review, the defense of oppositions and other similar proceedings with respect to such Patent Right.

1.107 "Region" means each of the PRC, Macau, Hong Kong, Taiwan, Thailand, Singapore, South Korea, Cambodia, Indonesia, Myanmar, Philippines, Thailand, and Vietnam.

1.108 "Regulatory Approval" means the final or conditional approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in a country(ies) or Region(s), excluding separate Pricing and Reimbursement Approval that may be applicable in a Region.

1.109 "Regulatory Approval Application" means an application to seek regular or expedited Regulatory Approval of the Licensed Product for sale or marketing in any country(ies) or Region(s) in the Territory, as defined in the applicable Laws and filed with the Regulatory Authority of such country(ies) or Region(s).

1.110 "Regulatory Authority" means any multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, Manufacture, marketing or sale of the Licensed Product in a Region, including the NMPA.

1.111 "Regulatory Exclusivity" means, with respect to a Licensed Product in a Region, the period of time during which: (a) a Party or its Affiliates or its or their Sublicensees has been granted the exclusive legal right by a Regulatory Authority in such Region to market and sell such Licensed Product; or (b) the data and information submitted by a Party or its Affiliates or its or their sublicensees to the relevant Regulatory Authority in such Region for purposes of obtaining Regulatory Approval of such Licensed Product in such Region may not be disclosed, referenced, or relied upon in any way by a Third Party or such Regulatory Authority (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval of any product of a Third Party in such Region.

1.112 "Regulatory Filing" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to the Licensed Product,

including any documents submitted to any Regulatory Authority, including INDs, Regulatory Approval Applications, and all correspondence with any Regulatory Authority with respect to any Licensed Product (including minutes of any meetings, telephone conferences, or discussions with any Regulatory Authority).

1.113 "Reversion License" has the meaning set forth in Section 12.4(a) (Effects of Termination Generally).

1.114 "Royalty Term" has the meaning set forth in Section 6.2(b) (Royalty Term).

1.115 "Rules" has the meaning set forth in Section 13.2 (Arbitration).

1.116 "Safety Data" means any Adverse Event information from Clinical Trials and all results from non-clinical safety studies, including toxicology and carcinogenicity data (if any), with respect to the Licensed Product required by one or more Regulatory Authorities to be collected or to be reported to such Regulatory Authorities under applicable Laws, but excluding any information related to the efficacy of the Licensed Product.

1.117 "Sales Milestone Event" has the meaning set forth in Section 6.1(c) (Sales Milestone Payments).

1.118 "Sales Milestone Payment" has the meaning set forth in Section 6.1(c) (Sales Milestone Payments).

1.119 "Selling Entities" has the meaning set forth in the Preamble.

1.120 "Sell-Off Period" has the meaning set forth in Section 12.4(g) (Inventory).

1.121 "Senior Officers" means the Chief Executive Officer of each Party. If the position of any of the Senior Officers identified in this definition no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, then the applicable title of the Senior Officer set forth herein will be replaced with the title of another executive officer with responsibilities and seniority comparable to the eliminated Senior Officer, and the relevant Party will promptly provide notice of such replacement title to the other Party.

1.122 "Sublicense" means a grant of rights from Lian to a Sublicensee or an Affiliate under any of the rights licensed to Lian by Licensor under Section 2.1 (License Grants; Right of Reference; Acknowledgment).

1.123 "Sublicensee" means a Third Party sublicensee to which a Party or its Affiliates has granted rights under this Agreement or a Third Party licensee of rights with respect to the Licensed Product, which rights are retained by a Party under this Agreement with respect to such Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers, or levels of sublicenses of such rights).

1.124 "Supply Agreement" has the meaning set forth in Section 4.1 (Supply Agreement).

1.125 "Supply Failure" means, for a given [***], that Licensor has failed to supply or cause to be supplied to Lian those quantities of Licensed Product forecasted and ordered in accordance with the terms of the applicable Supply Agreement, and the cumulative shortfall of Licensed Product [***].

1.126 "Tax Withholdings" has the meaning set forth in Section 6.5 (Tax Withholding).

1.127 "Term" has the meaning set forth in Section 12.1 (Term).

1.128 "Term Sheet" means that certain non-binding (except with respect to confidentiality obligations therein) term sheet by and between Lian and Licensor, dated as of March 4, 2021.

1.129 "Terminated Product" has the meaning set forth in Section 12.4(a) (Effects of Termination Generally).

1.130 "Terminated Region" has the meaning set forth in Section 12.4(a) (Effects of Termination Generally).

1.131 "Territory" means the PRC, Hong Kong, Macau, Taiwan, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand, and Vietnam.

1.132 "Territory-Specific Development Plan" has the meaning set forth in Section 3.2(a) (Territory-Specific Development Plan).

1.133 "Third Party" means any Person other than a Party or any of its Affiliates.

1.134 "Third Party Claim" has the meaning set forth in Section 10.3(a) (Notice).

1.135 "Third Party Losses" means Losses resulting from an Action by a Third Party.

1.136 "Trademark" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.137 "Transfer" has the meaning set forth in Section 6.5 (Tax Withholding).

1.138 "Transferred BT-11 Information" has the meaning set forth in Section 1.30 (Confidential Information).

1.139 "Trigger Notice" has the meaning set forth in Section 2.10 (Right of Negotiation).

1.140 "Two-Invoice Policy" means the policy described in "the Opinion on the Implementation of the 'Two-Invoices' System in the Procurement of Pharmaceutical Products by Public Medical Institutions (trial)" (Guoyigaibanfa [2016] No. 4), officially released on 9 January 2017 and in any other applicable Laws that mandates public hospitals or any other purchaser of drugs in mainland China to purchase drugs from the distributor that purchases the drugs directly from the drug manufacturer, limiting the total number of invoices to two.

1.141 "United States" or "U.S." or "US" means the United States and its territories, possessions and commonwealths.

1.142 "Upstream License(s)" means an agreement between Licensor or any of its Affiliates, on the one hand, and any Third Party, on the other hand, pursuant to which Licensor has (a) in-licensed any Patent Rights or Know-How owned or Controlled by such Third Party that are included as part of the Licensed Patent Rights or Licensed Know-How (to the extent necessary or useful for Lian's Development, Manufacture and Commercialization of any Licensed Product in the Territory) or (b) agreed to provisions that would require Lian to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field.

1.143 "Valid Claim" means either: (a) a claim of an issued and unexpired patent that (i) has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction; and (ii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise, or (b) a claim included in a patent application that has not been cancelled, withdrawn, or abandoned, nor been pending for more than [***] from the earliest filing date to which such patent application or claim is entitled.

Article 2
LICENSE GRANTS

1.1 License Grants; Right of Reference; Acknowledgement.

(a) License Grants to Lian. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Lian:

(i) an exclusive (even with respect to Licensor and its Affiliates, other than to perform Clinical Trials in accordance with Section 3.3(d) (Non-Participation, and subject to this Section 2.1(a) (License Grants to Lian) and Section 2.5) (Licensor Right of Access and Reference), sublicensable (solely as permitted under Section 2.2(a) (Lian Right to Sublicense)), non-transferable (except as provided Section 14.1 (Assignment)), royalty-bearing license under the Licensed Technology to Develop, Manufacture, and Commercialize and otherwise, make, have made, use, offer for sale, sell, have sold, and import the Compound and Licensed Products in the Field in the Territory; and

(ii) a non-exclusive, non-transferable (except as provided Section 14.1 (Assignment)), sublicensable (solely as permitted under Section 2.2(a) (Lian Right to Sublicense)) license under the Licensed Technology to Manufacture Compounds and Licensed Products outside the Territory solely for (A) Development solely for purposes of obtaining Regulatory Approval of Licensed Products in the Field in the Territory; and (B) Commercialization of Licensed Products in the Field in the Territory.

(iii) Notwithstanding the foregoing license grant under this Section 2.1(a) (License Grants to Lian), Licensor retains the right under the Licensed Technology to Manufacture (or have Manufactured) Compounds and Licensed Products in the Territory solely for Development or Commercialization of Licensed Products in the Field outside the Territory.

(b) Lian Right of Access and Reference. Licensor hereby grants Lian and its Affiliates and Sublicensees access to, and a right of reference with respect to, (i) the Regulatory Filings, Regulatory Approvals, Marketing Authorizations, and all corresponding documentation Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Term, and (ii) all data generated by or on behalf of Licensor or its Affiliates relating to the Licensed Products, including clinical and preclinical data (including any such data generated from any Clinical Trial performed by or be on behalf of Licensor or its Affiliates), Safety Data and CMC Data contained or referenced in any Regulatory Filings, and all corresponding documentation Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Term, in each case ((i) and (ii)) to the extent reasonably useful or necessary for Developing, seeking, and securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory. The foregoing rights include the right for Lian and, to the extent permitted under this Agreement, its Affiliates and Sublicensees, to make copies of and reproduce such documentation and information for the purposes set forth in this Section 2.1(b) (Lian Right of Access and Reference). Licensor will promptly provide to Lian all data generated by or on behalf of it or its Affiliates from any Clinical Trial for a Licensed Product that is necessary or reasonably useful to Lian or its Affiliates or Sublicensees for securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Compound or Licensed Products in Field and in the Territory, including any Clinical Trial conducted under Section 3.3(d) (Non-Participation).

(c) Acknowledgement. Lian hereby acknowledges and confirms that, simultaneously herewith, Landos has transferred and assigned, or otherwise licensed, to the Selling Entities all of its rights, title, and interests in and to all Licensed Technology relating to BT-11, and the Selling Entities subsequently have transferred and assigned the same to Licensor.

1.2 Sublicensing and Subcontracting.

(a) Lian Right to Sublicense. Lian will have the right to grant Sublicenses (through multiple tiers) to (i) its Affiliates and to independent contractors engaged pursuant to Section 2.3 (Performance by Independent Contractors) and to its Third Party

collaboration partners, in each case, of any and all rights granted to Lian by Licensor pursuant to Section 2.1 (License Grants; Right of Reference; [***], and (ii) to other Third Parties, [***] subject to the requirements of Section 2.2(b) (Sublicense Requirements).

(b) Sublicense Requirements. Each Sublicense granted by Lian to a Third Party pursuant to Section 2.2(a) (Lian Right to Sublicense) will be in writing and will be consistent with the relevant terms and conditions set forth in this Agreement. No Sublicense will diminish, reduce or eliminate any obligation of either Party under this Agreement. Lian will be liable for any act or omission of its Sublicensees as if such Sublicensees were Lian hereunder. Without limiting the foregoing, each Sublicense granted by Lian or its Affiliates to a Sublicensee will contain (i) confidentiality and non-use provisions at least as restrictive or protective as those set forth in Section 8.1 (Confidential Information) with respect to Licensor's Confidential Information, and (ii) invention ownership and assignment provisions consistent with those set forth in Section 7.1 (Ownership of Inventions).

(c) Sublicense Survival. Upon the termination of this Agreement, [***], Licensor will enter into a direct license agreement with such Sublicensee on the same terms as this Agreement, taking into account any difference in license scope, territory and duration of sublicense grant (each a "New License Agreement"). Under any New License Agreement between Licensor and a former Sublicensee, such Sublicensee will be required to pay to Licensor the same amounts in consideration for such direct grant as Licensor would have otherwise received from Lian pursuant to this Agreement on account of such Sublicensee's exploitation of the relevant Licensed Products had this Agreement not been terminated. Under such New License Agreement, Licensor will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than those rights and obligations contained in, this Agreement and all applicable rights of Licensor set forth in this Agreement will be included in such New License Agreement. Each Sublicensee will be an intended Third Party beneficiary of this Section 2.2(c) with the right to enforce the same against Licensor. At the request of Lian, Licensor will issue a comfort letter directly to any potential Sublicensee confirming the terms of this Section 2.2(c).

1.3 Performance by Independent Contractors. Lian may contract or delegate any portion of its obligations hereunder to a contractor subject to the terms and condition of Section 14.8 (Affiliates, Sublicensees, and Contractors).

1.4 License Grant to Licensor. Lian hereby grants Licensor and its Affiliates a non-exclusive, sublicensable (through multiple tiers), royalty-free, fully paid up, perpetual, and irrevocable license under (a) any Product Inventions invented or otherwise developed or generated during the Term by or on behalf of Lian (including its Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) and (b) Prior Product Inventions, in each case of (a) and (b), to Develop, Manufacture, and Commercialize and otherwise, make, have made, use, offer for sale, sell, have sold, and import the Compounds and Licensed Products in the Field outside the Territory.

1.5 Licensor Right of Access and Reference. Lian hereby grants Licensor, its Affiliates, and Sublicensees access to, and a right of reference with respect to, (a) the Regulatory Filings, Regulatory Approvals, Marketing Authorizations and all corresponding documentation Controlled by Lian, its Affiliates, or Sublicensees as of the Effective Date or at any time during the Term, and (b) all data generated by Lian or its Affiliates relating to the Licensed Products, including clinical and preclinical data, Safety Data and CMC Data contained or referenced in any Regulatory Filings, and all corresponding documentation Controlled by Lian, its Affiliates or Sublicensees as of the Original Agreement Effective Date or at any time during the Term. The foregoing rights include the right for Licensor and, to the extent permitted under this Agreement, its Affiliates, and Sublicensees, to make copies of and reproduce such documentation and information for the purposes set forth in this Section 2.4 (License Grant to Licensor). Lian will promptly provide to Licensor all data generated by or on behalf of it or its Affiliates from any Clinical Trial for a Licensed Product that is necessary or reasonably useful to Licensor or its Affiliates or licensees for securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Compound or Licensed Products in Field outside the Territory.

1.6 Rights in Bankruptcy.

(a) All rights and licenses now or hereafter granted by Licensor to Lian under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Lian pursuant to Section 2.1 (License Grants; Right of Reference; Acknowledgment) are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon any filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Licensor, Licensor agrees that the Lian, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Without limiting the generality of the foregoing, Licensor and Lian intend and agree that any sale of Licensor's assets under Section 363 of the Bankruptcy Code shall be subject to Lian's rights under Section 365(n), that Lian cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Lian's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Lian. Licensor acknowledges and agrees that "embodiments" of Intellectual Property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Licensed Know-How, Licensed Patent Rights, and all information related to the Licensed Know-How or Licensed Patent Rights. If (A) a case under the U.S. Bankruptcy Code is commenced by or against Licensor, (B) this Agreement is rejected as provided in the U.S. Bankruptcy Code and (C) Lian elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, Licensor (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will: (1) provide Lian with all such Intellectual Property (including all embodiments thereof) held by Licensor and such successors and assigns, or otherwise available to them, immediately upon Lian's written request. Whenever Licensor or any of its successors or assigns provides to Lian any of the Intellectual Property licensed hereunder (or any embodiment thereof) pursuant to this Section 2.6(a) (Rights in Bankruptcy), Lian will have the right to perform Licensor's obligations hereunder with respect to such Intellectual Property, but neither such provision nor such performance by Lian will release Licensor from liability resulting from rejection of the license or the failure to perform such obligations; and (2) not interfere with Lian's rights under this Agreement, or any agreement supplemental hereto, to such Intellectual Property (including such embodiments), including any right to obtain such Intellectual Property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

(b) All rights, powers and remedies of Lian provided in this Section 2.6 (Rights in Bankruptcy) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to Licensor. The Parties intend the following rights to extend to the maximum extent permitted by applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n): (A) the right of access to any Intellectual Property (and all embodiments thereof) of Licensor or any Third Party that is licensed or sublicensed to Lian under this Agreement; and (B) the right to contract directly with any Third Party to complete the contracted work.

1.7 No Implied Licenses; Reservation of Rights. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel, or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party, or its Affiliates to the other Party under this Agreement are reserved.

1.8 Transfer of Know-How. [***], Landos transferred to Lian or its Affiliates the Licensed Know-How relating to the Compound that existed as of the Original Agreement Effective Date, in the manner and pursuant to the timelines set forth in Schedule 2.8 (Know-How

Transfer) attached to the Original License Agreement. In addition, each Party will provide updates throughout the Term, in a manner established by the JSC, to the other Party of any Know-How that such Party or its Affiliates comes to Control that is necessary or reasonably useful for the Development, Manufacture or Commercialization of Compounds and Licensed Products in the Field (such updates to be made reasonably promptly after any Calendar Quarter in which such Know-How comes into Control of the applicable Party or its respective Affiliates). Additionally, [***] for a period of [***] after the initial Licensed Know-How transfer under the Original License Agreement, Landos provided Lian or its Affiliates with reasonable assistance to facilitate the successful transfer of such Licensed Know-How.

1.9 Exclusivity.

(a) Lian Exclusivity. Subject to the terms of this Agreement, neither Lian will, nor any of its Affiliates will, directly or indirectly, Develop, Manufacture, or Commercialize any Competitive Product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license or grant any right to any Third Party to Develop, Manufacture, or Commercialize any Competitive Product anywhere in the Territory.

(b) Licensor Exclusivity. Subject to the terms of this Agreement, neither Licensor will, nor any of its Affiliates will, directly or indirectly, Develop, Manufacture, or Commercialize any Competitive Product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license or grant any right to any Third Party to Develop, Manufacture, or Commercialize any Competitive Product anywhere in the Territory.

(c) Business Combinations. [***]

(d) Acquisition of a Competitive Product. [***]

1.10 Right of Negotiation. During the Term, Licensor grants to Lian an exclusive right of negotiation to obtain an exclusive license, under the applicable Patent Rights and Know-How Controlled by Licensor, to Develop, Manufacture, and Commercialize and otherwise, make, have made, use, offer for sale, sell, have sold, and import Additional Products in the Field in the Territory (an "Additional Product License"), subject to the remainder of this Section 2.10 (Right of Negotiation). From time to time, Licensor may present Lian with information regarding Additional Products and offer Lian an opportunity to negotiate an Additional Product License (a "Trigger Notice"). Licensee may exercise its exclusive negotiation right by submitting to Licensor a written offer for the proposed terms of such Additional Product License, including the material financial terms and a high-level development plan for the development and commercialization of the applicable Additional Product in the Territory in one or more of the applicable indications (an "Offer") within ninety (90) days after receiving the Trigger Notice (the "Offer Period"). If Lian submits an Offer to Licensor during the Offer Period, then Licensor and Lian shall enter into exclusive good faith negotiations regarding the terms for such Additional Product License for a period of ninety (90) days following Licensor's receipt of such Offer (the "Negotiation Period"). If the Parties agree on the terms for such Additional Products, then the Parties may amend this Agreement to include such Additional Product License or may enter in a separate written agreement with respect to such Additional Product License. If Lian does not submit an Offer for such Additional Product License during the Offer Period or the Parties are unable to agree on the terms of such Additional Product License or enter into an agreement with respect thereto during the Negotiation Period, then [***].

Article 3
DEVELOPMENT

1.1 Development Responsibilities in General.

(a) Development Diligence. Lian (directly, or through its Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for the Licensed Product in the Territory, and Licensor (directly, or through its respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for the

Licensed Product outside of the Territory. Without limiting the foregoing, Lian will use Commercially Reasonable Efforts to carry out any Development activities in the Territory assigned to Lian under the Territory-Specific Development Plan. [***].

(b) Development Responsibilities. Subject to the terms and conditions of this Agreement, including this Article 3 (Development) and Section 5.5 (Decision-Making; Escalation to Senior Officers), Lian will have sole authority to, at its own expense, Develop the Licensed Product for the purpose of obtaining Regulatory Approval in the Field in the Territory. Lian will be responsible for the day-to-day implementation of any Development activities for which it (or any of its Affiliates) is assigned responsibility under this Agreement (including the Development Plans).

1.2 Development Plans.

(a) Territory-Specific Development Plan. Except for the activities allocated to Lian under a Global Development Plan, all Development of Compounds and Licensed Products in the Territory will be conducted pursuant to a written a plan (the "Territory-Specific Development Plan"), the initial draft of which will be prepared by Lian and submitted to the JSC [***]. The Territory-Specific Development Plan will contain in reasonable detail (i) [***] (ii) [***]. Lian will update the Territory-Specific Development Plan not less than [***], and either Party may propose modifications to the Territory-Specific Development Plan at any time, [***], each update to the Territory-Specific Development Plan will become effective and supersede the then-current Territory-Specific Development Plan. In the event of any proposed change to the Development Plan as a result of any interaction with any Regulatory Authority, the JSC will meet as promptly as practicable to review and discuss any such proposed changes and determine an appropriate revision (if any) to the Territory-Specific Development Plan. If Lian is delayed in performing (or fails to perform) an obligation assigned to Lian in the Territory-Specific Development Plan as a result of Licensor's failure to timely perform any of its obligations under this Agreement or the Development Plan, then the timelines for the performance of Lian's obligations under the Territory-Specific Development Plan will be extended commensurate with the delay caused by Licensor.

(b) Global Development Plan. Licensor's global Development of the Compounds and Licensed Products inside and outside of the Territory will be conducted pursuant to a written plan (the "Global Development Plan"). Prior to [***], Licensor will provide to the JSC for its review and discussion the initial Global Development Plan. The Global Development Plan will include (i) [***], (ii) [***] and (iii) [***]. From time to time, Licensor may propose updates to the then-current Global Development Plan for the Licensed Products to the JSC to review and discuss and, to the extent relating to activities to be conducted in the Territory, to determine whether to approve.

1.3 Global Trial Participation.

(a) Global Phase III Trial Participation. In the event that Licensor decides to conduct a Global Phase III Trial for a Licensed Product, Lian (i) may elect, in its sole discretion, to participate in such Global Phase III Trial if such Global Phase III Trial is for ulcerative colitis and (ii) will participate in such Global Phase III Trial, if such Global Phase III Trial is the first Phase III Trial for a Licensed Product for Crohn's disease, and, in each case ((i) and (ii)), will include Clinical Trial sites for such Global Phase III Trial in the Territory, subject to [***]. In the event that Lian participates in such Global Trial, subject to this Section 3.3(a) (Global Phase III Trial Participation) and Section 3.3(c) (Study Design and Protocol), such activities to be conducted by Lian in support of such Global Phase III Trial will be included in the Global Development Plan, and Lian will support Licensor on such global development for such Global Trial by (A) including Clinical Trial sites in the Territory [***], (B) being responsible for any costs and expenses incurred by or on behalf of Lian for its participation in such Global Trial conducted in the Territory, and (C) if such Global Phase III Trial is the first such Global Phase III Trial for a Licensed Product for Crohn's disease, using Commercially Reasonable Efforts to enroll patients in the Territory equal to a minimum of [***] (or such other percentage as the Parties may agree) of the total

patients in such Global Phase III Trial (the "Patient Commitment"). In the event that Lian participates in such a Global Phase III Trial and fails to enroll sufficient patients in the Territory to meet the Patient Commitment (the "Patient Shortfall"), and Licensor instead enrolls patients in such Global Phase III Trial in lieu of Lian in order to meet the Patient Commitment, then Lian will reimburse Licensor for the number of patients representing the Patient Shortfall that Licensor so enrolls in such Global Phase III Trial (up to the Patient Commitment) based on the Average Cost Per Patient in the Territory. If Lian does not participate in a Global Phase III Trial for either of Crohn's disease or ulcerative colitis, then Lian will conduct a Clinical Trial in the Territory intended to support the Regulatory Approval for the use of the Licensed Product in the applicable disease in the Territory, and such Clinical Trial will be included in the Territory-Specific Development Plan. Additionally, in such event, Lian shall use good faith efforts to design the protocol for such Clinical Trial in a manner that would permit Licensor to use clinical data generated from such Clinical Trial to support the Regulatory Approval for the use of the Licensed Product in the applicable disease in the U.S.

(b) Other Global Trial Participation. In the event that Licensor decides to conduct a Global Trial for a Licensed Product, other than a Global Phase III Trial, that is primarily intended to support the Development or Regulatory Approval of any Compound or Licensed Product in the Field outside the Territory (each, an "Other Global Trial"), to the extent the Parties agree to Lian's participation in such Other Global Trial, then Lian will participate in such Other Global Trial and include Clinical Trial sites in the Territory, subject to (i) [***], (ii) [***], and (iii) [***]. For any Other Global Trial in which Lian agrees to participate, the Parties will prepare an update to the Global Development Plan to include the Development activities to be conducted by Lian in the Territory in support of such Other Global Trial, including the Clinical Trial sites in the Territory for such Other Global Trial, to be determined by Lian after considering in good faith Licensor's suggestions thereon.

(c) Study Design and Protocol. Licensor will determine the study design and study protocol for any Global Phase III Trial or Other Global Trial, and Lian will have the right to determine which patient types to enroll in the Territory for such Global Phase III Trial or Other Global Trial. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent that Lian participates in any such Global Phase III Trial or Other Global Trial, Lian's participation in such Global Phase III Trial or Other Global Trial is subject to the Parties' agreement on such study design and study protocol.

(d) Non Participation. If Lian elects not to participate in any Global Phase III Trial or Other Global Trial, then (i) the Parties will discuss Licensee's enrollment of patients from in the Territory and (ii) following such discussion, with Lian's prior written consent, not to be unreasonably withheld, Licensor may directly recruit and enroll patients in such Clinical Trial in the Field in the Territory, or enter into agreements with Third Parties relating to such enrollment or recruitment; *provided* that, in each case, such recruitment and enrollment of patients from in the Territory does not, and could not reasonably be expected to, have an adverse effect on (i) the conduct by or on behalf of Lian of any Phase III Clinical Trial or other registrational clinical trial for the Licensed Product in the Field in the Territory or (ii) the filing by or on behalf of Lian of any Regulatory Approval Application for the Licensed Product by or on behalf of Lian in the Field in the Territory or the receipt of Regulatory Approval for the Licensed Product in the Field in the Territory.

1.4 Development Records and Reporting.

(a) Records. Lian will maintain complete and accurate records of all work conducted by Lian in furtherance of seeking Regulatory Approval for the Licensed Product in the Field in the Territory. Such records will be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with applicable Laws. Lian will document all non-clinical studies and Clinical Trials for Licensed Products in formal written study records according to applicable Laws, including applicable national and international guidelines such as ICH, GCP and GLP, and shall, at Licensor's written request, provide Licensor

English translations thereof (to the extent prepared and originated in a language other than English and subject to reimbursement by Licensor of any cost of translation thereof). To the extent permissible, Licensor shall have the right to review and copy such records at reasonable times and to obtain access to the original to the extent necessary or useful for regulatory or patent purposes in accordance with this Agreement.

(b) Reporting. Lian will provide a written report to the JSC for review and discussion, at least [***], in English, summarizing Lian's activities and progress related to the pursuit of Regulatory Approval for the Licensed Product in the Field in the Territory.

1.5 Development Costs. Except as set forth in Section 3.3 (Global Trial Preparation) and this Section 3.5 (Development Costs), each Party will bear 100% of the costs and expenses it incurs in connection with the Development activities conducted under the Development Plans.

1.6 Regulatory Submissions and Approvals; Communications; Meetings.

(a) Regulatory Filings and Approvals. Lian, or its relevant Affiliates or Sublicensees, will have the sole and exclusive right to file and hold all Regulatory Filings, and to apply for and maintain all Regulatory Approvals and Pricing and Reimbursement Approvals, in each case, for all Licensed Products in the Field in the Territory at Lian's cost and expense in the name of Lian or any of its Affiliates and Sublicensees. The Parties will use good faith efforts to cooperate to effectuate this Section 3.6(a) (Regulatory Filings and Approvals), and if, after the Parties' use of good faith efforts, Lian, or its Affiliate or Sublicensee [***]. Subject to the terms and conditions of this Agreement, Lian will be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the obtaining of Regulatory Approvals and any Pricing and Reimbursement Approvals, as applicable, for Licensed Products in the Field from Regulatory Authorities or Governmental Authorities in the Territory. Lian will conduct such activities (and any and all regulatory activities delegated to Lian in this Agreement) (A) in its own name, if Lian is the legal and beneficial owner of the Regulatory Approvals for the Licensed Products in the Field in the Territory, or (B) as the express and authorized regulatory agent of record for Licensor in the Field in the Territory, [***].

(b) Regulatory Communications. Subject to applicable Law and this Section 3.5 (Development Costs), Lian will oversee, monitor, and manage all interactions and communications with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory. Lian will have final decision-making authority regarding all regulatory activities for the Licensed Products in the Field in the Territory, including the labeling strategy and the content of Regulatory Filings for Licensed Products.

(c) Regulatory Meetings. Until such time as Lian obtains Regulatory Approval for the Licensed Product in the Field in the Territory, to the extent legally permissible and practicable, Lian will provide Licensor with reasonable prior written notice of all substantive meetings with Regulatory Authorities regarding the Licensed Product if permitted by applicable Law or the Regulatory Authority. Licensor will have the right to request to be present as an observer at (but not to participate in, unless requested by Lian or the Regulatory Authority) all such meetings with Regulatory Authorities to the extent permitted under applicable Law, at Licensor's sole cost and expense, and Lian will consider any such request in good faith.

1.7 Termination or Suspension of Clinical Trials. Notwithstanding any provision to the contrary set forth in this Agreement or the Pharmacovigilance Agreement, the Parties hereby agree that Lian may terminate or suspend any Clinical Trial relating to the Licensed Products in the Field in the Territory, and Licensor may terminate or suspend any Global Trial, without the approval or consent of the JSC or the other Party, if (i) a Regulatory Authority, institutional review board or safety data review board for such Clinical Trial has required or recommended such termination or suspension or (ii) following review and discussion with the JSC, the Party seeking such termination believes in good faith that such termination or suspension is

warranted because of observed safety risks to the study subjects. In either case, such Party will promptly notify the other Party in writing of such termination or suspension.

1.8 No Harmful Actions. Each Party will promptly notify the other Party of all material communications or correspondence with Regulatory Authorities with respect to any Licensed Product in such Party's territory that are (a) received by such Party or its Affiliates, Sublicensees, or other licensees (to the extent that such Party has the right to disclose such material communications or correspondence of other licensees and *provided* that such Party uses commercially reasonable efforts to obtain such right from such other licensees) from any Regulatory Authority or submitted by such Party, its Affiliates or other licensees to any Regulatory Authority and (b) would reasonably be expected to impact the other Party's Development, Manufacture, or Commercialization of the Licensed Products in the Field in the other Party's territory. If either Party believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that could have a material adverse impact upon the regulatory status of any Licensed Product in such Party's territory, then such Party will have the right to bring the matter to the attention of the JSC and the JSC will discuss in good faith a resolution to such concern.

1.9 Pharmacovigilance. Within [***] after the Effective Date, the Parties will negotiate in good faith and finalize the actions that the Parties will employ with respect to the Licensed Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). These responsibilities will include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of Adverse Event reports and any other information concerning the safety of any Licensed Product, including recall and withdrawal responsibilities, processes and procedures. Such guidelines and procedures will be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Law. Furthermore, such agreed procedure will be consistent with relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting safety reporting requirements, in which case local reporting requirement will prevail. Lian will be responsible for reporting quality complaints, Adverse Events, and safety data related to the Licensed Products in the Field to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Products in the Field in the Territory. Licensor will be responsible for reporting quality complaints, Adverse Events, and safety data related to Licensed Product to applicable Regulatory Authorities outside the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Product outside the Territory. The Pharmacovigilance Agreement will also provide for a worldwide safety database to be maintained by Licensor at its sole cost and expense, which worldwide safety database will be accessible by Lian and its Affiliates, Sublicensees and contractors to the full extent necessary for Lian to exercise its rights under this Agreement, comply with its obligations under this Agreement and comply with all applicable Law. Each Party will comply with its respective obligations under such Pharmacovigilance Agreement and will cause its Affiliates and Sublicensees and contractors to comply with such obligations.

Article 4
MANUFACTURE, SUPPLY, AND COMMERCIALIZATION

1.1 Supply Agreement. Within [***] following the JSC's approval of the Territory-Specific Development Plan, the Parties will negotiate in good faith and enter into a supply agreement for the Manufacture and supply of clinical quantities of Licensed Products by Licensor to Lian for use solely in connection with Clinical Trials and other Development of Licensed Products in the Field in the Territory (the "Clinical Supply Agreement") and, no later than [***] prior to the date Lian anticipates its First Commercial Sale of the Licensed Products in the Territory, a supply agreement for the Manufacture and supply of commercial quantities of Licensed Products by Licensor to Lian for the commercial sale and distribution of Licensed Products in the Field in the Territory (the "Commercial Supply Agreement" and, together with the Clinical Supply Agreement, the "Supply Agreements"). Unless otherwise agreed or required by applicable Laws, the Supply Agreements will specify that (a) Licensor will (or will cause its Affiliates to) Manufacture and supply, and Lian will purchase from Licensor, all of Lian's, its Affiliates' and Sublicensees' requirements for the Licensed Products for the Development or Commercialization (as applicable) in the Field in the Territory in their

finished form and at a price equal to (a) under the Clinical Supply Agreement, [***] and (b) under the Commercial Supply Agreement, [***].

1.2 Two-Invoice Policy. The Parties agree that in the event, under the Two-Invoice Policy and tendering policies and applicable Laws in a given province in the PRC, neither Lian nor any of its Affiliates can, based on their existing qualifications, distribute the Licensed Products for such province directly or indirectly to its distributors for the PRC, then, the Parties will use reasonable efforts to discuss in good faith alternative arrangements for the distribution of the Licensed Product in such province that complies with the Two-Invoice Policy as implemented in such province and that maintains the economic interests of the Parties as agreed under this Agreement.

1.3 Manufacture Technology Transfer Option. At any time after the Effective Date, upon Lian's written request to Licensor, and Licensor's written consent (such consent not to be unreasonably withheld or delayed) or, in the event of a Supply Failure, upon Lian's written notice to Licensor, (a) the Parties will discuss in good faith and prepare a technology transfer plan pursuant to which Licensor will (i) provide access, and transfer, to Lian or its designated CMO, at Lian's sole cost (other than in the event that such transfer is following the occurrence of a Supply Failure, in which case the Parties will each bear their respective costs for such transfer) the Licensed Know-How Controlled by Licensor or its Affiliates that is necessary or reasonably useful for Lian or such CMO to Manufacture the Compounds and the Licensed Products in the Field in the Territory, and (ii) provide all other reasonably necessary assistance and services to Lian [***] to enable Lian or its designated CMO to Manufacture the Compounds and Licensed Products in substantially the same manner as Licensor or its Affiliates or CMOs (as applicable) Manufactures the Compounds and the Licensed Product for Lian; and (b) following agreement on such plan, Licensor will perform and execute the technology transfer plan in accordance with its terms.

1.4 Commercialization.

(a) Commercialization Diligence. Upon receipt of the Marketing Authorization for a Licensed Product in the Field in a given Region in the Territory, Lian (directly, or through its Affiliates, Sublicensees or contractors) will use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Field in such Region in the Territory. Lian will have sole decision-making authority and discretion with respect to Commercializing the Licensed Product in the Field in the Territory. [***].

(b) Reporting Obligations. Lian will report to Licensor in writing, on a [***] basis, beginning with the Calendar Year following the first Regulatory Approval of a Licensed Product in the Field in the Territory (for the period ending December 31 of the prior Calendar Year), a summary of Lian's material Commercialization activities for such Licensed Product performed to date (or updating such report for activities performed since the last such report was given hereunder, as applicable).

(c) Trademarks.

(i) Lian will have the right to brand the Licensed Products in the Field in the Territory using Lian related Trademarks and any other Trademarks and trade names (the "Lian Trademarks") it determines appropriate for the Licensed Products, which branding may vary by Region or within a Region. Lian will own all rights in the Lian Trademarks and register and maintain such Lian Trademarks in the countries and regions within the Territory, where and how it determines appropriate.

(ii) Lian will also have the right to brand the Licensed Products in the Field and in the Territory using the Licensed Marks, and Lian will comply with Licensor's reasonable trademark usage guidelines and quality control guidelines in effect from time to time as provided by Licensor. Licensor will own and retain all rights to the Licensed Marks (together with all goodwill associated therewith) in the Territory, and will prepare, file, prosecute, and maintain all Licensed Marks in the Territory at its own expense; provided, however, Licensor will provide to Lian copies of all applications,

submissions, communications, and correspondence intended to be sent to, sent to or received by Governmental Authorities or Third Parties in connection with such filing, prosecution, and maintenance of the Licensed Marks in the Territory so that Lian may review and comment thereon (which will be provided with sufficient advanced notice so that Lian may meaningfully review and comment, to the extent practicable), and will incorporate any reasonable comments provided by Lian with respect to such applications, submissions, communications, or correspondence. Subject to terms and conditions of this Agreement, Licensor will grant and hereby grants an exclusive, sublicensable (subject to Section 2.2) (Sublicensing and Subcontracting), fully paid-up, royalty free, non-transferrable (subject to Section 14.1 (Assignment)) license under the Licensed Marks for Lian to Commercialize the Licensed Products in the Field in the Territory.

(iii) Diversion. Subject to applicable Law, each Party hereby covenants and agrees that (A) it and its Affiliates will not, and it will contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its licensees, Sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like, in the other Party's territory, and (B) neither Party will engage, nor permit its Affiliates, Sublicensees, or contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, Region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, Region or jurisdiction in the other Party's territory.

(d) No Violation. Notwithstanding anything to the contrary contained herein, Lian (including its Affiliates, Sublicensees and contractors) will not be obligated to undertake or continue any Commercialization activities with respect to Licensed Products if Lian (or its Affiliates, Sublicensees or contractors, as applicable) reasonably determines that performance of such Commercialization activity would violate applicable Laws or infringe any Third Party Patent Rights.

Article 5
GOVERNANCE; JOINT STEERING COMMITTEE

1.1 Formation; Purposes and Principles. [***], Licensor and Lian will form a joint steering committee (the "JSC") to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement.

1.2 Specific Responsibilities. In addition to its overall responsibility to provide strategic oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement, the JSC will:

(a) share information with respect to the Development and Commercialization of the Licensed Products by Lian in the Territory (including, as applicable, any such information generated by Lian prior to the Effective Date pursuant to the Original License Agreement) and by Licensor outside the Territory;

(b) coordinate and share information with respect to the Manufacture of the Licensed Products by Licensor, for so long as Licensor is supplying Licensed Products to Lian;

(c) keep each Party reasonably informed of the other Party's Development and Commercialization activities and interactions with Regulatory Authorities in the other Party's territory, by receiving updates from the Party conducting such activities to the extent that such activities materially impact or would reasonably be expected to materially impact the other Party's Development, Manufacture or Commercialization of the Licensed Products in the Territory; attempt to resolve in the first instance all matters between the Parties that are in dispute, in accordance with Section 5.5

(Decision-Making; Escalation to Senior Officer) and Section 13.1 (Dispute Resolution; Escalation);

(d) [***];

(e) review and discuss the initial Global Development Plan, and each update thereto, as described in Section 3.2(b) (Global Development Plan);

(f) review, discuss, and determine whether to approve any activities to be conducted by Lian in the Territory under the Global Development Plan, as described in Section 3.2(b) (Global Development Plan);

(g) review, discuss, and determine matters that may have a material adverse impact upon the regulatory status of the Licensed Products, as described in Section 3.9 (Pharmacovigilance); and

(h) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

1.3 Membership. The JSC will be composed of a total of [***] representatives of each Party, which will be appointed by each of Licensor and Lian, respectively. Each individual appointed by a Party as a representative to the JSC will be an employee of such Party with sufficient seniority and decision-making authority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities, and have knowledge and expertise in the Development and Commercialization of compounds and products similar to the Compound and Licensed Products under this Agreement. The JSC may change its size from time to time by consent of its members, *provided* that the JSC will consist at all times of an equal number of representatives of each Party, unless otherwise agreed by the Parties in writing. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party's co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The co-chairperson of the JSC will cast its Party's vote on the JSC and such designee will have the authority to make decisions on behalf of such Party. Each co-chairperson will alternate being responsible for each meeting for (a) calling and conducting meetings, (b) preparing and circulating an agenda in advance of each meeting; *provided*, *however*, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda, (c) preparing minutes of each meeting that reflect the material decisions made and action items identified at such meetings promptly thereafter, and (d) sending draft meeting minutes to each member of the JSC for review and approval within [***] days after each JSC meeting. Meeting minutes issued in accordance with clause (d) of this Section 5.3 (Membership) will be deemed approved unless [***] members of the JSC objects to the accuracy of such minutes within [***] Business Days of receipt. The Alliance Managers will work with the chairpersons to prepare and circulate agendas and to ensure the preparation and approval of minutes. Each JSC representative will be subject to confidentiality obligations no less stringent than those in Article 8 (Confidentiality and Publicity).

1.4 Meetings; Reports. The JSC will hold meetings at least [***] per Calendar Quarter during the Term for so long as the JSC exists, unless the Parties agree in writing to a different frequency. No later than [***] Business Days prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the applicable co-chairperson will prepare and circulate an agenda for such meeting. Either Party may also call a special meeting of the JSC by providing at least [***] Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the applicable co-chairperson of the JSC and the Alliance Managers to provide the members of the JSC no later than [***] Business Day prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person or by audio or video conference as its representatives may agree. Other representatives of the Parties, their Affiliates, or Third Parties involved in the Development, Manufacture, or Commercialization of Licensed Products may be invited by the members of

the JSC to attend meetings as non-voting observers if such representatives are subject to confidentiality obligations no less stringent than those set forth in Article 8 (Confidentiality and Publicity). No action taken at a meeting will be effective unless at least [***] representative of each Party (which [***] not such Party's Alliance Manager) is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.

1.5 Decision-Making; Escalation to Senior Officers. The Parties will endeavor to reach unanimous agreement with respect to all matters within the JSC's authority. Each Party's representatives on the JSC will collectively have one vote, (the "Party Vote") and no action or decision will be taken by the JSC without unanimous Party Vote (*i.e.*, the affirmative Party Vote of each Party). If the JSC is not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, then either Party may refer such matter to the Senior Officers for resolution, and the Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [***] Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then Lian will have the final decision-making authority as to (a) [***] (b) [***], or [***], Licensor will have the final decision-making authority with respect to such matter. Subject to the foregoing sentence, Licensor will have final decision-making authority over [***]. The status quo with respect to any matter that is not subject to a Party's final decision-making authority, and is not resolved at the JSC or by escalation to the Senior Officers as described above, will [***].

1.6 Limitations. Notwithstanding anything to the contrary, neither Party will have the final decision-making authority on amending or updating the Development Plan in any way that would materially alter the scope of the other Party's obligations hereunder, increase the other Party's financial obligations hereunder, or result in the disclosure of the Confidential Information of the other Party, in each case, without the other Party's prior written consent. Notwithstanding any provision of this Article 5 (Governance; Joint Steering Committee) to the contrary, the JSC will not have the authority to amend the terms or conditions of this Agreement.

1.7 Alliance Managers.

(a) Appointment. Each Party will appoint a person to oversee interactions between the Parties for all matters related to the Development and Commercialization of Licensed Products between meetings of the JSC (each, an "Alliance Manager"). The Alliance Managers will have the right to attend all meetings of the committees as non-voting participants and may bring to the attention of the JSC any matters or issues either Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may agree in writing. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers with respect to Development and Commercialization matters, respectively, by notice in writing to the other Party.

(b) Responsibility. The Alliance Managers will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(i) provide a single point of communication within the Parties' respective organizations and between the Parties with respect to this Agreement;

(ii) coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and

(iii) take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including working with the co-chairpersons with respect to the giving of proper notice and the preparation and approval of

minutes) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

Article 6
FINANCIAL PROVISIONS

1.1 Milestone Payments.

(a) **[Intentionally omitted]**.

(b) Development Milestone Payment. During the Term, Lian will notify Licensor in writing of the achievement by or on behalf of Lian or its Affiliates or Sublicensees of any milestone event set forth in Table Section 6.1(b) (Development Milestone Payment) (each, a "Development Milestone Event") for the applicable Licensed Product promptly after the occurrence thereof, and Lian will pay Licensor the milestone payment set forth in the table below (each, a "Development Milestone Payment") no later than [***] days after the achievement of such milestone event by Lian or its Affiliates or any Sublicensees. Each of the milestone payments set forth in Table 6.1(b) (Development Milestone Payment) is payable only upon the first achievement of such milestone by the first applicable Licensed Product to achieve such Development Milestone Event, and none of the Development Milestone Payments will be payable more than once regardless of how many times such Development Milestone Event is achieved.

Development Milestone Event	Development Milestone Payment (in Dollars)
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
Total	[***]

(c) Sales Milestone Payments. During the Term, Lian will notify Licensor in writing of its achievement of each of the sales milestones below within [***] days after the [***] in which the cumulative Net Sales of all Licensed Products in the Territory first exceed the indicated Dollar value (each, a "Sales Milestone Event"). Lian will pay to Licensor each of the milestone payments set forth below within [***] days of providing notice of each Sales Milestone Event (each, a "Sales Milestone Payment"). Each of the milestone payments set forth in Table 6.1(c) (Sales Milestone Payments) is payable only upon the first achievement of such Sales Milestone Event and none of the Sales Milestone Payments will be payable more than once regardless of how many times such Sales Milestone Event is achieved.

Sales Milestone Event	Sales Milestone Payment (in Dollars)
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]
5. [***]	[***]
Total	[***]

1.2 Royalties.

(a) Royalty Rate. Subject to the terms and conditions of this Agreement, during the applicable Royalty Term, Lian will pay to Licensor a royalty on the Net Sales of all Licensed Products in the Territory that is the product of the aggregate annual Net Sales of all Licensed Products in the Territory and the applicable royalty rate in the following table, subject to the provisions of Section 6.3 (Payment Adjustments).

Portion of the Annual Net Sales of the Licensed Products in the Territory	Royalty Rate
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]

(b) Royalty Term. Royalties will be due under this Section 6.2 (Royalties) with respect to a given Licensed Product in a given Region in the Territory during the period commencing upon the First Commercial Sale of such Licensed Product in a specified Region and ending upon the latest of (i) the expiration of the last-to-expire Valid Claim of a Licensed Patent Right Covering any composition of matter (excluding formulations) of such Licensed Product that would be infringed by the sale of such Licensed Product in such Region, (ii) the expiry of the applicable Regulatory Exclusivity for such Licensed Product in such Region; or (iii) the [***] anniversary of the First Commercial Sale of such Licensed Product in such Region (such period, the "Royalty Term").

(c) Royalty Payments and Reports. Within [***] days following the end of [***] following the First Commercial Sale of a Licensed Product, Lian shall furnish to Licensor a written report for the [***] showing the [***]. Lian shall pay Licensor the royalty due for such [***] calculated in accordance with this Agreement within [***] days of delivery of the written report to Licensor.

1.3 Payment Adjustments. The following will apply to all royalties paid pursuant to Section 6.2(a) (Royalty Rate):

(a) Expiration of Valid Claims. On a Licensed Product-by-Licensed Product and Region by Region basis, if at any time during the Royalty Term in a given Region in the Territory, there is no Valid Claim of a Licensed Patent Right Covering a composition of matter (excluding formulation) of such Licensed Product that would be infringed by the sale of such Licensed Product in such Region, then the applicable royalty rate in effect with respect to such Licensed Product in such Region as specified in Section 6.2(a) (Royalty Rate) will be reduced by [***] for the remainder of the Royalty Term for such Licensed Product in such Region.

(b) Generic Entry. If, at any time during the Royalty Term, a Generic Product of a Licensed Product [***] in any Region in the Territory in which a Licensed Product is then being sold by Lian or an Affiliate or Sublicensee, then the applicable royalty rates in effect with respect to such Licensed Product in such Region as specified in Section 6.2(a) (Royalty Rate) will be reduced by [***] for the remainder of the Royalty Term for such Licensed Product in such Region.

(c) Third Party Payments. If Lian makes a payment under any agreement with a Third Party pursuant to which Lian obtains a license or other rights under a Patent Right or other Intellectual Property owned or controlled by such Third Party in a given Region (whether by acquisition or license) that is necessary or reasonably useful to Develop, Manufacture, or Commercialize one or more Licensed Products in such Region, then Lian may offset against the Milestone Payments or royalties due to Licensor for the Development and Commercialization of the Licensed Products in such Region covered by such license or rights an amount equal to [***] of the amounts paid to such Third Party under such agreement (including any upfront payments, milestone payments, and royalties), in all cases, subject to Section 6.4(d) (Cumulative Deductions).

(d) Cumulative Deductions. Notwithstanding the foregoing, in no event will the deductions set forth in Section 6.3(a) (Expiration of Valid Claims) through Section 6.3(c) (Third Party Payments) reduce (i) the royalties otherwise payable to Licensor as specified in Section 6.2(a) (Expiration of Valid Claims) or (ii) with respect to the deductions set forth in Section 6.3(c) (Third Party Payments), the Milestone Payments otherwise payable to Licensor as specified in Section 6.1(b) (Development Milestone Payment) and Section 6.1(c) (Sales Milestone Payments), in each case, by more than [***]. To the extent the foregoing limitation limits the reduction Lian is permitted to take during a Calendar Quarter, Lian will be entitled to carryforward the amount of the reduction Lian was unable to take during such Calendar Quarter and apply such amounts to royalties or Milestone Payments, as applicable, payable to Licensor in future Calendar Quarters until such amount is applied by Lian in full.

1.4 Audits. Each Party will maintain and will cause its Affiliates and all Sublicensees to maintain, complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of royalties, Milestone Payments, Fully Burdened Manufacturing Cost calculations, and other payments under this Agreement. Upon reasonable prior notice, but not more than [***] per Calendar Year and not more than [***] with respect to any records, such records will be available during regular business hours for a period of [***] years from the end of the [***] to which they pertain for examination at the expense of the requesting Party by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports and correctness of the payments furnished by the other Party pursuant to this Agreement. Any such auditor will not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement. The accountant's report will be disclosed simultaneously to both Parties, and such report will be the Confidential Information of each Party and subject to the terms of Article 8 (Confidentiality and Publicity). Any amounts shown to be owed but unpaid will be paid within [***] days from the accountant's report. Any amounts shown to have been overpaid will be refunded within [***] days from the accountant's report. The requesting Party will bear the full cost of such audit unless such audit discloses an underpayment by the other Party of more than [***] of the amount due, in which case the other Party will bear the full cost of such audit. The audit rights in this Section

6.4 (Audits) will survive the Term for [***] following the effective date of any termination or expiration of this Agreement.

1.5 Tax Withholding.

(a) In the event any withholding, value added, or other tax (including any tax based on income to Licensor) ("Tax Withholdings") is required to be withheld and deducted from payments by Lian (or its Affiliate paying on behalf of Lian) pursuant to this Agreement under applicable Laws, notwithstanding any provision to the contrary set forth under this Agreement, Lian (or its Affiliate paying on behalf of Lian) will make such deduction and withholding [***], and any amounts so withheld and deducted will be remitted by Lian (or its Affiliate paying on behalf of Lian) on a timely basis to the appropriate Governmental Authority for the account of Licensor and Lian (or its Affiliate paying on behalf of Lian) will provide Licensor reasonable evidence of the remittance within 30 days thereof and for the purposes of this Agreement, Lian will be deemed to have fulfilled all of its payment obligations to Licensor with respect to such payments paid to the such Governmental Authority. Lian may satisfy its withholding, value added or other tax obligations under this Section 6.6 (Currency of Payments) through its Affiliates.

(b) If as a result of any assignment, transfer by operation of law or other transfer (A) of this Agreement by Lian to an Affiliate or Third Party, or (B) some or all of the rights and obligations under this Agreement by Lian to an Affiliate or Third Party (in each case of (A) and (B), a "Transfer"), then the Tax Withholdings exceeds the Tax Withholdings that would have resulted in the absence of a Transfer, then [***].

(c) Without limiting Section 6.6(a), the Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate Tax Withholdings or similar obligations in respect of payments made by Lian to Licensor under this Agreement. Licensor shall provide Lian any tax forms that may be reasonably necessary in order for Lian or its Affiliates not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other Party and its Affiliates with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, VAT or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT. Specifically, in the event that any tax has been withheld upon a payment made under this Agreement and been remitted by Lian to a Governmental Authority, if requested by Licensor and if, and for so long as, the Parties acting in good faith mutually agree that there is a reasonable prospect of successfully obtaining a refund of such tax, then Lian shall, at Licensor's sole cost and expense, seek a refund of such tax from the proper Governmental Authority. Licensor agrees to reasonably cooperate with Lian and its Affiliates in the pursuit of such tax refund (including, if required by applicable Laws or by the applicable Governmental Authority, permitting Lian to seek such tax refund in Licensor's name and participating in any application or appeal that requires that Licensor be the party applying for such tax refund, solely with Licensor 'prior written consent); provided that, Licensor agrees to assume responsibility for direct payment of lawyers' and other advisors' fees and any other costs associated with seeking such refund.

1.6 Manner of Payment; Currency of Payments. All payments owed by Lian under this Agreement will be made by wire transfer in immediately available funds to a bank and account designated in writing by Licensor. All amounts payable and calculations under this Agreement will be in Dollars. As applicable, Net Sales and any royalty reductions will be translated into Dollars using the average of the applicable daily foreign exchange rates published in the *Wall Street Journal* (or any other qualified source that is acceptable to both Parties) [***] in which such Net Sales occurred.

1.7 Late Payments. Without limiting any other rights or remedies available to Licensor hereunder, any late payment by Lian will bear interest, to the extent permitted by Laws, at an annual rate of [***] or the highest rate permitted by applicable Law (whichever is lower), computed from the dated such payment was due until the date Lian makes the payment, with such interest compounded [***].

Article 7
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

1.1 Ownership of Inventions.

(a) Ownership of Inventions; Cross License of Product Inventions. Ownership will follow inventorship for any and all inventions, Know-How, developments, or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by either Party alone (including its Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) or jointly by both Parties (including jointly by their Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) in the performance of a Party's obligations or exercise of its rights under this Agreement (collectively, "Inventions") and such ownership will be determined based on the principles of inventorship in accordance with United States patent Laws.

(b) Assignment Obligation. Each Party will assign, and will cause its Affiliates to assign, its rights, and cause all employees of such Party or Affiliate who perform activities for such Party or Affiliate under this Agreement to be under an obligation to assign their rights, in any Patent Rights and Know-How, whether or not patentable, resulting therefrom to such Party or Affiliate to effectuate the terms and conditions set forth in Section 7.1(a) (Assignment Obligation). With respect to any activities of a Party or its Affiliate or exercise of its or their rights under this Agreement that are subcontracted to a Person that is not an employee, the Party or such Affiliate retaining such subcontractor will include in the applicable subcontract an assignment to such Party or such Affiliate of all rights in Patent Rights and Know-How made by such subcontractor resulting from such activities or exercise of its rights, and in any event will include in the applicable subcontract a license to such Party or Affiliate that is sublicensable (through multiple tiers) to the other Party under this Agreement, of any Patent Rights and Know-How made by such contractor or subcontractor resulting from such activities.

1.2 Prosecution and Maintenance of the Licensed Patent Rights and Joint Patent Rights.

(a) In the Territory. As between the Parties, Licensor will have the first right, at its expense, and will use diligent efforts to Prosecute the Licensed Patent Rights and Joint Patent Rights in all Regions in the Territory, at Licensor's sole cost and expense. Licensor will keep Lian reasonably informed of all steps with regard to and the status of such Prosecution of such Patent Rights, including by providing Lian with (i) copies of all correspondence and material communications it sends to or receives from any patent office or agency in the Territory relating to such Patent Rights, (ii) a draft copy of all applications, in each case ((i) and (ii)), sufficiently in advance of filing or response to permit reasonable review and comment by Lian, and (iii) a copy of applications as filed, together with notice of its filing date and serial number. Before Licensor submits any material filing, including a new patent application, or response to such patent authorities with respect to any Licensed Patent Rights or Joint Patent Rights, Licensor will provide Lian with a reasonable opportunity to review and comment on such filing or response and will incorporate any reasonable comments or suggestions provided by Lian regarding the Prosecution of such Licensed Patent Rights or Joint Patent Rights under this Section 7.2(a) (In the Territory).

(b) Step-In Right. If Licensor elects not to continue to Prosecute a given Patent Right within the Licensed Patent Rights or Joint Patent Rights in the Territory pursuant to Section 7.2(a) (In the Territory), then Licensor will give Lian notice thereof within a reasonable period (but not less than [***]) prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and Lian will have the right, but not the obligation, to assume the Prosecution of such Patent Rights in such Region, including paying any required fees to maintain such Patent Rights in such Region, all at Lian's sole expense and through patent counsel or agents of its choice. Upon transfer of Licensor's responsibility for Prosecuting any of the Patent Rights to Lian under this Section 7.2(b) (Step-In Right), (i) Licensor will promptly deliver to Lian copies of all

necessary files related to the Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for Lian to assume such Prosecution, and (ii) such Patent Right shall no longer extend the Royalty Term pursuant to Section 6.2(b) (Royalty Term). Thereafter, Lian will keep Licensor reasonably informed of the status of such Prosecution of such Patent Rights.

(c) Cooperation. Each Party will, and will cause its Affiliates to, reasonably cooperate, with the other Party with respect to the Prosecution of Licensed Patent Rights and Joint Patent Rights pursuant to this Section 7.2 (Prosecution and Maintenance of the Licensed Patent Rights and Joint Patent Rights), including with respect to obtaining patent term restoration, supplemental protection certificates or their equivalents, and patent terms extension with respect to the Licensed Patent Rights and Joint Patent Rights in any Region where applicable.

1.3 Third Party Infringement.

(a) Notice. Each Party will promptly notify the other in writing if such Party becomes aware of any suspected, threatened or actual infringement by any Third Party of any Licensed Technology or Joint Patent Right arising from the making, using, offering to sell, selling, or importing of a product in the Field in the Territory that could be competitive with a Licensed Product, and, in each case, will provide the other Party with all evidence in such Party's possession or control supporting such infringement or unauthorized use or misappropriation (each, an "Infringement").

(b) Lian First Right. As between the Parties, Lian will have the first right, but not the obligation, using counsel of its choosing and at its sole expense, to institute any infringement, misappropriation, or other appropriate Action against any Infringement of the Licensed Technology or Joint Patent Rights (any such Action, an "Infringement Action") in the Field in the Territory. Licensor shall have the right, at its own cost and expense, to be represented in any Infringement Action by counsel of its own choice. Lian will notify Licensor of its decision to commence an Infringement Action, will keep Licensor apprised in writing of any such Infringement Action, and will consider Licensor's reasonable interests and requests regarding such Infringement Action.

(c) Licensor Right. If Lian fails to commence a suit to enforce the Licensed Technology or Joint Patent Rights against such Infringement (or to settle or otherwise secure the abatement of such Infringement) within (i) [***] after its receipt or delivery of notice under Section 7.3 (Third Party Infringement), or (ii) [***] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, or ceases to diligently pursue such Infringement Action, then Licensor will have the right, but not the obligation, at its own expense to institute such Infringement Action against the applicable Third Party infringer(s).

(d) Cooperation. In any Infringement Action brought under the Licensed Technology or Joint Patent Rights pursuant to Section 7.3(b) (Lian First Right) and Section 7.3(c) (Licensor Right), each Party will, and will cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the Licensed Technology and Joint Patent Rights, and will join such suit as a party, if requested by the other Party. Furthermore, the Party initiating any Infringement Action pursuant to Section 7.3(b) (Lian First Right) or Section 7.3(c) (Licensor Right) will consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patent Rights. Neither Party will have the right to settle any Infringement Action under this Section 7.3 (Third Party Infringement) in a manner that diminishes the rights or interests of the other Party under this Agreement without the consent of such other Party, which consent will not be unreasonably withheld.

(e) Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party pursuant to any Infringement Action will (i) first be allocated to

reimbursing the Parties for their reasonable out-of-pocket expenses in making such recovery (which amounts will be allocated *pro rata* if insufficient to cover the totality of such expenses), and (ii) (A) [***].

1.4 Claimed Infringement. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by Lian or Licensor or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture or Commercialization of any Licensed Product or Joint Patent Rights (any such Action, an "Infringement Claim") in the Territory. Lian will have the right, but not the obligation, to control the defense and response to any such Infringement Claim in the Territory with respect to Lian's activities, at Lian's sole cost and expense, and Licensor will have the right, at its own expense, to be represented in any such Infringement Claim in the Territory by counsel of its own choice. Licensor will have the sole right, but not the obligation, to control the defense and response to any such Infringement Claim with respect to Licensor's activities, including any such Infringement Claim in the Territory or outside of the Territory. Upon the request of the Party controlling the response to the Infringement Claim, the other Party will reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation. If the Infringement Claim is brought against both Parties, then each Party will have the right to defend against the Infringement Claim. The Party defending an Infringement Claim under this Section 7.4 (Claimed Infringement) will (a) consult with the other Party as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense. The Party controlling the defense against an Infringement Claim will have the right to settle such Infringement Claim on terms deemed reasonably appropriate by such Party, provided, that, neither Party will have the right to settle any Infringement Claim under this Section 7.4 (Claimed Infringement) in a manner that diminishes the rights or interests of the other Party under this Agreement without the consent of such other Party, which consent will not be unreasonably withheld.

1.5 Common Interest. All information exchanged between the Parties regarding the Prosecution, enforcement, and defense, of Licensed Patent Rights and Joint Patent Rights under this Article 7 (Intellectual Property Ownership, Protection and Related Matters) will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution, enforcement, and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 7 (Intellectual Property Ownership, Protection and Related Matters), including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 7 (Intellectual Property Ownership, Protection and Related Matters) is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

Article 8
CONFIDENTIALITY AND PUBLICITY

1.1 Confidential Information.

(a) Confidentiality Obligation. During the Term and for a period of [***] after any termination or expiration of this Agreement, each Party agrees to, and will cause its Affiliates and Sublicensees and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party,

without the prior written consent of such disclosing Party. The existence and terms of this Agreement are the Confidential Information of each Party.

(b) Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, advisors, licensees, collaboration partners, and Sublicensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, in each case on a need to know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 8.1 (Confidential Information). Each Party will remain responsible for any failure by its Affiliates, licensees, collaboration partners, or Sublicensees, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under this Section 8.1 (Confidential Information) as if such Affiliates, employees, consultants, advisors, licensees, collaboration partners, and Sublicensees were parties directly bound to the requirements of this Section 8.1 (Confidential Information).

(c) Confidentiality Limitation. Notwithstanding any provision to the contrary set forth in this Agreement, each Party may use and disclose the other Party's Confidential Information as follows: (i) under appropriate written confidentiality and non-use obligations no less stringent than those in this Agreement, to its Affiliates, *bona fide* potential or actual collaboration partners, licensors, Sublicensees, licensees, or strategic partners and to employees, directors, agents, consultants, and advisers of any other Third Parties, (ii) to its financial advisors, attorneys and accountants, *bona fide* actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis, in each case under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement; provided, however, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 8.1 (Confidential Information) as if such individuals were parties directly bound to the requirements of this Section 8.1 (Confidential Information), or (iii) as required by any court or other governmental body or as otherwise required by applicable Laws (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval, Pricing and Reimbursement Approval, import authorization for any Licensed Product in the Territory, or the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity (including in connection with the public sale of securities)); provided, that, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information. Notwithstanding any provision to the contrary contained in this Article 8 (Confidentiality and Publicity), Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of Section 8.1(b) (Permitted Disclosures) and this Section 8.1(c) (Confidentiality Limitation). If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Governmental Authority in a country other than the United States, then such Party will, a reasonable time prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable Regulatory Authority.

(d) Secrecy of Licensed Know-How. Without limiting the generality of Section 8.1(a) (Confidentiality Obligation), during the Term the receiving Party will protect, and will cause, to the extent applicable, its Affiliates and Sublicensees, and its and their respective officers, directors, employees, and agents to protect, the secrecy and confidentiality of the Licensed Know-How and unpublished Patent Rights using at least the same degree of care as it uses to prevent the disclosure of its own other

confidential information of like importance and in any event a reasonable duty of care.

(e) Residual Knowledge. The Parties acknowledge the practical difficulty of policing the use of information inadvertently retained in the unaided memory of a receiving Party or its Affiliates and its and their officers, directors, employees, and agents who have had rightful access to the Confidential Information of the disclosing Party ("Residual Knowledge"), and as such each Party agrees that the receiving Party will not be liable for the inadvertent use (without reference to any Confidential Information of the disclosing Party) by any of its or its Affiliates' officers, directors, employees, or agents of the Residual Knowledge that is inadvertently retained in the unaided memory of such officer, director, employee, or agent; *provided* that such officer, director, employee, or agent has not been directed to or otherwise intentionally memorized or retained such Residual Knowledge for use other than as explicitly permitted under this Agreement. The receiving Party acknowledges and agrees that any use made by the receiving Party of any such Residual Knowledge is on an "as is, where is" basis and at its sole risk, with all faults and all representations and warranties disclaimed by the disclosing Party.

1.2 Publicity. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Product in the Field in the Territory, and each Party may make such disclosures from time to time, subject to the terms and conditions of this Agreement, including this Section 8.2 (Publicity). Such disclosures may include achievement of milestones, significant events in the Development process with respect to Licensed Products, or Commercialization activities with respect to Licensed Products.

(a) Except for disclosures permitted in accordance with Section 8.1(b) (Permitted Disclosures), whenever either Party elects to make any public disclosure regarding milestones or other significant events in the Development or Commercialization of the Licensed Products in the Field in the Territory, it will first notify the other Party of such planned press release or public announcement and provide a draft for review no less than [***] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Laws, with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [***] in advance). Each Party will have the right to review and approve any such planned press release or public announcement proposed by the other Party with respect to Licensed Products in the Field in the Territory, or that includes Confidential Information of the other Party. In such case, (i) the reviewing Party will attempt to provide such approval as soon as reasonably possible and will not unreasonably withhold such approval; (ii) the reviewing Party will provide explanations of its disapproval of such press release; and (iii) a Party desiring to make such public disclosure may issue such press release or public announcement without such prior review by the other Party if (A) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (B) such press release or public announcement is consistent with the previously issued press release or other publicly available information. The Party reviewing a press release provided under this clause (i) of this Section 8.2(a) (Publicity) will review and approve or disapprove such press release within [***] Business Days after its receipt thereof.

(b) In the event that either Party proposes to publish or present the results of Development or Commercialization carried out on the Licensed Product, including any oral presentation or abstract that contain clinical data or pertain to results of Clinical Trials or other studies, such publication or presentation will be subject to the prior review by the other Party for protection of such other Party's Confidential Information. Each Party will provide to the other Party the opportunity to review a draft of any proposed publication that covers the results of Development or Commercialization of Licensed Products during the Term, and the submitting Party will remove from such proposed publication any Confidential Information of the other Party as reasonably requested by the other Party.

Article 9
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

1.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) Organization. It is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement, and this Agreement and the performance by such Party of this Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

(c) Consents. Except for any Marketing Authorizations, Regulatory Approvals, Regulatory Filings, Manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

(d) No Conflict. It is not under any obligation, contractual or otherwise, to any Person that would affect the diligent and complete fulfillment of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws applicable to such Party, (ii) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party, and (iii) do not conflict with, violate, breach or constitute a default under, or give rise to any right of termination, cancellation or acceleration of, any contractual obligations of such Party or any of its Affiliates.

(e) Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Laws affecting the enforcement of creditors' rights generally.

1.2 Additional Representations and Warranties of Licensor. Licensor represents and warrants to Lian that, as of the Effective Date:

(a) Licensed Patent Rights. All Licensed Patent Rights as of the Effective Date are listed in Schedule 1.76 (Licensed Patents). Licensor is the sole and exclusive owner of the Licensed Patent Rights, all of which are free and clear of any claims, liens, charges or encumbrances. Except as otherwise noted in Schedule 1.76 (Licensed Patents), all Licensed Patent Rights owned or Controlled by Licensor have been filed and Prosecuted in good faith in the patent offices in accordance with applicable Laws, and all applicable fees have been paid on or before the due date for payment. All issued Licensed Patent Rights are valid, subsisting, and enforceable. Licensor does not own or hold any Patent Rights that would be necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Products in the Territory other than the Licensed Patent Rights.

(b) Licensed Know-How. Licensor owns or Controls the Licensed Know-How, and has the right to grant the licenses under the Licensed Know-How to Lian on and the terms set forth in this Agreement. Licensor has the right to use and disclose (in each case,

under appropriate circumstances of confidentiality) the Licensed Know-How free and clear of any claims, liens, charges or encumbrances.

(c) Licensed Technology. Licensor has not granted to any Third Party, including any academic organization or agency, any license, option or other rights to research, Develop, Manufacture, use or Commercialize the Compounds or the Licensed Products in the Territory. No Third Party has any license, option or other rights or interest in or to the Licensed Technology other than the rights that are expressly reserved or contingent under this Agreement.

(d) Licensed Marks. Licensor owns or Controls the Licensed Marks, and has the right to grant the licenses under the Licensed Marks to Lian on the terms set forth in this Agreement.

(e) Delivery of Documentation. Prior to the Effective Date, Licensor has made available to Lian true, complete, and correct copies of: (i) all existing material Regulatory Filings in its possession and control relating to Licensed Products, (ii) all material adverse information with respect to the safety and efficacy of the Licensed Products in Licensor's or its Affiliates' (to the extent applicable, in accordance with Section 2.1(b) (Lian Right of Access and Reference)) possession and control, and (iii) all material data and results relating to the Development of the Licensed Products in Licensor's or its Affiliates' (to the extent applicable, in accordance with Section 2.1(b)) (Lian Right of Access and Reference).

(f) Third Party Challenges. There are no claims, judgments, or settlements against, or amounts with respect thereto, made against Licensor or any of its Affiliates relating to the Licensed Patent Rights or the Licensed Know-How, and no written claim or litigation has been received by Licensor or its Affiliates or, [***], threatened by any Person (i) alleging that the Licensed Patent Rights are invalid or unenforceable, (ii) asserting the misuse of any of the Licensed Patent Rights, (iii) challenging Licensor's Control of the Licensed Patent Rights (i.e., alleging that a Third Party has a right or interest in or to the Licensed Technology), or (iv) alleging misappropriation of the Know-How of any Third Party used in the Development, Manufacture or Commercialization of Licensed Products by or on behalf of Licensor prior to the Effective Date.

(g) Non-Infringement of Third Party IP. [***], the Development, Manufacture, or Commercialization of the Licensed Product in the Territory does not infringe any Patent Right or misappropriate or otherwise violate or misappropriate any Know-How of any Person (in the case of pending Patent Rights, evaluating them as if issued). No written claim of infringement of the Patent Rights or misappropriation of the Know-How of any Third Party has been received by Licensor, [***], threatened, against Licensor, any of its Affiliates or its or their Sublicensees with respect to the Development, Manufacture or Commercialization of Licensed Products. [***], the practice by Lian under the Licensed Technology or the Development, Manufacture, or Commercialization of the Compounds or Licensed Products as contemplated under this Agreement will not infringe, misappropriate or otherwise violate any Intellectual Property of any Third Party.

(h) Absence of Litigation. There are no judgments or settlements against or owed by Licensor or its Affiliates or Sublicensees, or, [***], pending litigation against Licensor or its Affiliates or Sublicensees, or litigation threatened against Licensor or its Affiliates or Sublicensees, in each case, related to Compounds or Licensed Products, including any such litigation any relating to any Regulatory Filings, Regulatory Approvals, or Marketing Authorizations Controlled by Licensor, its Affiliates or its Sublicensees.

(i) Maintenance of Regulatory Filings, Good Laboratory, and Clinical Practices. Licensor maintains control over all Regulatory Filings pertaining to the Licensed Products in the Field in the Territory. Licensor and its Affiliates and Sublicensees have generated, prepared, maintained, and retained all Regulatory Filings and Marketing Authorizations in its control that are required to be maintained or retained

pursuant to and in material compliance with applicable Laws, and have conducted in material compliance with applicable Laws, including GLP and GCP all Development of Licensed Products in the Field conducted prior to the Effective Date.

(j) Confidentiality of Know-How. Licensor has taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality, and value of all Licensed Know-How. [***], the Licensed Know-How existing as of the Effective Date has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality.

(k) Assignment of Third Party Rights; Third Party Consents.

(i) Licensor has obtained from each of its employees and agents, and from the employees and agents of its Affiliates, who are performing Development activities under the Global Development Plan for Licensed Products, rights to any and all Know-How created by such employees and agents in the course of such activities that relates to Licensed Products, such that Lian will, by virtue of this Agreement, receive from Licensor, without payments beyond those required by Article 6 (Financial Provisions), all licenses and other rights granted to Lian under this Agreement.

(ii) Each Person who has or has had any ownership rights in or to any Licensed Patent Rights purported to be owned solely by Licensor, has assigned and has executed an agreement assigning its entire rights, title, and interests in and to such Licensed Patent Rights to Licensor, and [***], no current officer, employee, agent, or consultant of Licensor or any of its Affiliates is in violation of any term of any assignment or other agreement, in each case, regarding the protection of the Licensed Patent Rights.

(iii) Prior to the Effective Date, Licensor has obtained all consents from Third Parties necessary to grant Lian the licenses and rights Licensor purports to grant to Lian under this Agreement.

(l) Statements to Regulatory Authorities. Neither Licensor nor any of its Affiliates, nor, [***], its Sublicensees nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products, or failed to disclose a material fact required under applicable Laws to be disclosed to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products.

(m) Compliance with Laws. All of the studies, tests, and pre-clinical and Clinical Trials of Licensed Products conducted prior to, or being conducted as of, the Effective Date by or on behalf of Licensor have been and are being conducted in all material respects in accordance with applicable Laws.

(n) Upstream Licenses. As of the Effective Date, Licensor owns all Licensed Technology and does not Control any such Licensed Technology pursuant to any Upstream License except for a license granted by Landos to the Selling Entities included in the Asset Purchase and Redemption Agreement dated as of the date hereof between Landos, Dr. Joseph Bassaganya-Riera, Raquel Hontecillas and the Selling Entities, listed on Schedule A annexed thereto, with respect to certain "Licensed Technology" defined therein, a copy of which has been provided to Lian, and the Selling Entities in turn have transferred and assigned all of their rights related to the Transferred BT-11 Technology to Licensor.

(o) No Other Disclosures. [***], there is no material information, including regarding any safety, efficacy, or regulatory issues, within Licensor's Control that has not been disclosed to Lian and that would materially adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any Regulatory Filing for a Licensed Product in the Field and in the Territory.

(p) Continuity of Rights. As of the Effective Date, Licensor owns or Controls all Licensed Technology and Regulatory Filings that were owned or Controlled by Landos immediately prior to the Effective Date.

1.3 No Conflict. During the Term, Licensor and its Affiliates will not grant any interest in the Licensed Technology that is inconsistent with the terms and conditions of this Agreement.

(a) Additional Representations, Warranties and Covenants of Lian. Lian hereby covenants to Licensor that neither Lian nor any of its Affiliates or Sublicensees, will employ or use the services of any Person who is debarred or disqualified under laws in the Territory comparable with the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 et seq., or the Public Health Service Act, 42 U.S.C. §§262 et seq. in connection with activities relating to any Licensed Product; and in the event that Lian becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to Lian or any of its Affiliates with respect to any activities relating to any Licensed Product, Lian will immediately (but in any event no later than [***]) notify Licensor in writing and Lian will cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to any Licensed Product.

1.4 Compliance with Laws. Each Party shall, and shall ensure that its Affiliates and their respective Sublicensees will, comply in all respects with all applicable Laws (including Anti-Corruption Laws), including in the Development, Manufacturing, and Commercialization of Licensed Products and performance of its obligations under this Agreement, including the ICH, GCP, GLP and any Regulatory Authority and Governmental Authority health care programs having jurisdiction in such Party's respective territory, each as may be amended from time to time.

1.5 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN SECTION 9.1 (MUTUAL REPRESENTATIONS AND WARRANTIES) AND SECTION 9.2 (ADDITIONAL REPRESENTATIONS AND WARRANTIES OF LICENSOR), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED PRODUCT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Article 10
INDEMNIFICATION; DAMAGES

1.1 Indemnification by Licensor. Licensor will defend, indemnify and hold harmless Lian, its Affiliates and their respective directors, officers, employees and agents (each, a "Lian Indemnified Party"), from, against and in respect of any and all Third Party Losses incurred or suffered by any Lian Indemnified Party to the extent arising from or relating to: (a) any breach of any representation or warranty made by Licensor in this Agreement, or any breach by Licensor of any obligation, covenant, or agreement in this Agreement; (b) the gross negligence or intentional misconduct of Licensor or any of its Affiliates, (sub)licensees (other than Lian), or contractors, or any of their respective directors, officers, employees, or agents, in performing Licensor's obligations or exercising Licensor's rights under this Agreement; (c) activities conducted by or on behalf of Licensor or its Affiliates or Sublicensees or contractors related to the Development, Manufacture, or Commercialization of Licensed Products anywhere in the world prior to the Effective Date; and (d) the Development, Manufacture, or Commercialization of the Licensed Products by or on behalf of Licensor, any of its Affiliates, Sublicensees (other than Lian), or contractors; *provided*, *however*, that Licensor's obligations pursuant to this Section 10.1 (Indemnification by Licensor) will not apply to the extent such Third Party Losses result from Third Party Losses for which Lian has an obligation to indemnify Licensor pursuant to Section 10.2 (Indemnification by Lian).

1.2 Indemnification by Lian. Lian will defend, indemnify and hold harmless Licensor, its Affiliates, and each of their respective directors, officers, employees and agents (each, a "Licensor Indemnified Party") from, against and in respect of any and all Third Party Losses incurred or suffered by any Licensor Indemnified Party to the extent arising from or relating

to: (a) any breach of any representation or warranty made by Lian in this Agreement, or any breach by Lian of any obligation, covenant, or agreement in this Agreement, (b) the gross negligence or intentional misconduct of, or violation of Laws by, Lian, any of its Affiliates, Sublicensees, or contractors, or any of their respective directors, officers, employees, or agents, in performing Lian's obligations or exercising Lian's rights under this Agreement, or (c) the Development, Manufacture, or Commercialization of the Licensed Product by or on behalf of Lian or its Affiliates or Sublicensees (other than Licensor) or contractors; *provided*, *however*, that Lian's obligations pursuant to this Section 10.2 (Indemnification by Lian) will not apply to the extent such Third Party Losses result from Third Party Losses for which Licensor has an obligation to indemnify Lian pursuant to Section 10.1 (Indemnification by Licensor).

1.3 Claims for Indemnification.

(a) Notice. An Indemnified Party entitled to indemnification under Section 10.1 (Indemnification by Licensor) or Section 10.2 (Indemnification by Lian) will give prompt written notification to the Indemnifying Party from whom indemnification is sought of the commencement of any Action by a Third Party for which indemnification may be sought (a "Third Party Claim") or, if earlier, upon the assertion of such Third Party Claim by a Third Party; *provided*, *however*, that failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 10.3(a) (Notice) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is materially prejudiced as a result of such failure to give notice.

(b) Defense. Within [***] days after delivery of a notice of any Third Party Claim in accordance with Section 10.3(a) (Notice), the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, then the Indemnified Party may control such defense (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld). The Party not controlling such defense may participate therein at its own expense.

(c) Cooperation. The Party controlling the defense of any Third Party Claim will keep the other Party advised of the status and material developments of such Third Party Claim and the defense thereof and will reasonably consider recommendations made by the other Party with respect thereto. The other Party will reasonably cooperate with the Party controlling such defense and its Affiliates and agents in defense of the Third Party Claim, with all out-of-pocket costs of such cooperation to be borne by the Party controlling such defense.

(d) Settlement. The Indemnified Party will not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. The Indemnifying Party will not agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than a monetary obligation on the Indemnifying Party), without the prior written consent of the Indemnified Party, which will not be unreasonably withheld (unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party (in which case, (i) through (iii), the Indemnified Party may withhold its consent to such settlement in its sole discretion)).

(e) Mitigation of Loss. Each Indemnified Party will take and will procure that its Affiliates and Sublicensees take all such reasonable steps and actions as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this Article 10 (Indemnification;

Damages). Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

1.4 Insurance. Each Party, at its own expense, will maintain liability insurance (or self-insure) with respect to its activities under this Agreement in an amount consistent with industry standards. Each Party will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Without limiting the foregoing, during the Term and thereafter for the period of time required below, each Party will maintain on an ongoing basis comprehensive general liability insurance policies which are consistent with normal business practices of prudent companies similar situated in such Party's territory. Not later than [***] days following receipt of written request from a Party, the other Party will provide to the requesting Party a certificate of insurance evidencing such insurance policies. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term and for a period of [***] thereafter, and, if applicable, will provide certificates or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [***] days' prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.

Article 11
LIMITATION OF LIABILITY

1.1 NO CONSEQUENTIAL OR PUNITIVE DAMAGES. EXCEPT AS SET FORTH IN SECTION 11.2 (EXCLUSION FROM LIABILITY LIMITATION), NEITHER PARTY NOR ANY OF ITS AFFILIATES OR AFFILIATED ENTITIES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, OR ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

1.2 EXCLUSION FROM LIABILITY LIMITATION. THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 11.1 (NO CONSEQUENTIAL OR PUNITIVE DAMAGES) WILL NOT APPLY TO A CLAIM: (A) FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) FOR A BREACH OF SECTION 2.9 (EXCLUSIVITY), SECTION 9.2(a) (LICENSED PATENT RIGHTS), ARTICLE 8 (CONFIDENTIALITY AND PUBLICITY); OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 10.1 (INDEMNIFICATION BY LICENSOR) OR SECTION 10.2 (INDEMNIFICATION BY LIAN), AS APPLICABLE.

Article 12
TERM AND TERMINATION

1.1 Term. Unless terminated earlier in accordance with this Article 12 (Term and Termination), this Agreement will become effective as of the Effective Date and will continue in full force, on a Licensed Product-by-Licensed and Region-by-Region basis, until the expiration of the Royalty Term applicable to such Licensed Product and such Region (the "Term").

1.2 Paid-Up License Upon End of Royalty Term. Upon the expiration of the Royalty Term for a given Licensed Product in a given Region in the Territory, the licenses and rights of reference granted to Lian pursuant to Section 2.1 (License Grants; Rights of Reference; Acknowledgment) will become perpetual, irrevocable, fully paid-up, royalty free, fully sublicensable, and transferable with respect to such Licensed Product in such Region.

1.3 Early Termination.

(a) Termination for Material Breach. Upon (i) any material breach of this Agreement by Licensor or (ii) any material breach of this Agreement by Lian (the Party so allegedly

breaching being the "Breaching Party"), the other Party (the "Non-Breaching Party") will have the right, but not the obligation, to terminate this Agreement by providing written notice to the Breaching Party within [***] days' in the case of a payment breach, or [***] days' in the case of any other material breach, which notice will, in each case (A) expressly reference this Section 12.3(a) (Termination for Material Breach), (B) reasonably describe the alleged breach that is the basis of such termination, and (C) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. If such breach relates solely to one or more Licensed Products or Regions of the Territory, then the non-breaching Party will have the right to terminate this Agreement solely with respect to such Licensed Product(s) or Region(s), as applicable. Notwithstanding the foregoing, if such material breach, by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period will be extended by up to an additional [***] days if the Breaching Party provides a reasonable written plan for curing such breach to the Non-Breaching Party and uses reasonable efforts to cure such breach in accordance with such written plan. In addition, if the Breaching Party disputes (A) whether it has materially breached this Agreement, (B) whether such material breach is reasonably curable within the applicable cure period, or (C) whether it has cured such material breach within the applicable cure period, then the dispute will be resolved pursuant to Article 13 (Dispute Resolution), and the applicable cure period will be tolled during the pendency of such dispute resolution procedure.

(b) Termination for Patent Challenge. Except to the extent the following is unenforceable under the Laws of a particular jurisdiction in the Territory or as otherwise provided in this Section 12.3(b) (Termination for Patent Challenge), Licensor may terminate this Agreement upon written notice to Lian if Lian, its Affiliates, or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability, or scope of any Licensed Patent Rights in a court or other governmental agency of competent jurisdiction in the Territory, including a reexamination or opposition proceeding (a "Patent Challenge"); *provided* that, if Lian or its Affiliate or Sublicensee withdraws (or causes to be withdrawn) such Patent Challenge within [***] days after being requested to do so by Licensor in writing (which termination notice will be deemed a request), then Licensor will have no right to terminate this Agreement pursuant to this Section 12.3(b) (Termination for Patent Challenge). In addition, and notwithstanding any provision to the contrary set forth in this Agreement, Licensor may not terminate this Agreement pursuant to this Section 12.3(b) (Termination for Patent Challenge) (i) if Lian or its Affiliate or Sublicensee is required by legal process to be joined as a party in any Patent Challenge by a Third Party, or (ii) with respect to: (A) any affirmative defense or other validity, enforceability, or non-infringement challenge, whether in the same action or in any other agency or forum of competent jurisdiction, advanced by Lian, or any of its Affiliates or Sublicensees in response to any claim or action brought in the first instance by, or on behalf of, Licensor, (B) any Patent Challenge to the extent commenced by a Third Party that after the Effective Date acquires or is acquired by Lian or any of its Affiliates or its or their business or assets, whether by stock purchase, merger, asset purchase, or otherwise; *provided* that such proceeding commenced prior to the closing of such acquisition, or (C) any Patent Challenge that is commenced by a Sublicensee; *provided* that Lian demands that such Sublicensee withdraw such Patent Challenge promptly after Lian becomes aware of such Patent Challenge and terminates the sublicense agreement with the applicable Sublicensee if such Sublicensee does not withdraw such Patent Challenge within [***] days after receipt of notice from Lian.

(c) Termination for Insolvency. Subject to Section 2.6 (Rights in Bankruptcy), either Party may terminate this Agreement upon delivery of written notice to the other Party if (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] days of its filing, or (iii) such

other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(d) Termination by Lian for Convenience. Lian may, upon [***] days' prior written notice to Licensor, terminate this Agreement for convenience, without cause, and for any or no reason.

12.4 Effects of Termination.

(a) Effects of Termination Generally. Upon any termination of this Agreement with respect to the Licensed Products (a "Terminated Product") or Regions (a "Terminated Region"), then the Parties' rights, licenses and obligations under this Agreement will terminate with respect to the Terminated Product in the Terminated Region and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination with respect to the Terminated Product in the applicable Terminated Region, except as set forth in this Section 12.4 (Effects of Termination).

(b) Winding Down of Activities. If there are any on-going Development or Commercialization activities with respect to the Terminated Product in the Terminated Regions at termination or expiration of this Agreement, then the Parties will negotiate in good faith and adopt a plan to wind-down such activities in an orderly fashion or, at Licensor's election and unless prohibited by any Regulatory Authority or applicable Law, promptly transition such activities from Lian to Licensor or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of the Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and, with respect to any Clinical Trial transitioned to Licensor or its designee, to minimize any disruption to such Clinical Trial, and in compliance with all applicable Law.

(c) License Grant to Licensor.

(i) Upon termination of this Agreement, Lian, on behalf of itself and its Affiliates hereby grants (effective on delivery of the notice of termination) to Licensor a worldwide, irrevocable, perpetual, transferable, exclusive license under the Product Inventions and Prior Product Inventions and Patent Rights controlled by Lian that cover any of the foregoing Product Inventions, in each case, in existence as of the applicable effective date of termination, to Develop, Manufacture, and Commercialize Compounds and Licensed Products in the Field in the Territory (the "Reversion License"). If any rights granted by Lian under the Reversion License are Controlled by Lian or its Affiliates or Sublicensees pursuant to an agreement with a Third Party, then Licensor will pay all amounts due under any such agreement to the extent reasonably allocable to Licensor's exercise of the rights granted thereunder.

(ii) Effective upon any termination of this Agreement in all Regions of the Territory, if, as of the effective date of termination, any Terminated Product has achieved First Commercial Sale in any Region in the Territory, then Lian will assign and transfer (and if unable to assign and transfer, exclusively license) to Licensor any Trademarks owned or Controlled by Lian that are specific to such Terminated Products for the purpose of Commercializing such Terminated Products, together with all goodwill associated with the specific Trademarks. If this Agreement is terminated with respect to one or more, but not all, Regions in the Territory, then Lian will grant an exclusive license to Licensor under any Trademarks in the Terminated Region owned or Controlled by Lian or its Affiliates that are specific to such Terminated Products for the purpose of Commercializing such Terminated Products in the Terminated Regions.

(iii) If Licensor or its or their Affiliates or Sublicensees exercises the Reversion License or the rights granted pursuant to Section 12.4(h) (Transfer of

Regulatory Filings and Regulatory Approvals) and this Agreement has been terminated by Lian pursuant to Section 12.3(a) (Termination for Material Breach), then Licensor will pay to Lian, in consideration of the rights granted to Licensor, [***].

(d) Discontinuation of JSC. Upon termination of this Agreement in its entirety, the JSC will cease to exist; provided, however, that if this Agreement is terminated with respect to the Terminated Products in one or more Terminated Regions only, then the JSC will continue with respect to the non-Terminated Regions only.

(e) Accrued Obligations. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability that, on the effective date of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination.

(f) Survival. This Section 12.4(f) (Survival), the provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement in its entirety: Articles 6 (solely to the extent any payment obligations have accrued prior to expiration or termination), 8, 10, 11, 13 and 14 and Sections 2.4, 2.5, 2.6, 2.7, 3.4(a), 7.1, 9.5, 12.2 and 12.4. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in Article 1 (Definitions), will survive to the extent required. Except as otherwise expressly provided in this Agreement, including this Section 12.4(f) (Survival), any licenses granted under this Agreement will terminate upon expiration or termination of this Agreement in its entirety or solely with respect to a Terminated Product or Terminated Region, as the case may be, for any reason.

(g) Inventory.

(i) Sell-Off Period. Lian will have the right, for a period of [***] days following termination of this Agreement in any Region, to sell or otherwise dispose of any Licensed Products in such Terminated Regions, as applicable, on hand at the time of such termination or in the process of Manufacturing (the "Sell-Off Period").

(ii) Licensor Buy-Back. Upon expiration of any Sell-Off Period in any Region, Licensor will have the right to purchase all of Lian's and its Affiliates' remaining inventory of Licensed Products held as of the effective date of expiration of such Sell-Off Period at a price equal to (A) [***], if supplied by Licensor or (B) if Manufactured by Lian, [***].

(h) Transfer of Regulatory Filings and Regulatory Approvals. Following the effectiveness of any termination of this Agreement pursuant to Section 12.3 (Early Termination), after Licensor's written request, Lian will, to the extent permitted under applicable Laws, and at Licensor's sole cost and expense (unless the applicable termination giving rise to Licensor's rights under this Section 12.4(h) (Transfer of Regulatory Filings and Regulatory Approvals) was initiated by Licensor pursuant to Section 12.3 (Early Termination), in which case such transfer will be at Lian's sole cost and expense), assign and transfer to Licensor all Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products that are held by or owned by Lian or its Affiliates or Sublicensees as of the effective date of termination, with respect to the terminated Region, as the case may be.

(i) Return of Confidential Information. Within [***] days after the effective date of termination (but not expiration) of this Agreement in its entirety, each Party will, and cause its Affiliates to (i) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (ii) prepare such tangible items of the other Party's Confidential

Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; and (B) each Party may retain copies of the Confidential Information of the other Party for its legal archives.

Article 13
DISPUTE RESOLUTION

1.1 Dispute Resolution; Escalation. The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising out of or in connection with this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, any and all disputes between the Parties arising out of or in connection with this Agreement (other than matters within the purview of the JSC, which will be resolved in accordance with Section 5.5 (Decision-Making; Escalation to Senior Officers)), will first be referred to the Senior Officers for resolution. The Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [***] Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 13.2 (Arbitration).

1.2 Arbitration. Except as set forth in Section 12.4(c) (License Grant to Licensor) and this Section 13.2 (Arbitration), each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof that cannot be resolved pursuant to Section 13.1 (Dispute Resolution; Escalation) will be referred to and finally resolved by arbitration in accordance with the International Chamber of Commerce (the "Rules") by an arbitral tribunal composed of three arbitrators, all of whom will have previous judicial experience and significant experience in the biopharmaceutical industry, with each Party appointing one arbitrator and the third arbitrator to be selected by agreement of the two arbitrators appointed by the Parties. If the two initial arbitrators are unable to select a third arbitrator within [***] days, then the third arbitrator will be appointed in accordance with ICC rules. The foregoing arbitration proceedings may be commenced by either Party by notice to the other Party. Unless otherwise agreed by the Parties, all such arbitration proceedings will be held in [***]. All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be determined by the arbitrators, or, in the absence of such determination, each Party will pay its own expenses. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrators will be final. Notwithstanding any provision to the contrary set forth in this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 13.2 (Arbitration). The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 13.2 (Arbitration) may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this Section 13.2 (Arbitration) will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the

interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patent Rights or of any Trademark rights relating to any Licensed Products will not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

1.3 JURY WAIVER. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN SECTION 13.2 (ARBITRATION). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

Article 14
MISCELLANEOUS

1.1 Assignment. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party), (A) to an Affiliate or (B) to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. Any assignment in violation of this Section 14.1 (Assignment) will be null and void.

1.2 Choice of Laws. This Agreement will be governed by and interpreted under the Laws of the State of New York, without regard to the conflicts of law principles thereof. Any dispute, controversy, claim or difference of any kind whatsoever arising out of or in connection with this Agreement will be resolved exclusively in accordance with Section 13.2 (Arbitration); provided, however, that all questions concerning (a) inventorship of Patent Rights under this Agreement will be determined in accordance with Section 7.1 (Ownership of Inventions) and (b) the construction or effect of Patent Rights will be determined in accordance with the Laws of the country, Region or other jurisdiction in which the particular patent within such Patent Rights has been filed or granted, as the case may be. Any communication or proceedings resulting from disputes under this Agreement will be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

1.3 Notices. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Licensor:	[***]
With copies to:	[***]
If to Lian:	[***]
With copies to:	[***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on [***] after dispatch if sent by internationally-recognized overnight courier; or (b) on the [***] after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

1.4 Severability. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

1.5 Integration. This Agreement, together with all schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Term Sheet (provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information hereunder). In the event of a conflict between the Development Plan or any schedules or attachments to this Agreement, on the one hand, and this Agreement, on the other hand, the terms of this Agreement will govern. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

1.6 Waivers and Amendments. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein will not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding the authority granted to the JSC under this Agreement, (a) no waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and (b) no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

1.7 Independent Contractors; No Agency. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision to the contrary set forth in this Agreement, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by applicable Law.

1.8 Affiliates, Sublicensees, and Contractors. To the extent that this Agreement imposes obligations on Affiliates, Sublicensees, or contractors of a Party, such Party will cause its Affiliates and its Sublicensees and contractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates, Sublicensees, or contractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; provided that (a) each such Affiliate, Sublicensee, or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate, Sublicensee, or contractor were a party hereto, (b) the performance of any obligations of a Party's by its Affiliates, Sublicensees, or contractors will not diminish, reduce, or eliminate any obligation of such Party under this Agreement, and (c) subject to such Party's assignment to an Affiliate pursuant to Section 14.1 (Assignment), such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement. Subject to this Section 14.8 (Affiliates, Sublicensees, and Contractors), if a Party exercises its rights

and performs its obligations under this Agreement through one or more of its Affiliates, "Licensor" will be interpreted to mean "Licensor or its Affiliates" and "Lian" will be interpreted to mean "Lian or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations under this Agreement.

1.9 Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in achieving any objective, satisfying any condition, or performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts or events beyond the reasonable control of such Party, including, without limitation, acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances, government actions, unavailability of supplies, materials or transportation, fire, earthquakes, floods, epidemics, pandemics, the spread of infectious diseases, and quarantines ("Force Majeure"). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable as of the Effective Date. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), or other Force Majeure event, such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other Force Majeure event. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder due to any such Force Majeure circumstances affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances as soon as reasonably practical, and will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information. The affected Party shall promptly undertake all reasonable efforts necessary to cure such Force Majeure circumstances.

1.10 No Third Party Beneficiary Rights. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Third Party. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in Article 10 (Indemnification; Damages), the Indemnified Parties.

1.11 Non-exclusive Remedy. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement.

1.12 Interpretation. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise explicitly specified to the contrary, (a) references to an Article, Section or Schedule means an Article or Section of, or a Schedule to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to particular Laws mean such Laws as in effect as of the relevant time, including all rules and regulations thereunder and any successor Laws in effect as of the relevant time, and including the then-current amendments thereto; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified,

and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis, (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365-day period unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (o) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (p) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (q) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Schedules); (r) neither Party or its Affiliates will be deemed to be acting "on behalf of" the other Party under this Agreement, except to the extent expressly otherwise provided; (s) provisions that require that a Party, or the JSC hereunder "agree", "consent" or "approve" or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding e-mail and instant messaging; and (t) the word "will" will be construed to have the same meaning and effect as the word "shall."

1.13 Further Assurances. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement (including working collaboratively to correct and clerical, typographical, or other similar errors in this Agreement).

1.14 Ambiguities; No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party under the rule of construction, irrespective of which Party may be deemed to have authored the ambiguous provision.

1.15 Export Control. This Agreement is made subject to any restrictions required by applicable Laws concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, except in compliance with U.S. export Laws and regulations.

1.16 Execution in Counterparts; Electronic Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative under seal, in duplicate on the Effective Date.

NIMMUNE BIOPHARMA, INC.

/s/ Josep Bassaganya-Riera
Name: Josep Bassaganya-Riera
Title: Executive Chairman, President and CEO

LIANBIO DEVELOPMENT (HK) LIMITED

/s/ Raphael Ho
Name: Raphael Ho
Title: Director

SCHEDULE 1.29

LICENSED COMPOUNDS

[***]

SCHEDULE 1.76

LICENSED PATENTS

Patent Rights licensed by Licensor

[***]

AMENDMENT NO. 1 TO

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amendment No. 1 to the License, Development and Commercialization Agreement (this "**Amendment No. 1**") is entered into on March 16, 2023, by and between Nanobiotix S.A., a French société anonyme having its registered office located at 60 Rue de Wattignies, 75012, Paris, France, registered under number 447 521 600 (RCS Paris) ("**Nanobiotix**"), and Lian Oncology Limited, a Hong Kong company limited by shares, having its principal place of business located at Rooms 05-15, 13A/F, South Tower, World Finance Centre, Harbour City, 17 Canton Road, Tsim Sha Tsui, Kowloon, Hong Kong (formerly Room 1902, 10/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong) ("**Lian**"). Nanobiotix and Lian are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

In presence of LianBio, an exempted company organized and existing under the laws of Cayman Islands having its registered office located at c/o International Corporation Services Ltd., 2nd Floor, Harbour Place, 103 South Church, Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands (formerly c/o Ogier Global (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman, Cayman Islands KY1-9009) ("**LianBio Cayman**"), who is entering into this Amendment No. 1 for the purposes of acknowledging and agreeing to this Amendment No. 1 in so far as it relates to the obligations imposed on it pursuant to Section 15.13 of the License Agreement (defined below).

Recitals

WHEREAS, the Parties have entered into that certain License, Development and Commercialization Agreement (the "**License Agreement**"), dated as of May 11, 2021 (the "**Original Effective Date**").

WHEREAS, the License Agreement was executed in the presence of LianBio Cayman, who executed the License Agreement for the purpose of acknowledging and accepting the obligations imposed on it pursuant to Section 15.13 of the License Agreement.

WHEREAS, pursuant to Section 15.4 of the License Agreement, the License Agreement may be amended.

WHEREAS, due to a scrivener's error in a Party name as set forth in the License Agreement, the License Agreement erroneously refers to Lian as "LianBio Oncology Limited" instead of "Lian Oncology Limited" (the "**Scrivener's Error**").

WHEREAS, the Parties desire to correct the Scrivener's Error and ratify and confirm that Lian Oncology Limited is a party to the License Agreement, and that all references to "LianBio Oncology Limited" in the License Agreement shall be deemed to refer to "Lian Oncology Limited".

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Nanobiotix and Lian hereby agree as follows:

1. **Definitions**. Capitalized terms used herein and not defined herein shall have the meaning ascribed to such term as set forth in the License Agreement and all references to Sections, Exhibits, Schedules, cover page, preamble, recitals, and signature page shall mean the Sections, Exhibits, Schedules, cover page, preamble, recitals, and signature page of the License Agreement. For purposes hereof, all references to the License Agreement, shall mean the License Agreement as amended by this Amendment No. 1.

2. **Amendments**. The Parties hereby agree that (a) any and all references to "LianBio Oncology Limited" in the License Agreement, including without limitation as they appear on the cover page, preamble, and signature page of the License Agreement, are hereby amended as, restated in its entirety to read as and deemed references to "Lian Oncology Limited", and (b) Lian Oncology Limited is

a party to the License Agreement executed by "LianBio Oncology Limited" as if Lian Oncology Limited was originally a party thereto.

3. Counterparts. This Amendment No. 1 may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. This Amendment No. 1 may be signed electronically by each of the authorized representatives of the Parties. The Parties acknowledge and agree that electronic signatures via DocuSign may be used for the execution of this Amendment No. 1 by such signatories. Each Party acknowledges that it has received all the information required for the electronic signature of this Amendment No. 1 and that it is signing this Amendment No. 1 electronically in full knowledge of the technology used and its terms and conditions, and consequently waives any claim and/or legal action challenging the reliability of this electronic signature system and/or its intention to enter into this Amendment No. 1. Furthermore, the obligation to deliver an original copy to each of the Parties is not necessary as proof of the commitments and obligations of each Party to this Amendment No. 1. The delivery of an electronic copy of this Amendment No. 1 directly by DocuSign to each Party shall constitute sufficient and irrefutable proof of the commitments and obligations of each Party to this Amendment No. 1.

4. No Other Modification. Except as amended hereby, the terms and provisions of the License Agreement are hereby ratified and shall remain in full force and effect without modification or amendment. From and after the date of this Amendment No. 1, the License Agreement and this Amendment No. 1 shall be read as one document.

[signature page to follow]

IN WITNESS WHEREOF, the Parties by their respective authorized representatives have executed this Amendment No. 1 as of the date first above written.

Nanobiotix S.A.

By: /s/ Laurent LEVY

Name: Laurent LEVY

Title: Chairman of the Executive Board

[*Signature Page to Amendment No. 1 to Licensed, Development and Commercialization Agreement*]

IN WITNESS WHEREOF, the Parties by their respective authorized representatives have executed this Amendment No. 1 as of the date first above written.

Lian Oncology Limited

By: /s/ Raphael Ho

Name: Raphael Ho

Title: Director

[Signature Page to Amendment No. 1 to Licensed, Development and Commercialization Agreement]

IN WITNESS WHEREOF, the Parties by their respective authorized representatives have executed this Amendment No. 1 as of the date first above written.

In the presence of and in agreement by:

LianBio

By: /s/ Yizhe Wang

Name: Yizhe Wang

Title: Director

[Signature Page to Amendment No. 1 to Licensed, Development and Commercialization Agreement]

Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation or Organization
LianBio Development (Cayman) Limited	Cayman Islands
LianBio, LLC	Delaware
Lian Cardiovascular	Cayman Islands
LianBio Development (HK) Limited	Hong Kong
LianBio Licensing, LLC	Delaware
Lian Oncology Limited	Hong Kong
Lian Cardiovascular Limited	Hong Kong
LianBio Respiratory Limited	Hong Kong
LianBio Ophthalmology Limited	Hong Kong
LianBio Inflammatory Limited	Hong Kong
Shanghai LianBio Development Co., Ltd. (上海联拓生物科技有限公司)	People's Republic of China
Shanghai LianBio Oncology Development Co., Ltd. (上海联愈生物科技有限公司)	People's Republic of China
Shanghai LianBio Cardiovascular Development Co., Ltd. (上海联旬生物科技有限公司)	People's Republic of China
LianBio Development (SG) Pte. LTD.	Singapore

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements listed below of our report dated March 28, 2023, with respect to the consolidated financial statements of LianBio and subsidiaries.

-Form S-8 dated November 3, 2021 (File No. 333-260732)
-Form S-8 dated March 31, 2022 (File No. 333-264021)
-Form S-3 dated November 10, 2022 (File No. 333-268317)

/s/ KPMG LLP

New York, New York

March 28, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yizhe Wang, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 of LianBio;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statement for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yi Larson, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 of LianBio;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statement for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of LianBio (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yizhe Wang, Chief Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PERIODIC FINANCIAL REPORTS PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of LianBio (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yi Larson, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)