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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

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

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 o No x

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 x No o

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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	x		

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. x

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the Registrant's ordinary shares held by non-affiliates of the Registrant was $682.0 million as of the closing of the Registrant's initial public offering on November 3, 2021 (based on a closing price of $13.50 per ADS as quoted by the Nasdaq Global Market 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 18, 2022, 107,275,458 ordinary shares of the registrant, par value $0.000017100448 per share, were outstanding, of which 20,906,116 ordinary shares were held in the form of American Depositary Shares.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A for its 2022 Annual Meeting of Shareholders scheduled to be held on June 8, 2022. 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, NX-13 and sisunatovir, 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 a 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 ADSs. Recent statements made 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 new Cybersecurity Review Measures (which became effective on February 15, 2022), 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"), the Accelerating Holding Foreign Companies Accountable Act (the "AHFCA Act") (if enacted) or the America COMPETES Act (if enacted) 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 approval of, or filing or other procedures with, the China Securities Regulatory Commission ("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.
- 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.

- 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.
- 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.
- 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.
- 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.
- 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.
- 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 ("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. As of March 18, 2022, Perceptive and its affiliates beneficially own 52.5% of our ordinary shares, based on the number of shares outstanding as of March 18, 2022. Two of our current non-employee directors are affiliated with Perceptive. We have also entered into a director nomination agreement (the "Director Nomination Agreement") with Perceptive that provides Perceptive the right to designate nominees 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. 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 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.
- 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

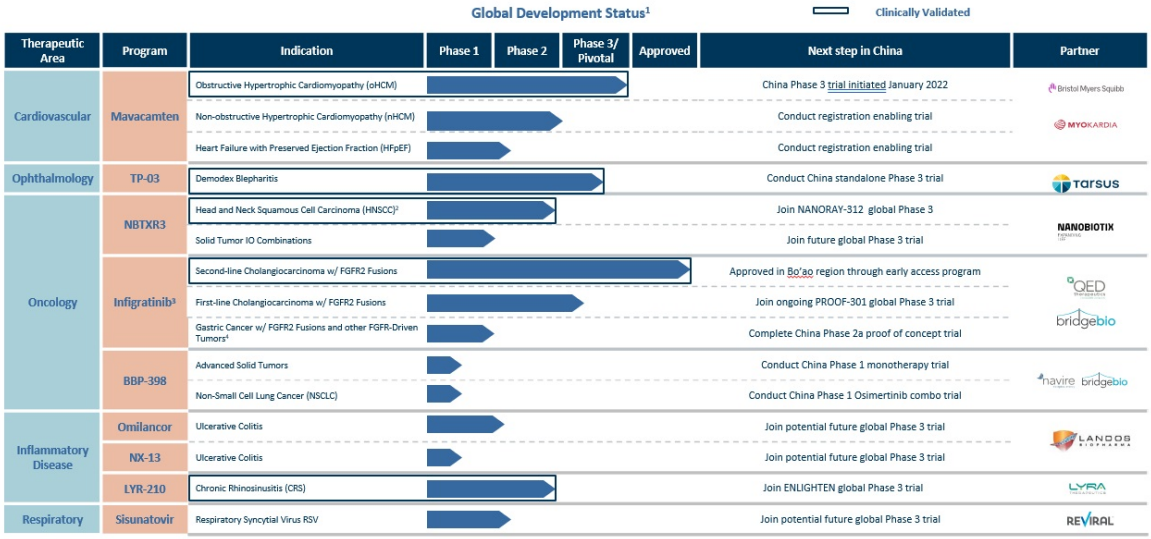
Overview

We are a global, science-driven biopharmaceutical company dedicated to developing and commercializing innovative medicines for patients with unmet medical needs, with an initial focus on in-licensing assets for Greater China and other Asian markets. We have purposefully designed our organization to successfully execute on our vision by identifying, sourcing, developing and commercializing product candidates and partnering with highly innovative biopharmaceutical companies around the world. We are establishing an international infrastructure to position ourselves as a partner of choice with a platform to provide access to our target markets.

Our model leverages a number of key elements, including transformative in-licensing, development and commercialization approaches that we believe will enable us to deliver innovative therapeutic solutions to patients in Greater China, including Mainland China, Hong Kong, Taiwan and Macau, and other Asian markets. Our deep relationships with our founder, Perceptive Advisors ("Perceptive"), as well as our broader investor base, position us to access and capture attractive business development opportunities. We have also entered into high-value strategic collaborations with Pfizer Inc. ("Pfizer"), which offers optionality to leverage its broad reach and commercial infrastructure in Greater China, and BridgeBio Pharma LLC ("BridgeBio"), which provides us with preferential access to an innovative pipeline of more than 20 product development candidates. We have assembled a strong pipeline of nine assets across five therapeutic areas, each with its own distinct value proposition and the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications. We are currently conducting one registrational study, EXPLORER-CN for mavacamten in obstructive hypertrophic cardiomyopathy ("oHCM"), and plan to initiate three additional registrational studies over the next 12 months to advance our product candidates towards regulatory approval in China.

Today, China represents the second largest pharmaceutical market in the world, with estimated branded pharmaceutical market revenues of $89 billion in 2020, and which are expected to reach $187 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.

Since our incorporation, we have rapidly assembled a broad, robust pipeline of nine product candidates across five 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 upcoming 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] 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.

[3] 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 a fibroblast growth factor receptor 2 ("FGFR2") fusion or other rearrangement.

[4] Ongoing Phase 2a standalone clinical trial in China in gastric cancer and other FGFR-driven tumors. Separate investigator sponsored Phase 2 clinical trial of infigratinib in FGFR-driven tumors is ongoing in the United States.

Regulatory developments

Revised cybersecurity review measures

On July 10, 2021, the Cyberspace Administration of China ("the CAC"), published a draft revision to the existing Cybersecurity Review Measures for public comment, ("the Revised Draft CAC Measures") and, together with 12 other Chinese regulatory authorities, released the final version of the Revised Draft CAC Measures (the "Revised CAC Measures") on December 28, 2021, 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.

Currently, the Revised CAC Measures have not materially affected our business and operations, and as we do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China, we do not believe our business activities affect, nor would be interpreted to affect, national security. As of the date of this Annual Report on Form 10-K, we have not been informed by any relevant Chinese government authorities that we are identified as or considered a "critical information infrastructure operator" or "online platform operator." However, in anticipation of the strengthened implementation of cybersecurity laws and regulations, there can be no assurance that we will not be deemed as a critical information infrastructure operator or online platform operator under the Chinese cybersecurity laws and regulations in the future, or that the Revised CAC Measures will not be further amended or other laws or regulations will not be promulgated to subject us to the cybersecurity review or other compliance requirements. In such case, we may face challenges in addressing such enhanced regulatory requirements. For additional information, see "Part I—Item 1A—Risk Factors—Risks Related to our Business Operations—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," "Part I—Item 1A—Risk Factors—Risks Related to Doing Business in China and Our International Operations—Compliance with the Data Security Law of the People's Republic of China, Cybersecurity Review Measures, the Personal Information Protection Law of the People's Republic of China, regulations and guidelines relating to the multi-level protection scheme and any other future laws and regulations may entail significant expenses and could materially affect our business," and "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."

Proposed network data security management

On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft 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 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 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 Management Regulations were released for public comment only, and the draft provisions and anticipated adoption or the effective date are subject to change, the interpretation and implementation of such measures remain substantially uncertain. We cannot predict the impact of the Draft Management Regulations, if any, on the operations of our Company at this stage, and we will closely monitor and assess any development in the rule-making process.

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. 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 December 24, 2021, the China Securities Regulatory Commission ("CSRC") released for public comment draft rules titled Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Draft Overseas Listing Rules"), which, among other things, require certain companies to fulfill a filing procedure in respect of their overseas offerings and listings if such companies meet the criteria set forth in the Draft Overseas Listing Rules. However, there remains uncertainty as to the final version and effective date of the Draft Overseas Listing Rules, how the Draft Overseas Listing Rules will be interpreted or implemented and whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Draft Overseas Listing Rules.

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 or other procedures in connection with offering our equity securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. However, any existing or future laws or regulations relating to our business, industry or cross-border financing activities such as securities offerings and listings, or interpretations of these laws or regulations, may change. As a result, it is uncertain whether we will be required to obtain approval from or complete filing or other procedures with the Chinese government for our offerings, or to list or remain listed on U.S. exchanges in the future. If such an approval, filing or other procedure is required, 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 procedures, despite our best efforts. Even if such approval is obtained or filing or other procedures are completed, it could be withdrawn or rescinded. If we, or our subsidiaries were required to obtain such approval or complete such filing or other procedures in the future but fail to do so, we may not be able to become listed, or maintain our listing status, on a U.S. exchange, which could materially affect the interest of investors.

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 ("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, Building 5, Enterprise World, 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

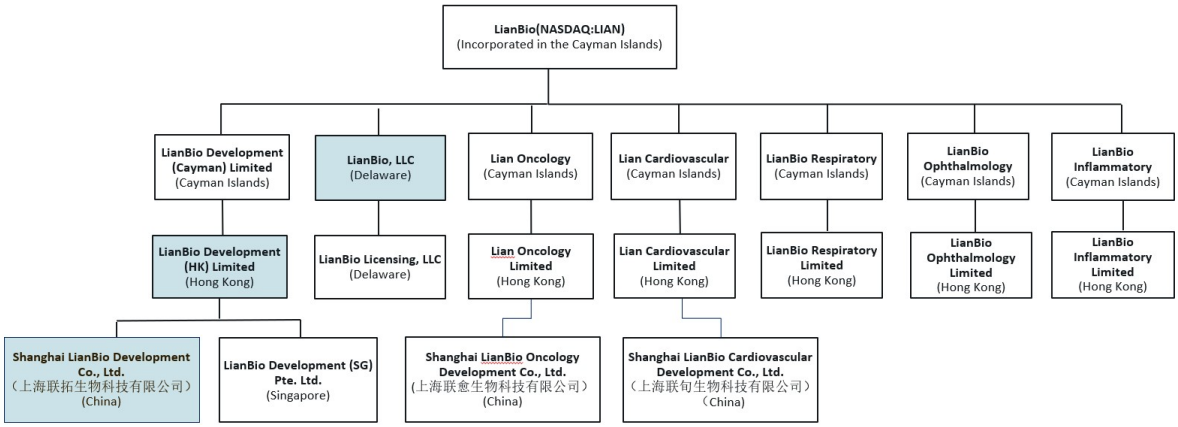
We are a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt 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, $9,999,905 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 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 RMB or any foreign currency. According to the Company Law of the People's Republic of China 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—China 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, 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 initially being studied for the treatment of hypertrophic cardiomyopathy ("HCM") and has potential therapeutic applications for other diseases of diastolic dysfunction. 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, obstructive hypertrophic cardiomyopathy ("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. We have completed enrollment in a pharmacokinetics ("PK") trial and begun dosing patients in a Phase 3 clinical trial, EXPLORER-CN, in China. 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"). 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.

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. 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 (New York Heart Association ("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 (1) 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 (2) 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 ($p\leq0.0006$) 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.

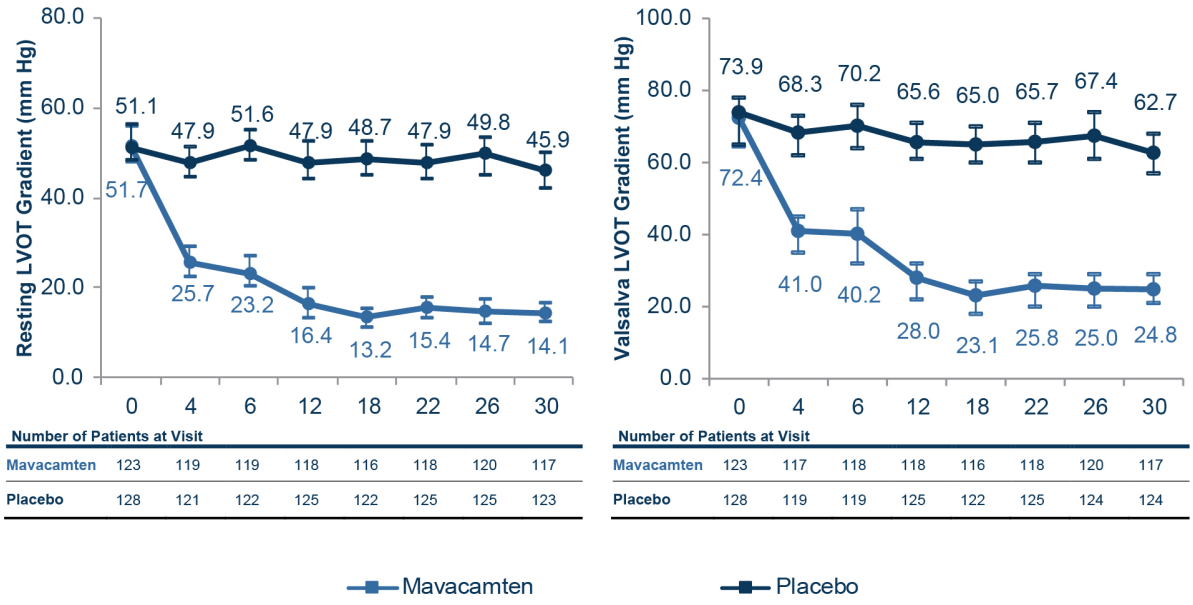
[2] Patients with a non-evaluable primary endpoint and NYHA secondary endpoint were considered as non-responders. The response rates were calculated with the N value as the denominator.

[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, 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 are currently conducting a Phase 3 clinical trial and a PK clinical 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 subject dosing in the PK trial in November 2021 and initiated the Phase 3 EXPLORER-CN clinical trial in January 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 expect to enroll approximately 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 are also conducting a PK trial of mavacamten in healthy adults in China.

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 the first of two pivotal trials of TP-03 for the treatment of DB in the United States, Saturn-1. All pre-specified primary and secondary endpoints were met in Saturn-1, and complete resolution of DB signs was demonstrated in patients treated with TP-03. The second pivotal trial of TP-03 in DB, Saturn-2, has completed enrollment and is expected to announce topline results in April 2022. 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.

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 the first of two pivotal trials of TP-03 for the treatment of DB in the United States, Saturn-1. All pre-specified primary and secondary endpoints were met in Saturn-1, and complete resolution of DB signs was demonstrated in patients treated with TP-03. Tarsus initiated a second pivotal clinical trial, Saturn-2, in May 2021, which has a similar design to Saturn-1. Saturn-2 has completed enrollment, and Tarsus is expected to announce topline results in April 2022. If successful, Tarsus has indicated that it expects these trials to support a new drug application ("NDA") submission to the FDA. Tarsus has also announced plans to initiate clinical trials of TP-03 for the treatment of MGD. Previously, Tarsus conducted four Phase 2 clinical trials of TP-03 in patients with DB. Each of these trials demonstrated statistically significant collarette cure and mite eradication rates.

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

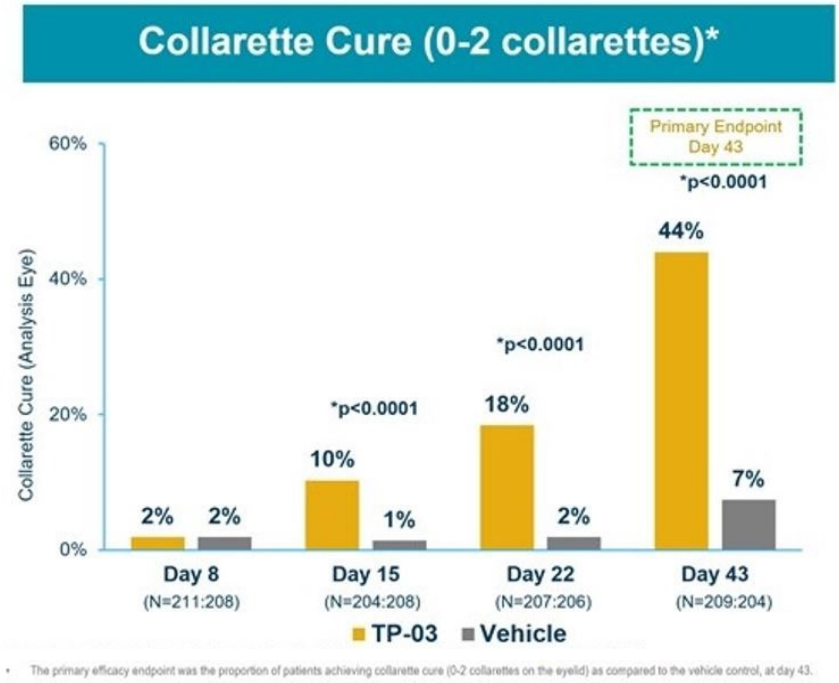
In June 2021, Tarsus announced positive results of the pivotal Phase 2b/3 Saturn-1 pivotal trial. All pre-specified primary and secondary endpoints were met, and complete resolution of DB signs was demonstrated in patients treated with TP-03.

- 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 ($p<0.0001$).

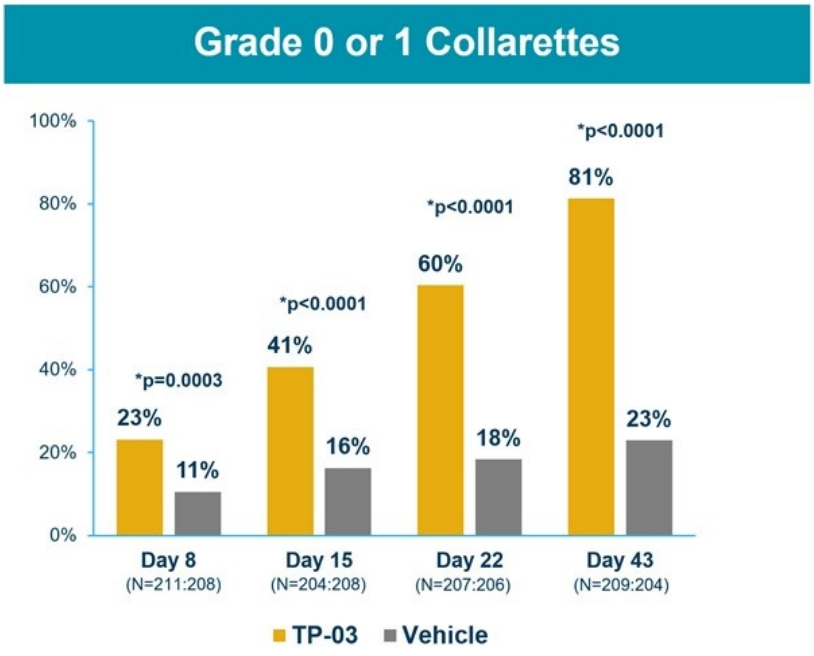
Additionally, significant efficacy in lid erythema (redness) was demonstrated across multiple measures including complete and clinically meaningful composite cures, and in erythema alone. Results showed 45% of patients improved erythema by one (1) grade or more (compared to 28% of patients on vehicle, $p=0.0002$) 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 adverse events nor any treatment-related adverse events leading to treatment discontinuation.

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2



Clinically Meaningful Collarette Cure Observed by Week 1: Over 90% Avg. Reduction in Collarettes (Over 100 to Less than 10 per Lid)



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 with no significant adverse events. Based on the strength and consistency of the Phase 2 and Phase 2b/3 data, we believe TP-03 has the potential to have a global impact, and that we will be able to leverage this data to move into a Phase 3 clinical trial in China and potentially establish a new standard of care for the treatment of DB in China.

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 plan to conduct a Phase 3 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 initiate clinical development of TP-03 in China in the second half of 2022.

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 head and neck 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. When exposed to ionizing radiation, NBTXR3 has been shown to enhance the localized effect of radiotherapy, in our licensed territories of Mainland China, Hong Kong, Taiwan, Macau, South Korea, Singapore and Thailand. NBTXR3 is designed to increase the dose of radiotherapy 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 radiotherapy 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 head and neck cancer, for which the FDA has granted Fast Track designation for the treatment of elderly patients ineligible for platinum-based chemotherapies. 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 eight 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 head and neck ("H&N") cancer.

Radiotherapy overview

Radiotherapy ("RT") 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.

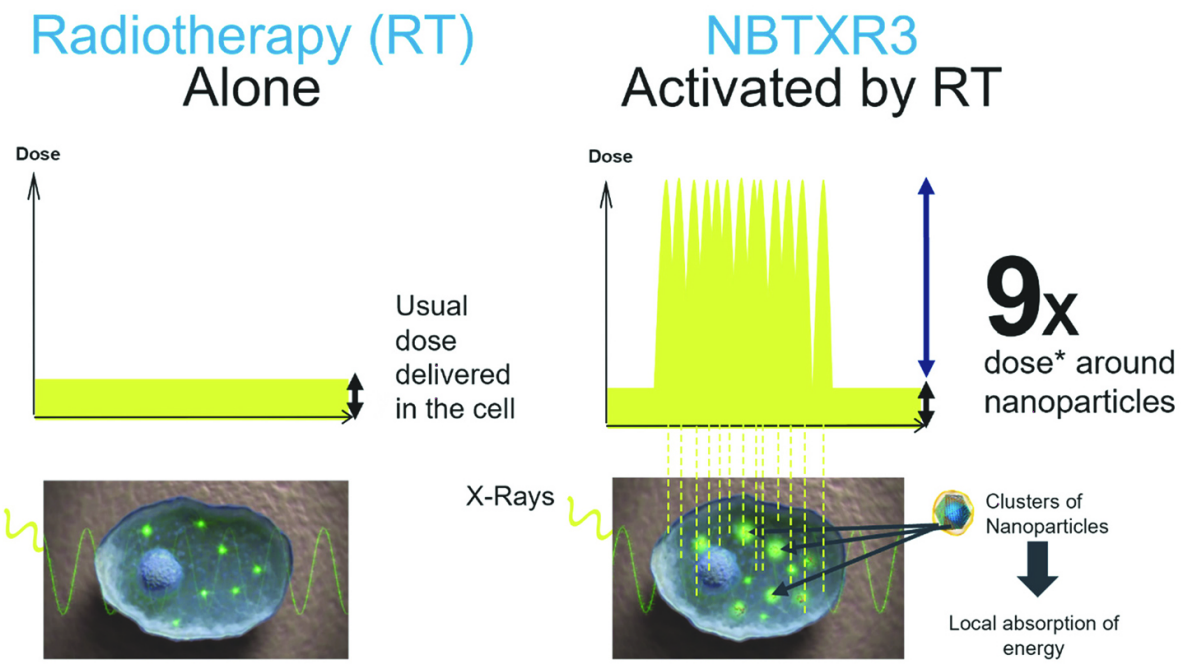
In developed countries, more than half of cancer patients receive RT as part of their treatment protocol. Currently, 20-25% of cancer patients in China are treated with RT, due in part to a shortage of equipment. In recent years, the government has issued policies aimed at expanding the availability 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 adverse events.

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

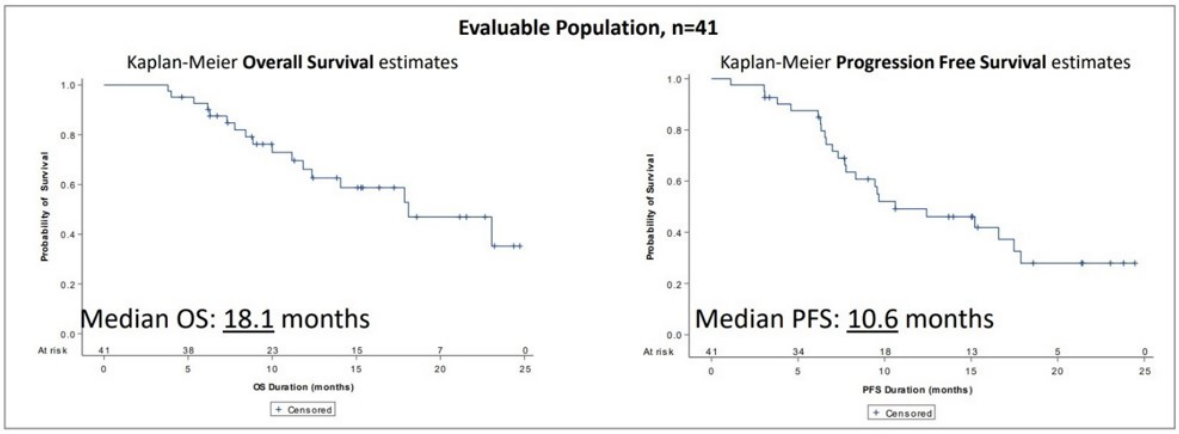
Chemotherapy in combination with concomitant radiation is the current standard of care for inoperable locally advanced H&N cancer. In China, KOL research indicates most patients with inoperable locally advanced H&N cancer are eligible to be treated by RT. This presents limitations in elderly patients, for whom these cancers are more prevalent, due to their reduced ability to withstand chemotherapy and its associated adverse events. 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 October 2021, Nanobiotix presented data at the 2021 Annual Meeting of the American Society for Radiation Oncology. The first analysis of overall survival ("OS") and progression-free survival ("PFS") from the ongoing Phase 1 trial of NBTXR3 in elderly and frail locally advanced head and neck squamous cell carcinoma patients ineligible for cisplatin and intolerant to cetuximab (Study 102) demonstrated median OS of 18.1 months and median PFS of 10.6 months in the evaluable population (n=41) from the dose expansion part of the study. NBTXR3 administration was feasible and well-tolerated overall. A total of 8 Grade 3-4 NBTXR3-related adverse events ("AEs") were observed in 8 patients. Of these AEs related to NBTXR3, 5 serious adverse events ("SAEs") were observed including dysphagia, sepsis, soft tissue necrosis, stomatitis, and tumor hemorrhage. Of the SAEs, one death from sepsis assessed by the investigator as possibly related to NBTXR3, radiotherapy, and cancer was observed.



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 H&N squamous cell carcinoma ("HNSCC") who are ineligible for platinum-based chemotherapy. Nanobiotix initiated this clinical trial by enrolling the first patient in January 2022.

NBTXR3 in immuno-oncology

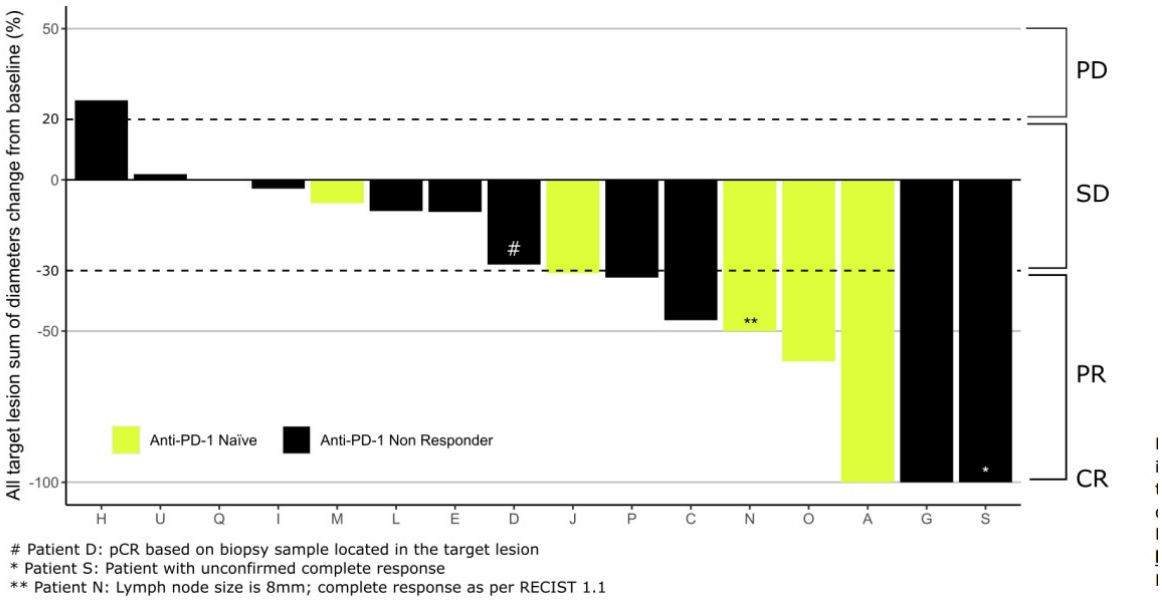
Nanobiotix has generated preclinical data demonstrating that RT-activated NBTXR3 resulted in greater tumor cell death than RT alone due to higher tumor recognition by the patient's immune system.

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 October 2021, Nanobiotix presented updated data from Study 1100 at ASTRO. Disease control rate in 16 evaluable patients was 81% and 73% within a subgroup of patients with prior primary or secondary resistance to anti-PD-1. In the evaluable patient population, 3 complete responses and 5 partial responses were reported. Some patients in the study showed delayed tumor response and/or abscopal effect, suggesting NBTXR3 may potentially prime an immune response. The results suggest that NBTXR3 administration was feasible and well-tolerated.

Study 1100: Best Observed Target Lesion Response (Evaluable Population n=16)



Nanobiotix has announced plans to assess NBTXR3 in combination with several immune checkpoint inhibitors, including anti-PD-1, anti-PD-L1 and anti-CTLA-4 therapeutics in patients across various indications, including inoperable, locally advanced HNSCC, recurrent or metastatic HNSCC, advanced solid tumors, and lung or liver metastases from solid malignancies.

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 may join five of Nanobiotix's 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 plan to pursue for NBTXR3 in China is locally advanced HNSCC as part of the ongoing Phase 3 NANORAY-312 clinical trial. We plan to initiate the China portion of the Phase 3 NANORAY-312 clinical trial in the second half of 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 radiotherapy and immunotherapy.

Infigratinib, a targeted FGFR1-3 inhibitor for the potential treatment of cholangiocarcinoma ("CCA") and gastric cancer

We have partnered with BridgeBio Pharma, Inc. 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, including CCA, urothelial carcinoma and achondroplasia. Infigratinib is approved in the United States for the treatment of patients with previously-treated, unresectable locally advanced or metastatic 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 CCA and 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
CCA	~11k	14-17%	~72k	14-17%	FGFR2 fusions
GC	~26k	4.0 %	~480k	4.6 %	FGFR2 amplification

CCA is a highly invasive, malignant carcinoma that originates from bile duct epithelial cells. A number of factors associated with liver damage, such as biliary stone, exposure to toxins and hepatitis B and hepatitis C virus infections, increase the risk of developing CCA. Patients diagnosed with CCA have a one-year survival rate of 50% and a five-year survival rate of approximately 10% with few therapeutic options. First-line therapy is limited to cytotoxic chemotherapy with agents such as gemcitabine and cisplatin, gemcitabine and oxaliplatin, and fluorouracil monotherapy. PFS with gemcitabine and cisplatin combination therapy is approximately 8.0 months. PFS after second line chemotherapy is only 2.7 months.

Approximately 72,000 patients in China are diagnosed with intrahepatic CCA annually. Given the severity of the disease, the lack of highly effective therapies and the high prevalence rate in China, there is an urgency to bring innovative treatments to this patient population. Approximately 14-17% of patients with intrahepatic CCA, or 10,000 to 12,000 patients in China, have FGFR2 gene fusions.

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. QED is currently studying infigratinib in multiple clinical trials, including the Phase 3 PROOF-301 clinical trial in first-line CCA patients with FGFR2 gene fusions/translocations and a Phase 3 clinical trial in urothelial cancer patients with a targetable FGFR3 alteration. 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. Additionally, we plan to join QED's ongoing Phase 3 PROOF-301 clinical trial in first-line CCA in the second half of 2022 and we have received clearance from the NMPA to initiate the China portion of this trial. We also intend to explore development and patient access strategies in our territories for infigratinib in previously treated, unresectable locally advanced or metastatic CCA with FGFR2 fusion or other rearrangement (second-line CCA).

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 progression-free survival (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 Adverse events 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 and CCA 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.

Additionally, we plan to join QED's ongoing global Phase 3 PROOF-301 clinical trial of infigratinib in first-line locally advanced or metastatic CCA patients with FGFR2 gene fusions or translocations by enrolling patients in China in the clinical trial.

We also intend to explore development and patient access strategies in our territories for infigratinib in second-line CCA. 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.

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

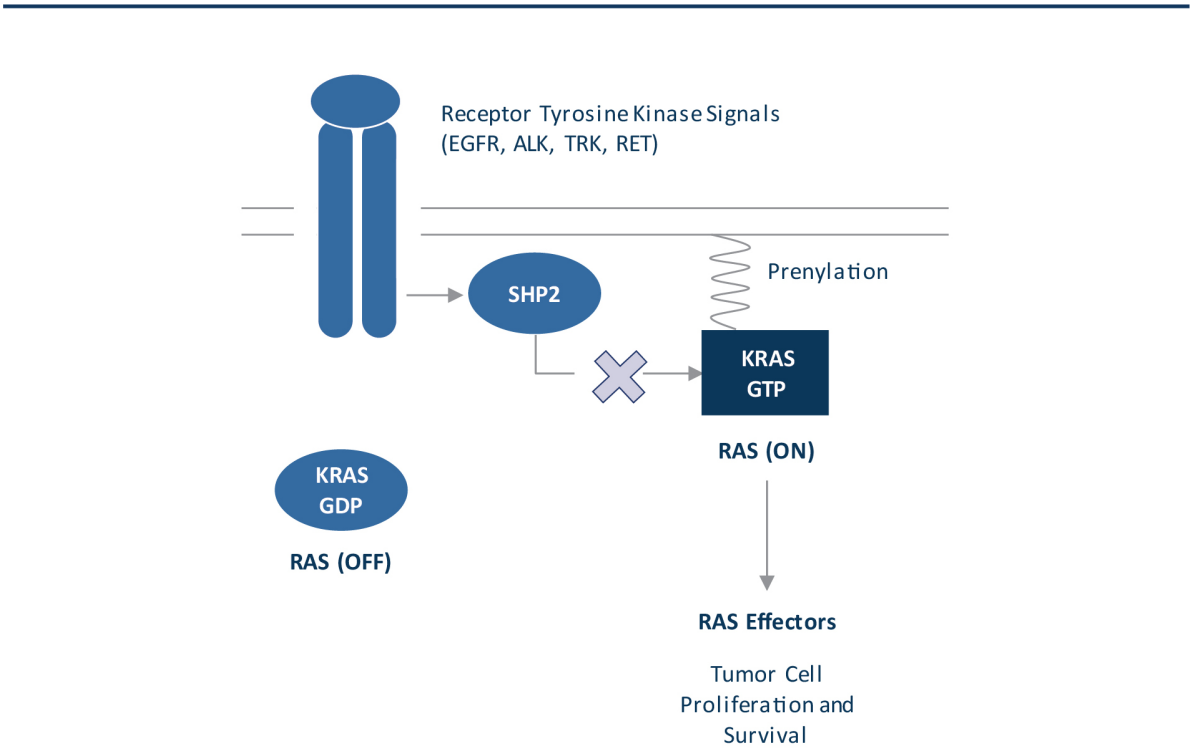
BBP-398 is an orally available allosteric inhibitor of SHP2, a tyrosine phosphatase that plays a key role in the RTK-mediated MAPK signal transduction pathway. We have partnered with BridgeBio Pharma, Inc. and its affiliate Navire Pharma, Inc. ("Navire") to develop and commercialize BBP-398 in Greater 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 received clearance from the NMPA to enroll patients in China in a local Phase 1 clinical trial of BBP-398 and a local Phase 1a/1b clinical trial of BBP-398 in combination with osimertinib.

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



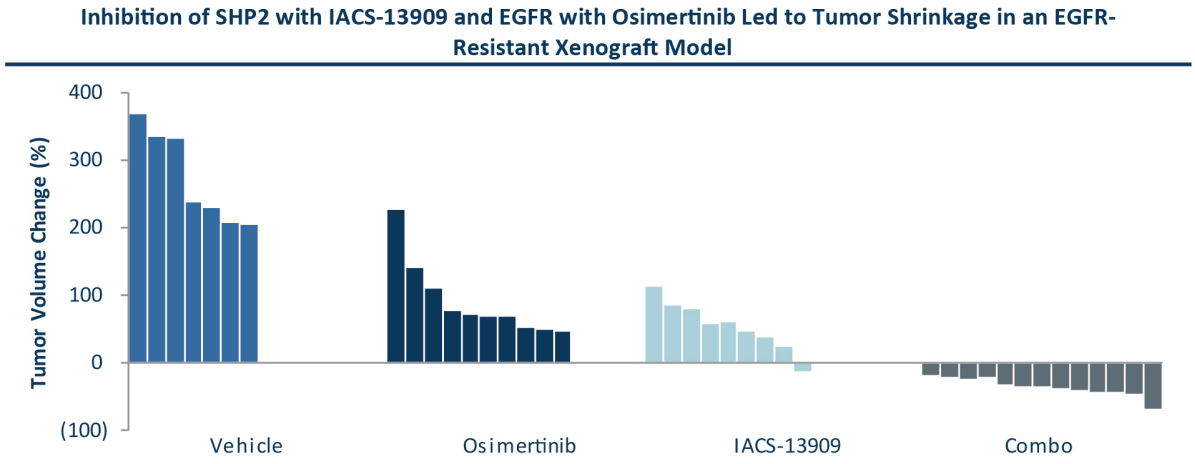
NSCLC current standard of care

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 adverse events 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.



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 has indicated its plans to treat expansion cohorts in patients with NSCLC with KRAS or EGFR mutations and in other solid tumor types with KRAS mutations or MAPK pathway alterations.

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.

We received clearance from the NMPA to enroll patients in China in a local Phase 1 clinical trial of BBP-398 and a local Phase 1a/1b clinical trial of BBP-398 in combination with osimertinib.

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, mid-year 2022. We plan to join the LYR-210 clinical development program by enrolling patients in China in one of Lyra’s planned pivotal Phase 3 clinical trials.

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.

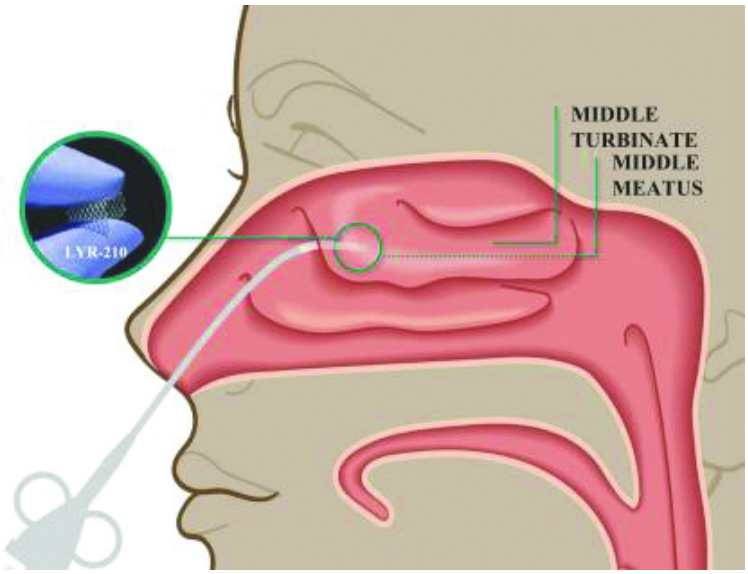
CRS patients whose symptoms persist despite medical management are generally recommended to undergo functional endoscopic sinus surgery ("FESS") or balloon sinus dilation ("BSD"), or both. FESS is a highly invasive surgery performed in the operating room, under full anesthesia, to open the blocked sinus 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.

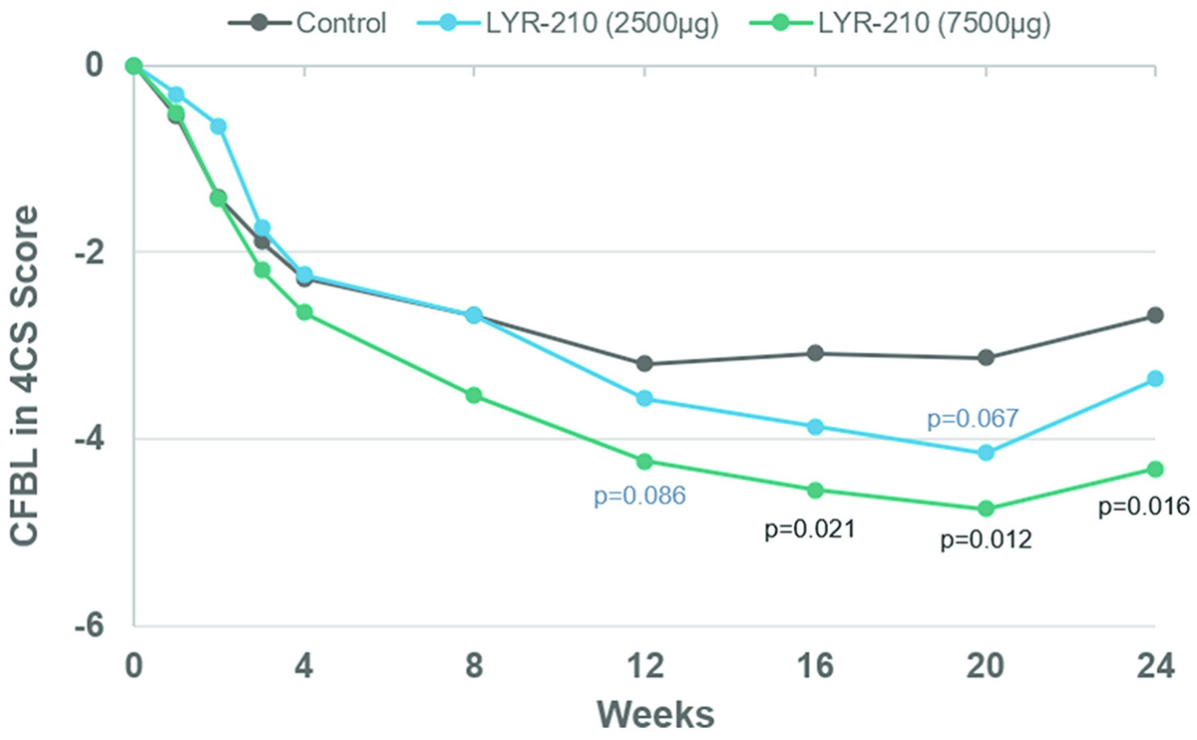
LYR-210 development path

Lyra's Phase 2 LANTERN clinical trial was designed to inform a pivotal Phase 3 program for LYR-210. Lyra has announced that the first patient was dosed in its first Phase 3 clinical trial, ENLIGHTEN I, in February 2022. The second Phase 3 trial, ENLIGHTEN II is anticipated to commence mid-year 2022.

Results from phase 2 LANTERN clinical trial

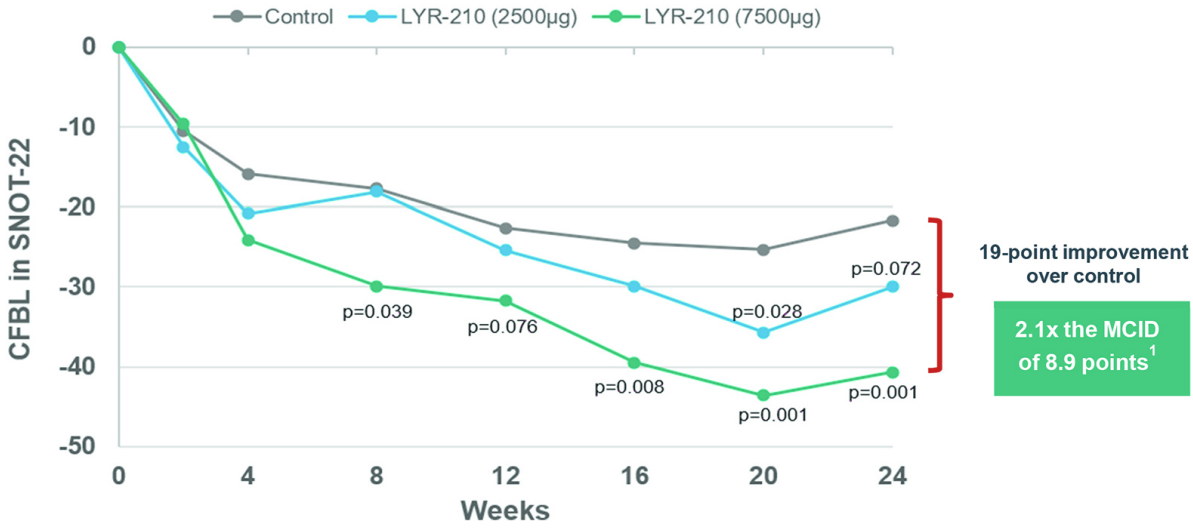
Lyra presented positive topline and full results from its Phase 2 LANTERN clinical trial in December 2020 and April 2021. The LANTERN clinical trial was a randomized, sham procedure-controlled, patient-blinded study that evaluated adult patients with CRS who had failed previous medical management and 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).

Results 22-Item Sino-Nasal Outcome Test (SNOT-22)



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. Adverse events 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 adverse events 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 adverse events 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 join the LYR-210 clinical development program by enrolling patients in China in one of Lyra's planned pivotal Phase 3 clinical trials.

Inflammatory disease

Omilancor for the potential treatment of inflammatory bowel disease

We have partnered with Landos BioPharma, Inc. ("Landos") to develop and commercialize omilancor in Greater China, Cambodia, Indonesia, Myanmar, Philippines, Singapore, South Korea, Thailand, and Vietnam in inflammatory bowel disease ("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. IBD can be further categorized into ulcerative colitis ("UC") and Crohn's disease ("CD"). Landos has announced plans to initiate a Phase 2b clinical trial of omilancor in moderate to severe UC patients. Should this trial be successful, we plan to join the omilancor development program by enrolling patients in China in Landos's potential future global pivotal trials.

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 serious adverse events, 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.

Omilancor development path

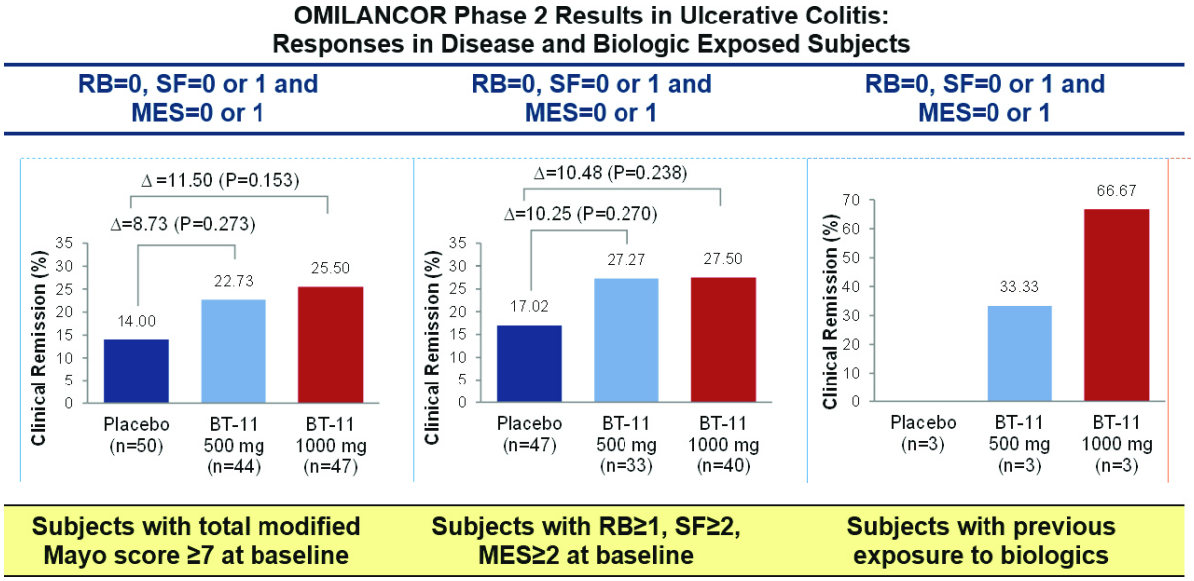
Landos has completed the induction phase of a Phase 2 clinical trial of omilancor in patients with mild to moderate UC in the United States, Russia and Europe. Omilancor was observed to be gut-restricted and well-tolerated in the Phase 2 clinical trial. A positive trend was observed in absolute clinical remission rates following treatment with omilancor. Based on these data, Landos has announced that it expects to initiate a Phase 2b clinical trial in moderate to severe UC.

Results from phase 2 clinical trial in UC

Landos announced data from their Phase 2 clinical trial in mild to moderate UC in January 2021. The trial was a randomized, placebo-controlled, double-blind, clinical trial of 198 patients across 53 sites in the United States, Europe and Russia. The trial showed a 12-week clinical remission rate of 30.3% in the 500mg cohort and 31.8% in the 1000mg cohort compared to placebo remission rate of 22.7%. Remission was defined by the 3-component modified Mayo Score, consisting of a rectal bleeding subscore of 0, a stool frequency subscore of 0 or 1, and an endoscopic subscore of 0 or 1. Placebo-adjusted clinical remission rates were 9.1% and 7.6% for the 1000mg and 500mg dose groups, respectively, which is consistent with certain currently approved agents. Omilancor was well-tolerated with an adverse effect profile similar to placebo.

	Placebo (n = 66)	Omilancor 500 mg (n = 66)	Omilancor 1000 mg (n = 66)
Clinical Remission (%)	**22.7**	**30.3**	**31.8**
P Value	—	0.340	0.235

Results were also analyzed in a more moderate subset of patients, defined as having a Mayo score equal to or greater than 7 at baseline. Placebo-adjusted clinical remission rates were 11.5% and 8.7% for the 1000 (n=47) and 500 mg (n=44) dose groups, respectively, as compared to placebo (n=50). In a small subset of biologic experienced patients, positive placebo-adjusted remission trends were also observed (66% and 33% in the 1,000 (n=3) and 500 mg (n=3) cohorts, respectively, as compared to placebo (n=3, 0%)).



In May 2021, Landos initiated a Phase 2 clinical trial in moderate to severe CD. In January 2022, Landos halted further enrollment in this trial for a number of reasons, including low enrollment, and will evaluate reinitiating clinical development in CD pending results of the expected Phase 2b trial in moderate to severe UC.

Our strategy to seek regulatory approval of omilancor in China

Should omilancor advance into Phase 3 studies, we plan to join Landos's potential future global pivotal trials of omilancor by opening sites and enrolling patients in China.

NX-13 for the potential treatment of 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 UC and CD. Landos announced positive results from a Phase 1 trial of NX-13 in healthy volunteers in March 2021. NX-13 was shown to be well-tolerated with no reported SAEs. All primary and secondary endpoints were met. Landos initiated a Phase 1b study in patients with UC in April 2021.

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.

Respiratory

Sisunatovir for the potential treatment of respiratory syncytial virus ("RSV")

We have partnered with ReViral Ltd. ("ReViral") to develop and commercialize sisunatovir in Mainland China, Hong Kong, Macau and Singapore. Sisunatovir is a highly potent, selective, orally administered fusion inhibitor designed to block RSV replication by inhibiting F-protein mediated fusion with the host cell. RSV is a respiratory pathogen that can lead to severe and life-threatening lower respiratory tract infections ("LRTIs") in high-risk populations, including infants, immunocompromised individuals and the elderly. RSV constitutes a substantial disease burden, affecting approximately 64 million people and causing approximately 160,000 deaths globally each year. In China, RSV is the leading pathogen causing acute respiratory tract infection ("ARTI"), particularly in infants and young children. RSV is common in the Chinese pediatric patient population and is the major cause of viral community-acquired pneumonia ("CAP"), especially in the first year of life. Currently, there are no effective therapeutic treatment options for patients who develop RSV infection. We believe there is substantial unmet medical need for efficacious RSV treatments for high-risk populations in Asia. ReViral is currently conducting a Phase 2 clinical trial of sisunatovir in infants hospitalized due to RSV-LRTI. ReViral has also indicated plans to study sisunatovir in adult patients with RSV infections who are at risk of severe outcomes, including the elderly and adult patients with chronic obstructive pulmonary disease, asthma and cardiac failure. Should these clinical trials be successful, ReViral intends to initiate global pivotal Phase 3 clinical trials, and we anticipate joining these potential future global pivotal clinical trials by enrolling patients in China.

RSV disease overview

RSV is an enveloped virus with an RNA genome that encodes for 11 viral proteins, including 3 surface glycoproteins, fusion (F) protein, G glycoprotein and small hydrophobic protein. RSV is highly infectious and is transmitted through respiratory secretions, droplets or contaminated surfaces. RSV causes annual outbreaks of respiratory tract disease around the world. Nearly all children have been infected with RSV by the age of 2. Infection does not result in sustained immunity, and RSV reinfection is common throughout life. The majority of people with RSV infection develop upper respiratory tract disease, with mild symptoms similar to those caused by the common cold including cough and low-grade fever. Certain high-risk populations, including infants, young children, immunocompromised individuals and the elderly are vulnerable to LRTI. RSV infection that spreads to the lower respiratory tract can cause pneumonia or bronchiolitis, inflammation of the small airway passages entering the lungs that is characterized by respiratory distress and wheezing. The very young and elderly are at the highest risk for serious complications from RSV infection. Rates of RSV infections requiring medical attention are high throughout the first five years of life, and RSV is a common cause of pediatric hospitalization globally. RSV also constitutes a substantial disease burden among older adults. Among the elderly, hospitalization rates for RSV-acute respiratory infections increase with age. In China, 3.2 million pediatric and elderly RSV-LRTIs occur each year, leading to an estimated four hundred thousand hospitalizations annually.

Current standard of care for RSV

Currently, there are no available vaccines or effective RSV-specific antivirals for active infection in China. Ribavirin, a nucleoside analogue, is the only antiviral therapeutic approved for the treatment of RSV in infants aged zero to three in China and the United States. Ribavirin is infrequently used for the treatment of RSV in clinical practice due to its limited antiviral potency and toxicity concerns including bone marrow suppression and teratogenic and oncogenic potential, and is primarily used when the outcome of an RSV-LRTI could be fatal. Synagis (Paluvizimab), a prophylactic monoclonal antibody that has been shown to help prevent RSV infection, is approved in some countries, but not in China. Synagis is used in some developed countries in babies and young children at high risk of complications from RSV, such as those who are born premature or with chronic health conditions. Synagis use is limited by the therapy's high cost and because it must be given before infection and throughout the RSV season.

Sisunatovir development path

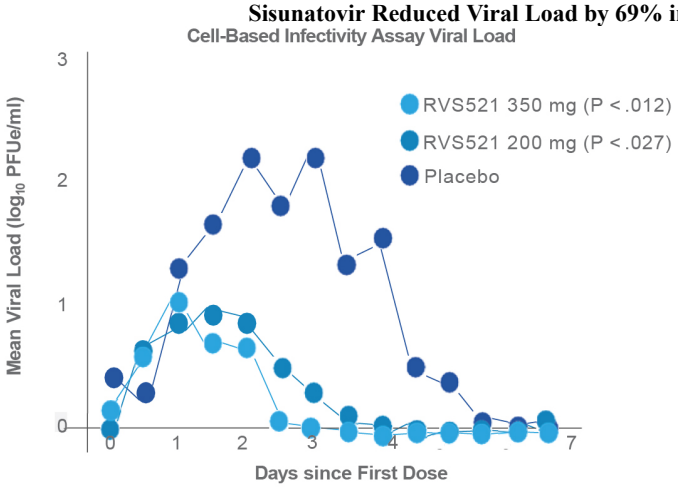
Sisunatovir is a small-molecule antiviral designed to inhibit RSV replication by preventing F-mediated fusion with the host cell. We believe fusion inhibitors represent a promising treatment approach for RSV because the RSV-F protein plays a key role in infectivity and pathogenesis. The RSV-F protein is essential for the entry of the virus to the host cell. Additionally, cell surface expression of the RSV-F protein causes cell-to-cell fusion, leading to the giant syncytia characteristic of RSV infection. Based on the potency, bioavailability and tolerability demonstrated in preclinical studies and clinical trials, we believe that sisunatovir has the potential to become the new standard of care for RSV infection globally and in China.

Results from the Phase 2a challenge study

In a Phase 2a challenge study in healthy adult volunteers conducted to assess the antiviral efficacy, safety and PK of sisunatovir, sisunatovir reduced RSV viral load and disease severity and was well-tolerated. In this randomized, double-blind, placebo-controlled trial, 66 healthy adults were challenged with RSV. After infection was confirmed, or five days after RSV inoculation, patients received sisunatovir or placebo for five days. The study enrolled 66 patients randomized 1:1:1 to receive sisunatovir 350 mg, sisunatovir 200 mg or placebo.

The primary endpoint was area under the curve ("AUC") for viral load, as assessed by reverse transcriptase quantitative PCR ("RT-qPCR") of nasal wash samples. The primary efficacy analysis set included patients successfully infected with RSV who received ≥1 dose of study drug. The mean AUC of RT-qPCR-assessed RSV viral load (log10 PFU equivalents [PFUe]/ml · h) was significantly lower with sisunatovir 350 mg (185.26; standard error [SE], 31.17; P = 0.002) and 200 mg (224.35; SE, 37.60; P = 0.007) versus placebo (501.39; SE, 86.57). The mean AUC of RSV viral load assessed by cell-based infectivity assay (log10 PFU/ml · h) was significantly lower with sisunatovir 350 mg (38.29; SE, 13.36; P = 0.012) and 200 mg (50.98; SE, 14.89; P = 0.027) versus placebo (162.35; SE, 37.77).

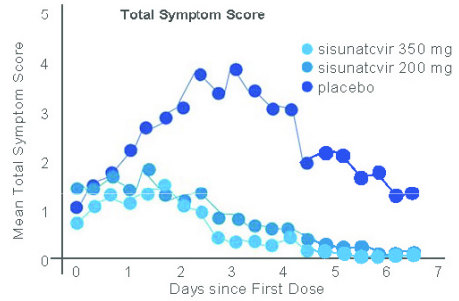
Sisunatovir Reduced Viral Load by 69% in Phase 2 Challenge Study

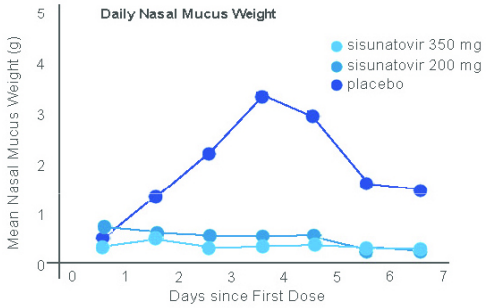


Dose	Viral Load (AUC)	%Change	P-value
200	50.98 ±	68.6%	p=0.027
350	38.29 ±	76.4%	p=0.012
pb	162.35 ±	0%	

Disease severity improved with sisunatovir 350 mg and 200 mg versus placebo (P = 0.002 and P = 0.009, respectively, for AUC total symptom score [score × hours]). Daily nasal mucus weight was significantly reduced (P = 0.010 and P = 0.038 for sisunatovir 350 mg and 200 mg, respectively, versus placebo).

Sisunatovir Cleared RSV Symptoms by Day 4





Dose	Symptom Score (AUC)	%change	P-value
200 mg.	111 ± 34	70.8%	p=0.009
350 mg.	82 ± 24	78.4%	p=0.002
pbo	382 ± 112		

Dose	Mucus Weight (g)	%change	P-value
200 mg.	5.7 ± 1.6	84.9%	p=0.035
350 mg.	4.6 ± 2.0	87.9%	p=0.007
pbo	38.0 ± 10.7		

Safety and tolerability data were favorable. Adverse events were primarily graded 1 in severity and were transient in nature. There were no treatment-related SAEs and no subject discontinuations due to adverse events. GI treatment-emergent adverse events occurred more frequently with sisunatovir than with placebo. The majority of these events were transient, mild and resolved without concomitant medication and did not lead to discontinuation in any individual.

Treatment-Emergent adverse events

Treatment-emergent adverse events that occurred in > 2 subjects in any treatment group (safety analysis set)[a]

TEAE[b]	No. of subjects (%) for treatment group: RV521 350 mg (N = 22)	RV521 200 mg (N = 22)	Placebo (N = 22)
Abdominal pain	5 (23)	2 (9)	0
Diarrhea	9 (41)	3 (14)	1 (5)
Nausea	12 (55)	2 (9)	2 (9)
Vomiting	2 (9)	1 (5)	0
Rhinitis	2 (9)	1 (5)	1 (5)
URTI	0	2 (9)	0
Viral URTI	2 (9)	0	0
Headache	0	0	2 (9)
Rash	0	0	2 (9)

a Respiratory tract infection symptoms were only captured as an AE if they were unexpected as a result of the virus challenge, met the criteria for an AE, and were deemed clinically significant in the opinion of the investigator.

b AE, adverse event; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection

There was no evidence of clinical resistance observed in the Phase 2a challenge study.

Our strategy to seek regulatory approval of sisunatovir in China

ReViral has conducted a Phase 1 pharmacokinetic and safety trial of sisunatovir in healthy adults and a Phase 2a RSV challenge trial in healthy adults. Overall, sisunatovir has been studied in more than 200 subjects to date, with no SAEs reported and no neutropenia or cardiovascular toxicity demonstrated, which has been observed in trials of previous fusion inhibitors. ReViral is currently conducting a global three-part Phase 2 trial of sisunatovir in pediatric patients who are hospitalized due to RSV infection to evaluate the clinical efficacy, safety, tolerability and virologic activity of sisunatovir. Part A is an open-label, single-dose trial to assess the safety, tolerability, and PK profile of single doses of sisunatovir. Part B is a randomized, double-blind, placebo-controlled trial, in which multiple doses of sisunatovir or placebo are administered to assess the safety, tolerability, PK profile, and antiviral effects of multiple doses of sisunatovir. Part C is a larger randomized, double-blind, multiple dose, placebo-controlled trial. The aim of Part C is to assess reduction of viral load (antiviral effect) as the primary endpoint, with clinical signs and symptoms as secondary endpoints.

ReViral initiated a global Phase 2 clinical trial of sisunatovir in immunocompromised patients but suspended the trial in late 2021, as it was unable to enroll patients due to the COVID-19 pandemic. ReViral has announced plans to initiate a Phase 2 clinical trial of sisunatovir in adult patients with RSV infections who are at risk of severe outcomes, including the elderly and adult patients with chronic obstructive pulmonary disease, asthma and cardiac failure.

We licensed sisunatovir from ReViral for development and commercialization in Mainland China, Hong Kong, Macau and Singapore. We plan to focus our initial development efforts on RSV infection in pediatric and at-risk adult populations. Should ReViral advance sisunatovir into pivotal Phase 3 trials, we anticipate joining these Phase 3 trials by enrolling patients in China. We believe that enrollment contribution in China in global Phase 3 clinical trials may expedite the global development program as well as support regulatory approval in China.

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

MyoKardia exclusive license agreement

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 2038 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 enter each of such licensed territory 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 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.

QED license agreement

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 PCT application and will have a twenty-year statutory expiration date in 2040 in each licensed territory, provided the PCT application will 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.

Navire exclusive license agreement

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 agreement

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.

Nanobiotix license, development and commercialization agreement

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 radiotherapy 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. 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 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.

Tarsus development and license agreement

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 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.

Landos license and collaboration agreement

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.

We granted to Landos a non-exclusive license under any inventions and discoveries that we invent relating to the licensed products, for use in the development, manufacture, commercialization, and exploitation of the compounds and licensed products 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 products 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 certain percentage of study patients in the territory.

We agreed to purchase all licensed products 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 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 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 up to $95.0 million and $105.0 million, respectively, to Landos. In addition, if we successfully develop and commercialize the licensed products, we will pay Landos tiered royalties at percentage rates ranging from the low- to the mid-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 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 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 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 licensed products or 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 products 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.

Lyra license and collaboration agreement

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. Should we participate in a global Phase 3 clinical trial for a licensed product, then we are obligated to use commercially reasonable efforts to engage clinical trial sites and enroll up to a certain percentage of study patients in the 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 $40.0 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 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.

ReViral co-development and license agreement

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. Under the ReViral Agreement, both parties agreed not to develop, manufacture, commercialize, or promote competing products in the licensed territory.

We granted to ReViral a license under any know-how or patents that we develop relating to the licensed products, for use in the development and commercialization of the licensed products by ReViral outside of the territory and in the manufacture of the licensed products anywhere in the world for use outside of the territory.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in the licensed field and in the licensed territory. Should we decide to participate in a pivotal global clinical study that targets either the pediatric or elderly adult patient populations, we also are obligated to use commercially reasonable efforts to enroll a certain percentage of study patients in the territory.

We agreed to purchase all licensed products for development and commercialization purposes from ReViral. The parties agreed to execute a separate manufacturing and supply agreement for development and commercial supply of licensed products for the licensed territory.

Under the terms of the ReViral Agreement, we paid to ReViral an upfront payment of $14.0 million. If we achieve specified development and commercial milestone events, we may be required to pay further milestone payments up to $45.0 million and $60.0 million, respectively, to ReViral. In addition, if we successfully develop and commercialize the licensed products, we will pay ReViral tiered royalties at percentage rates ranging from ten to the low-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 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 or region-by region basis in the licensed territory. 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 2035 in Mainland China, Macau, and Singapore. 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 ReViral 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 ReViral 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 or insolvency. ReViral 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 ReViral.

Upon termination of the ReViral Agreement in whole or with respect to one or more countries, we must grant to ReViral an exclusive, perpetual, sublicensable license to certain intellectual property rights and commercial information relating to the licensed product for use in the terminated territory. If after termination of the agreement, ReViral develops or commercializes a product under such license in the terminated territory, then ReViral agrees to pay us standard milestone and royalty payments, the specific details of which are to be agreed upon at the time of termination.

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, 2021, our patent portfolio includes 33 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, 2021, 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 includes a pending PCT application directed to the administration of mavacamten and the polymorph. 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, 2021, our patent portfolio related to infigratinib included four patent families, three of which are owned by Novartis and sublicensed to us by QED and one of which is 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 patent family licensed from QED is directed to treating urothelial carcinoma and CCA, respectively, with infigratinib. This patent family includes two pending applications in Mainland China. 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.

BBP-398

As of December 31, 2021, 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, 2021, 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 a pending Mainland China application that can be extended to 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, 2021, we licensed from Nanobiotix nine families of patent applications. The first patent family is directed to the use of NBTXR3 in radiotherapy 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 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 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 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 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, 2021, we licensed from ReViral three families of patent applications. The first patent family is directed to a set of molecules with certain general formula as RSV inhibitors, covering sisunatovir. The family includes issued patents in China. Any patent that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2032, excluding any patent term extension or patent term adjustment, if applicable, that may be available. The second patent family is directed to the sisunatovir molecule, for treating RSV infection. The family includes issued patents in Mainland China, Macau and Singapore. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date in 2035, excluding any patent term adjustment and patent term extension, if applicable, that may be available. The third patent family is a defensive filing, directed to other compounds as RSV inhibitors. The family includes pending applications in Mainland China and Hong Kong. Any patents that may issue from these families 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.

Omilancor

As of December 31, 2021, we licensed from Landos four 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 the method of use of omilancor in cell therapy. The family includes pending applications in Mainland China, Hong Kong and South Korea. 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 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 fourth 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 third and fourth families to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines.

NX-13

As of December 31, 2021, we licensed from Landos one family of patent applications directed to a composition of matter for NX-13. The family includes pending applications in Mainland China, Hong Kong 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.

LYR-210

As of December 31, 2021, 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 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 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 ("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 People's Republic of China Drug Administration Law ("PRC Drug Administration Law"), which became effective on December 1, 2019. The State Administration for Market Regulation ("SAMR") has promulgated two key implementing regulations for the PRC Drug Administration Law: (1) the amended Administrative Measures for Drug Registration and (2) 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 ("CFDA") established in March 2013, the State Food and Drug Administration ("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, 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 ("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, the approval of clinical trial application should be issued by the Center for Drug Evaluation (the "CDE") in the name of the CFDA.

The National Health and Family Planning Commission ("NHFPC") was rebranded as the National Health Commission ("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 State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the Ministry of Health ("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.

PRC drug administration law

The PRC Drug Administration Law as promulgated by the SCNPC in 1984, and the Implementing Measures of the PRC 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 PRC Drug Administration Law also regulates the distribution, packaging, labels and advertisements of pharmaceutical products in China.

Certain amendments to the PRC 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 PRC Drug Administration Law applies to entities and individuals engaged in the development, production, distribution, application, supervision and administration of pharmaceutical products. The PRC 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 PRC 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 PRC 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 (1) the formalization of the drug marketing authorization holder system (the "MAH system"); (2) expedited approval pathway; and (3) 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 PRC 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 PRC Drug Administration Law. As of the date of this Annual Report on Form 10-K, the Implementing Measures of the PRC Drug Administration Law have not been further amended to reflect the changes in the 2019 Amendment.

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 (1) definitions of drug marketing authorization applications and regulatory responsibilities of the former SFDA; (2) general requirements for drug marketing authorization; (3) drug clinical trials; (4) application, examination and approval of drugs (such as new drugs, generic drugs, imported drugs and OTC drugs); (5) supplemental applications and marketing authorization renewals of drugs; (6) re-registration of drugs; (7) inspections; (8) marketing authorization standards and specifications; (9) time limits; (10) re-examination; and (11) 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: (1) fully implementing the MAH system and implied approval for the commencement of clinical trials; (2) implementing associated review of drugs, excipients and packaging materials; and (3) 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 and derived data

In June 1998, the Ministry of Science and Technology ("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' human genetic resources 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 human genetic resources for the purpose of seeking marketing authorization of drugs in China.

In May 2019, the State Council of China issued the Regulation on the Administration of Human Genetic Resources ("HGR Regulation"), which stipulates the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. 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 China Biosecurity Law, which became effective on April 15, 2021. The China 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 human genetic resources.

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 a bioequivalence trial. 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 the 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 recordal procedures. Pursuant to the rules, a clinical trial institution should comply with the requirements of the Good Clinical Practices ("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 PRC 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 ("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 ("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 PRC 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 statutory 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 ("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 ("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 ("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 specific 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.

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 ("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 ("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: (1) marketing authorization of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (2) marketing authorization of pediatric drugs; (3) marketing authorization of drugs treating specific or prevalent diseases in elders; (4) marketing authorization of drugs listed in national major science and technology projects or national key research and development plans; (5) marketing authorization of drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits that are urgently needed clinically; (6) marketing authorization of foreign innovative drugs to be manufactured locally in China; (7) 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 (8) 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 (1) the review and approval procedures for break-through therapeutic drugs; (2) the review and approval procedures for drug conditional approval application; (3) the priority review procedures for drug marketing authorization approval; and (4) 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 PRC 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 ("CNIPA"), jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) ("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 Patent Law of the People's Republic of China (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. The Measures on Patent Linkage provide operational details.

The Measures on Patent Linkage describe a framework for a patentee to defend their patent exclusivity. Under the patent linkage system, along with the generic applications, the generic drug companies are required to submit a patent statement disclosing any relevant patent listed on the patent information platform. 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.

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

China continues to strengthen its regulation of network security, data protection, 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 the network information management. For instance, under the Cyber Security Law, network operators of key information infrastructure generally shall, during their operations in the PRC, store the personal information and important data collected and produced within the territory of the PRC. When collecting and using personal information, in accordance with the Cyber Security Law, network operators shall abide by the "lawful, justifiable and necessary" principles. The network operator shall collect and use personal information by announcing rules for collection and use, expressly notify the purpose, methods and scope of such collection and use, and obtain the consent of the person whose personal information is to be collected. The network operator shall neither collect the personal information unrelated to the services they provide, nor collect or use personal information in violation of the provisions of laws and administrative regulations or the agreements with such persons, and shall process the personal information they store in accordance with the provisions of laws and administrative regulations and agreements reached with such persons. The network operator shall not disclose, tamper with or destroy personal information that it has collected, or disclose such information to others without prior consent of the person whose personal information has been collected, unless such information has been processed to prevent a specific person from being identified and such information from being restored. Each individual is entitled to require a network operator to delete his or her personal information if he or she finds that collection and use of such information by such operator violate the laws, administrative regulations or the agreement by and between such operator and such individual, and is entitled to require any network operator to make corrections if he or she finds errors in such information collected and stored by such operator. Such operator shall take measures to delete the information or correct the error. Any individual or organization may neither acquire personal information by stealing or through other illegal ways, nor illegally sell or provide personal information to others.

In July 2018, the National Health Commission promulgated the Measures on Health and Medical Big Data, which set out the guidelines and principles for standards management, security management and services management of health and medical big data. Pursuant to the Measures on Health and Medical Big Data, the healthcare data produced by the PRC citizens in the PRC can be managed and used by the state for the purposes of the state strategic safety and the benefits of the life and health of the PRC citizens, provided that the state guarantees the PRC citizens their respective right of information, usage and personal privacy.

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 their importance, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, shall be treated with higher level of protection. Specifically, the Data Security Law provides that processors of important data shall appoint a "data security officer" and a "management department" to take charge of data security. In addition, such processor shall evaluate the risk of its data activities periodically and file assessment reports with relevant regulatory authorities. Since the Data Security Law is relatively new, uncertainties still exist in relation to its interpretation and implementation.

In July 2021, the Cyberspace Administration of China (the "CAC") published a draft revision to the existing Cybersecurity Review Measures for public comment (the "Revised Draft CAC Measures"). In January 2022, the CAC, the National Development and Reform Commission (the "NDRC") and several other administrations jointly released the amended Cybersecurity Review Measures (the "Revised CAC Measures"), which became effective in February 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. Since the Revised Cybersecurity Review Measures are relatively new, uncertainties remain in relation to the implementation and interpretation of the Revised Cybersecurity Review Measures.

In November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft 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 Management Regulations reiterate that data processors shall be subject to cybersecurity review if they process personal information of more than one million persons and aiming to list on foreign stock markets, or the data processing activities influence or may influence national security. The Draft 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 Management Regulations was released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty.

Additional regulations, guidelines, and measures relating to data privacy and data protection are expected to be adopted, including the Measures for Data Security Management (Draft for Comment), published in 2019, the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, and the Measures on Security Assessment of Outbound Data Transfers (Draft for Comment), published in October 2021, each of which indicates a trend of more stringent compliance requirements, and, if adopted or effective, would require security assessment and review before transferring personal health information out of China.

Good pharmacovigilance practice

The latest Drug Administration Law provides that China 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 Good Laboratories Practice for Nonclinical Laboratory Studies in 2003 (the "GLP 2003"), and the GLP 2003 was then abolished and replaced by the Good Laboratories Practice for Nonclinical Laboratory Studies promulgated in 2017 (the "GLP 2017"). In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratories Practice for Nonclinical Laboratory Studies, 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 Laboratories Practice for Nonclinical Laboratory Studies, 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.

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 Technology Transfer Registration of Drugs 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 candidates 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 PRC 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 2-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 PRC Drug Administration Law and the Implementing Measures of the PRC 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 PRC 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 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 GLP regulations;
- submission to the FDA of an 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") 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 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 API and finished drug product are produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP");
- 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 adverse events 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 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. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events 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 provides authorization for whether or not 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 cGMP 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 cGMP 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 cGMP. 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 cGMP. 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 cGMP 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 cGMP, 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: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) 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 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 December 2021, the NHSA and the Chinese Ministry of Human Resources and Social Security released the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance ("2021 NRDL"), and 74 new drugs were admitted to the 2021 NRDL. Previous updates to the NRDL occurred in 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 ("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 ("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 and 2021. In 2021, 74 new drugs were added to the 2021 NRDL, among which the average price reduction of 67 drugs is 61.71%.

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 catalogue 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 by the General Office of the State Council 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 for 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 by 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 Drug, 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 to sixth round of the national centralized volume-based procurement and tender program published on August 24, 2020, February 8, 2021, June 28, 2021, and November 30, 2021 respectively, show similar levels of reduction in average price reduction of around 50%.

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 Catalogue (Version 1.0). In July 2020, the NHSA issued the Payment 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 Main Tasks of Strengthening the Reform of Healthcare System for each year of 2017, 2018, 2019, and 2021. 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. 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: (1) to deepen the reform of public hospitals, (2) to accelerate the development of a graded diagnosis and treatment system, (3) to consolidate and improve the universal medical insurance system, (4) to guarantee drug supply, (5) to establish and improve a comprehensive supervision system, (6) to cultivate talented health-care practitioners, (7) to stabilize and perfect the basic public health service equalization system, (8) to advance the construction of health information technology, (9) to accelerate the development of the health services industry generally, and (10) 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 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).

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 Federal Food, Drug, and Cosmetic Act, 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 Company Law of the People's Republic of China (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. 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 draft amendment to the PRC Company Law for comment (the "Draft PRC Company Law Amendment"). The Draft PRC Company Law Amendment has made roughly 70 substantive changes on the basis of the 13 chapters and 218 articles of the current PRC Company Law. The Draft PRC Company Law Amendment would, if and when came into effect, (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.

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 ("MOFCOM") and 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 of the People's Republic of China (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 on Wholly Foreign-Owned Enterprises of the People's Republic of China, the Law on Sino-foreign Equity Joint Ventures of the People's Republic of China and the Law on Sino-foreign Contractual Joint Ventures of the People's Republic of China 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: 1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; 2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in China alone or jointly with other investors; 4) 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 Sino-Foreign Equity Joint Venture Enterprise Law, Provisional Regulations on the Duration of Sino- Foreign Equity Joint Venture Enterprise, the Regulations on Implementing the Wholly Foreign-Owned Enterprise Law and the Regulations on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law 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 Investment 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 amended People's Republic of China Anti-Unfair Competition Law, commercial bribery is prohibited. Both the bribe giver and bribe recipient are subject to civil and criminal liability. 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 ("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 ("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 ("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 may be subject to civil or criminal liability and have their business licenses revoked.

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. According to which, 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 ("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 if there is no patent term extension involved, 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, inventiveness, and deficiencies in patent application. In China, a patent must have novelty, inventiveness 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 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 offences 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, and punitive damages for intentional infringement are set to be one to five times of the damages calculated as above. 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.

The most recent amendment to the Patent Law of the People's Republic of China (the "PRC Patent Law"), which was promulgated by the SCNPC in October 2020 and became effective in June 2021, 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.

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 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 People's Republic of China Anti-Unfair Competition Law promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019, 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: (1) 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; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) 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 (4) 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.

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 the 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 March 7, 2022, we had ten trademark applications pending in Mainland China, four trademarks registered in Hong Kong, two trademarks registered in Singapore and two trademark applications pending in Singapore, two trademark applications pending in the United States, four trademark applications pending in Taiwan, four trademark applications registered in Macau, two trademark applications pending in South Korea, one trademark application pending in Thailand, two trademark applications in Cambodia, two trademark applications in Indonesia and two trademark applications 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.

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 Law of Manufacturing Safety 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 Administrative Measures Governing the Production Quality of Pharmaceutical Products 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 ("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 ("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 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: (1) 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 (2) 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 December 24, 2021, the CSRC promulgated the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Draft Administration Provisions"), and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Draft Filing Measures") to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

The Draft Administration Provisions 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 Draft Filing 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, and its main places of business operation are located in China or main business activities are conducted in China.

Under the Draft Administration Provisions and the Draft Filing Measures, 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, issue a filing notice thereof 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, after the issuer completes the overseas initial public offering and listing, it shall file the status of overseas offering and listing as required by the CSRC.

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 constitute a threat to or 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, major assets, and core technologies, etc. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the CSRC and the competent authorities under the State Council shall impose a postponement or termination of the intended overseas offering and listing. The CSRC may cancel the corresponding filing if the intended overseas offering and listing application documents has been filed.

If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they would be warned and fined up to RMB10 million and even ordered to suspend relevant business or halt operation for rectification, revoke relevant business permits or business license in severe cases. The controlling shareholders, actual controllers, directors, supervisors, and senior management of such domestic companies would be warned and fined up to RMB5 million separately or in the aggregate.

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.

Except for the clinical supply agreement with QED with respect to the supply of infigratinib for clinical trials in China (and an addendum to such clinical supply agreement with respect to the supply of the commercial pack of infigratinib in connection with the early access program in Bo'ao), as well as the clinical supply agreement with MyoKardia with respect to the supply of mavacamten for clinical trials in China, we currently do not have any clinical or commercial supply contracts for our product candidates. We plan to enter into additional clinical and commercial supply contracts with our licensing partners, with whom we are in discussions for supply arrangements, and we believe that these contracts will be sufficient to accommodate our planned clinical trials of our current product candidates. However, 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, 2021, we had 107 full-time employees. Of these full-time employees, 48 employees are engaged in research and development activities and 59 are engaged in general and administrative activities. As of December 31, 2021, 22 employees were employed in the United States and 85 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"), 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.

China has implemented or will implement extensive data protection, privacy and information security rules and is considering a number of additional proposals relating to these subject areas. We face significant uncertainties and risks related to these laws, regulations and policies, some of which were only recently enacted, and the interpretation of these legal requirements by government regulators as applied to biopharmaceutical companies like us.

For example, 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 "personal data" or "important data" by government regulators. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized health data for clinical trials may be subject to the new national security legal regime, including the Data Security Law, the Cyber Security Law of the People's Republic of China (the "Cyber 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.

China's Data Security Law took effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. 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 the 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.

Additionally, 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 the network is free from interference, disruption or unauthorized access, and prevent network data 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 takes substantial time, effort and cost, and we may not be able to establish and maintain such systems as fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not adequately protect 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, can include foreign licensors, or share data stored in Mainland China with judicial and law enforcement authorities outside of Mainland China. 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.

The Cyberspace Administration of China (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."

On July 10, 2021, the CAC, published a draft revision to the existing Cybersecurity Review Measures for public comment (the "Revised Draft CAC Measures"), and, together with 12 other Chinese regulatory authorities, released the final version of the Revised Draft CAC Measures, (the "Revised CAC Measures"), on January 4, 2022, 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 November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft 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 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 if the data processing activities influence or may influence national security. The Draft 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 Management Regulations was released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty.

It is 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. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and the imposition of any such penalties on our business could cause a material adverse effect on our business, financial condition, results of operations, prospects and the trading price of our ADSs, and could lead to our delisting from the Nasdaq. As of the date of this Annual Report on Form 10-K, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor," or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. However, there remains uncertainty as to how the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, will be interpreted or implemented and whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Draft 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 Revised CAC Measures, the Draft Management Regulations or other laws and regulations related to privacy, data protection and information security.

Additionally, the National People's Congress of the People's Republic of China (the "National People's Congress") released the PIPL, which became effective on November 1, 2021. The PIPL provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The PIPL also provides that critical information infrastructure operators and personal information processing entities that process personal information meeting a volume threshold to be set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the PIPL contains proposals for significant fines for serious violations of up to RMB 50 million, or 5% of annual revenues from the prior year, and penalties, including that companies found to have violated the PIPL may 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.

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 and the PIPL could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings 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, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law 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. 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 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 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 December 24, 2021, the CSRC promulgated the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (collectively, the "Draft Overseas Listing Rules"), which, among others, require certain companies to fulfill a filing procedure in respect of its offering and listing in the stock markets outside of China if such companies meet the criteria set forth in the Draft Overseas Listing Rules. As the Draft Overseas Listing Rules were released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty. For more details, see "Regulation – Chinese Regulations on Securities Offering and Listing outside of China."

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 offering our equity securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. However, there remains significant uncertainty as to the enactment, interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities. 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 for issuing our equity securities to foreign investors, it is uncertain whether we will be able to and how long it would take for us to obtain the approval or complete the filing or other procedure, 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 approval(s), filing or other procedure(s), we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operations in China, delay or restrict the repatriation of funds into 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. In addition, if the CSRC or other regulatory authorities later promulgate new rules requiring that we obtain their approvals or complete filing or other procedures for any future public offerings, we may be unable to obtain a waiver of such requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such a requirement 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 State Administration for Market Regulation ("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"), the Accelerating Holding Foreign Companies Accountable Act (the "AHFCA Act") (if enacted) or the America COMPETES Act (if enacted) 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. 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 three consecutive years, and this ultimately could result in our ADSs being delisted.

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 February 4, 2022, the U.S. House of Representatives passed the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (COMPETES) Act of 2022 (the "America COMPETES Act"), which similarly would amend the HFCA Act to shorten the three-year period to two years. The America COMPETES Act, however, includes a broader range of legislation than the AHFCA Act in response to the U.S. Innovation and Competition Act passed by the U.S. Senate in 2021. The U.S. House of Representatives and the U.S. Senate will need to agree on amendments to these respective bills to allow the legislature to pass their amended bills before the President can sign the bill into law. It is unclear if or when these bills will be signed into law.

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, 2021 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.

While we understand that there has been dialogue among the CSRC, the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in China, there can be no assurance that we will be able to comply with requirements imposed by U.S. regulators or Nasdaq. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules adopted by the SEC under the HFCA Act (or, if enacted into law, the AHFCA Act and/or America COMPETES Act) as we will not know whether the SEC identifies us as a Commission-Identified Issuer until the SEC reviews this Annual Report on Form 10-K. 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.

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. 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.

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 RMB100,000 and RMB500,000. 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 State Administration of Foreign Exchange ("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 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 did not record any government grants or subsidies related to financial incentives given by the Chinese government in either of the years ended December 31, 2021 or 2020, but we currently expect to receive certain financial grants in 2022 from the Science and Technology Commission of Shanghai Municipality pursuant to a technology project agreement for selected research projects. We cannot assure you that we will receive these government incentives, or of the continued availability of any government incentives we do receive. 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 Company Law of the People's Republic of China 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 these rules and notices are relatively new and 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.

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, 2021 and 2020, our net losses were $196.3 million and $139.6 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 $164.0 million and $98.1 million for the years ended December 31, 2021 and 2020, 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, 2021 will enable us to fund our operating expenses and capital expenditure requirements through at least the next 24 months. 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.

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 cancer and other solid tumors. With respect to certain of our product candidates, including NBTXR3, infigratinib, LYR-210, omilancor, and sisunatovir, we plan to join our partners' planned and ongoing Phase 3 global clinical trials 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 change their Phase 3 clinical trial strategies for a product candidate or indication for which we had anticipated joining their Phase 3 global clinical trial, 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 serious adverse events, 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. Incyte Corporation and its partner Innovent Biologics, Inc. are developing pemigatinib, an FGFR inhibitor approved for the treatment of second line CCA in the United States, for the treatment of both frontline and second line CCA in China, and Amgen and its partner Zai Lab are developing bemarituzumab (FPA144) for tumors that overexpress FGFR2b, including gastric and gastroesophageal junction cancers. There are also several programs in development targeting SHP2, including clinical programs run by Novartis AG, Revolution Medicines, Inc. and its partner Sanofi, Relay Therapeutics, Inc. and its partner Genentech, Inc. and Jacobio Pharmaceuticals Co. Ltd. and its partner AbbVie Inc. Programs in development for RSV include those run by ArkBio and Johnson and Johnson, Inc. There are a number of biologics that are approved or currently in development for the treatment of IBD, including therapeutics developed by AbbVie Inc. and Eli Lilly and Company.

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.

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. 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 Human Genetic Resources Administration of China ("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; 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, we expect to design our clinical trials to 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, in our planned Phase 3 clinical trial of infigratinib as part of the PROOF trial led by QED, we plan to focus on enrolling patients who have advanced, metastatic or inoperable CCA with FGFR2 gene fusions, which limits the total size of the patient population available for such trial and may cause delays in the clinical trial. In addition, our or our partners' ability to enroll patients has been and may be further delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point. 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, 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 CCA, HCM and RSV.

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 adverse events 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 adverse events 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 adverse events 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 adverse events 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 adverse events 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 (1) the review and approval procedures for break-through therapeutic drugs; (2) the review and approval procedures for drug conditional approval application; (3) the priority review procedures for drug marketing authorization approval; and (4) 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 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 in 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.

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, Yi Larson, our Chief Financial Officer, and Debra Yu, M.D., our President and Chief Strategy 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 current 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 also conducting a PK trial of mavacamten 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 human genetic resources ("HGR");
- 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 a New Drug Application ("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 Practice regulations ("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 pseudonymized health data for clinical trials in compliance with local regulations. This data could be deemed as personal data or important data. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized 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. Certain draft regulations, including the Measures for Security Assessment for Cross-border Transfer of Personal Information and Important Data (Draft for Comment), published in 2017, and the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, have been proposed by the Chinese government that specify the procedures and stipulate more detailed compliance requirements relating to such assessment, and in certain circumstances, government approval, prior to the transmission of such information and data outside of China.

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.

In October 2021, the CAC published the Measures on Security Assessment of Outbound Data Transfers (Draft for Comment) (the "Draft Measures"). The Draft Measures are enacted in accordance with the Cyber Security Law, the Data Security Law and the PIPL. Under the Draft 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) where the outbound data is personal information and important data collected and generated by critical information infrastructure operators; (ii) where the outbound data contains important data; (iii) where a personal information processor that has processed personal information of more than one million people transfers personal information overseas; and (iv) where the personal information of more than 100,000 people or sensitive personal information of more than 10,000 people is transferred overseas accumulatively; or (v) other circumstances under which a security assessment of outbound data transfers is required as prescribed by the CAC.

In November 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft 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 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 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 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 Regulation on the Administration of Human Genetic Resources (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 National Healthcare Security Administration ("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 catalogues 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 December 3, 2021, the NHSA published the 2021 NRDL, which included 74 additional drugs, among which 67 drugs with an exclusive source of supply were added to the 2021 NRDL via price negotiation with drug companies, resulting in an average price reduction of 61.71%.

We expect that most of our product candidates will be eligible for inclusion in the NRDL for the National Medical Insurance scheme, but the NHSA will likely expect that our products be in clinical use for some time before they are approved for inclusion. As a result, 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 desirable. 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 catalogues, 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 catalogues.

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"), sisunatovir from ReViral Ltd. ("ReViral"), and omilancor and NX-13 from Landos BioPharma, Inc. ("Landos"). 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, ReViral, Tarsus and Landos 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 ("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 18, 2022, Perceptive and its affiliates beneficially own 52.5% of our ordinary shares, based on the number of shares outstanding as of March 18, 2022. 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 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 cGMP 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 and 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 expect to source our clinical and 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 cGMP and China GMP standards. Any failure by the third-party manufacturers retained by us or our licensing partners to comply with cGMP 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, sisunatovir from ReViral, and omilancor and NX-13 from Landos. 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 13 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. 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 March 7, 2022, we had ten trademark applications pending in Mainland China, four trademarks registered in Hong Kong, two trademarks registered in Singapore and two trademark applications pending in Singapore, two trademark applications pending in the United States, four trademark applications pending in Taiwan, four trademarks registered in Macau, two trademark applications pending in South Korea, one trademark application pending in Thailand, two trademark applications in Cambodia, two trademark applications in Indonesia and two trademark applications 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 $1.07 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, we are required to file a report by our management on our internal control over financial reporting starting with our second Annual Report on Form 10-K. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. To prepare for eventual compliance 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 will need to continue 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. Despite our efforts, we might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will 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.

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.

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 the early months of 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 18, 2022, 107,275,458 ordinary shares were outstanding, of which 20,906,116 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. The remaining ordinary shares will be available for sale, subject to restrictions as applicable under Rule 144 under the Securities Act, beginning April 29, 2022, the expiration date of the 180-day lock-up arrangements entered into by our executive officers, directors and shareholders in connection with our initial public offering. There are certain exceptions to these lock-up arrangements. Any major disposal of our ordinary shares and/or ADSs by any of them upon expiration of the relevant lock-up periods (or the perception that these disposals may occur upon the expiration of the lock-up period) 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 a Form S-8 registering the issuance of approximately 24.9 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.

If we are classified as a passive foreign investment company, U.S. investors could be subject to adverse U.S. federal income tax consequences.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the average quarterly value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a "passive foreign investment company" ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are a PFIC for any taxable year during which a shareholder that is a U.S. person for U.S. federal income tax purposes (a "U.S. Holder") holds our ADSs or ordinary shares, such U.S. Holder may suffer adverse U.S. federal income tax consequences, including having gains realized on the sale of our ADSs or ordinary shares treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on our ADSs or ordinary shares by individuals who are U.S. Holders, having interest charges apply to distributions by us and the proceeds of sales of our ADSs or ordinary shares, and having additional reporting requirements. Additionally, if we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to such U.S. Holder for all succeeding taxable years during which the U.S. Holder holds our ADSs or ordinary shares (unless the investor timely makes a valid "deemed sale" election), even if we cease to meet the threshold requirements for PFIC status. A mark-to-market election may be available with respect our ADSs or ordinary shares, which would result in U.S. federal income tax consequences to holders of our ADSs or ordinary shares that are different from those described above.

Whether we are a PFIC for any taxable year is a factual determination made on an annual basis applying principles, methodologies and legal rules that in some circumstances are unclear and subject to varying interpretation. For instance, whether we are a PFIC for any taxable year depends on the composition and nature of our income and the composition, nature and value of our assets for the relevant taxable year. We do not believe we were a PFIC for the taxable year ended December 31, 2021. However, it is uncertain whether we will be a PFIC for our taxable year ending December 31, 2022 or future taxable years because the determination of whether a corporation will be a PFIC for any taxable year is a fact-intensive determination subject to various uncertainties that generally can only be made after the close of such taxable year. Because we hold, a substantial amount of passive assets, including cash, and because the value of our assets for purposes of the PFIC rules (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, and by how, and how quickly, we use our cash, we cannot give any assurance that we will not be a PFIC for our taxable year ending December 31, 2022 or any future taxable years. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the U.S. Internal Revenue Service (the "IRS") will agree with our determination and that the IRS would not successfully challenge our position.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, whether or not such U.S. Holder makes a timely "qualified electing fund" or mark-to-market election may affect the U.S. federal income tax consequences to such U.S. Holder with respect to the acquisition, ownership and disposition of our ADSs or ordinary shares. Shareholders should consult their own tax advisors regarding all aspects of the application of the PFIC rules 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, 2020 and 2021. In addition, we believe that certain of our subsidiaries were CFCs for the taxable years ended December 31, 2020 and 2021. We believe we will likely be a CFC for the taxable year ending December 31, 2022. 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, 2021, we had U.S. federal net operating losses ("NOLs") of approximately $11.2 million that do not expire. We also had foreign NOLs of approximately $20.1 million, which if not utilized, generally begin to expire in 2025. These NOLs could expire unused and be unavailable to offset future income tax liabilities. Certain of our subsidiaries may not generate U.S. taxable income in the future, in which case their NOLs will expire unused. 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, 2021. 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. The Biden Administration has proposed significant changes to the existing U.S. tax rules, and there are a number of proposals in Congress that would similarly modify the existing U.S. tax rules. The likelihood of any such legislation being enacted is uncertain but could adversely impact 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: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) 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 (5) 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, 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 (such as local resurgences and related lockdowns in certain locations in China, including locations in which we are conducting clinical trials), which could cause business disruptions in the future. 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. 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, in December 2019, the COVID-19 pandemic began to impact the population in China, and since January 2020, the COVID-19 pandemic has spread around the world. COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, lockdowns, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including limiting non-essential travel. These measures could negatively affect our business. For instance, if all employees are required to temporarily work remotely as a result of local government mandates, company policy updates, or otherwise, absenteeism or employee turnover could increase, or we may experience disruptions to our operations or increased risk of a cybersecurity incident.

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 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 operate. To the extent we or any of the third parties with which we engage or on which we rely experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and results of operations.

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, Building 5, Enterprise World, 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 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 18, 2022, we had approximately 31 holders of record of our ordinary shares and one holder of record of our 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 and sold 52,947 Series A Preferred Shares at a purchase price of $56.66 per share, for an aggregate amount of approximately $3.0 million, to AEG 2021 TRUST, whose trustee and beneficiary is Tassos Gianakakos, a director of the Company. These Series A Preferred Shares converted to 309,623 of our ordinary shares in connection with the completion of our initial public offering.

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.

On October 5, 2021, QED exercised its option to convert the QED Warrants that were granted in 2019. 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 September 2021, a former employee exercised certain of his vested options in accordance with their terms for 1,309,907 of our ordinary shares and in December 2021 a current member of our board of directors exercised certain of his vested options in accordance with their terms for 36,548 of our ordinary shares.

Grants of share options and restricted share units

During the year ended December 31, 2021, we granted options to purchase an aggregate of 10,098,677 ordinary shares to employees, senior management and non-employee directors at exercise prices ranging from $6.16 to $16.00 per share and 626,459 RSUs to employees. The issuances of these securities were exempt pursuant to Rule 701, as transactions pursuant to a compensatory benefit plan, or Section 4(a)(2) of the Securities Act for transactions by an issuer not involving a public offering or Regulation S under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information. On November 3, 2021, we filed a registration statement on Form S-8 under the Securities Act to register all of our ordinary shares subject to outstanding options and RSUs and all of our ordinary shares otherwise issuable pursuant to our equity compensation plans.

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. Goldman Sachs & Co. LLC, Jefferies LLC, and BofA Securities, Inc. acted as joint lead book-running managers and Raymond James & Associates, Inc. acted as a lead manager for the offering.

Our initial public offering closed on November 3, 2021. In connection with the initial public offering, we granted the underwriters a 30-day option to purchase an additional 3,046,875 ADSs representing 3,046,875 ordinary shares. On December 1, 2021, pursuant to the partial exercise by the underwriters of such option, we issued an additional 593,616 ADSs representing 593,616 of our ordinary shares. We received gross proceeds of $334.5 million in connection with the initial public offering and subsequent exercise of the underwriters' option and aggregate net proceeds of $304.8 million after deducting underwriting discounts, commissions and other offering expenses. In connection with our initial public offering, no payments were made by us to directors, officers or persons owning ten percent or more of our ordinary shares or to their associates or to our affiliates. 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 (1) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (2) 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.

Our ADSs are listed on the Nasdaq Global Market, which is an established securities market in the United States. IRS guidance indicates that the ADSs will be readily tradable for these purposes.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a Chinese resident enterprise under the EIT Law (see "─Material Chinese Taxation" above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-China Tax Treaty, and if we were eligible for such benefits, dividends paid on the ADSs or ordinary shares, regardless of whether the ADSs or ordinary shares are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of U.S. federal income taxation, subject to applicable limitations. 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. 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.

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: (1) 75% or more of our gross income consists of certain types of passive income (the Income Test), or (2) 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 do not believe we were a PFIC for the taxable year ended December 31, 2021. However, it is uncertain whether we will be a PFIC for our taxable year ending December 31, 2022 or future taxable years because the determination of whether a corporation will be a PFIC for any taxable year is a fact-intensive determination subject to various uncertainties that generally can only be made after the close of such 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, 2022 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 (1) 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 (2) 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.

Recently 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 global, science-driven biopharmaceutical company dedicated to developing and commercializing innovative medicines for patients with unmet medical needs, with an initial focus on in-licensing assets for Greater China and other Asian markets. We have assembled a pipeline of nine assets across five therapeutic areas, each with its own distinct value proposition and the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications.

Recent Business Highlights and Clinical Development Updates

Initial Public Offering

In November 2021, we completed an initial public offering ("IPO") of our ordinary shares through the sale and issuance of 20,312,500 American Depositary Shares ("ADSs"), at a public offering price of $16.00 per ADS. 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. 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.

Mavacamten

In November 2021, we initiated and completed enrollment and dosing in a pharmacokinetic ("PK") study of mavacamten in healthy volunteers.

In November 2021, our partner Bristol-Myers Squibb ("BMS") announced a Prescription Drug User Fee Act ("PDUFA") target action date of April 28, 2022 for its New Drug Application to the U.S. Food and Drug Administration ("FDA") for mavacamten for the treatment of patients with oHCM.

In November 2021, BMS presented data at the American Heart Association Scientific Sessions 2021 from the Phase 2 MAVERICK study demonstrating long-term efficacy and safety of mavacamten in patients with non-obstructive hypertrophic cardiomyopathy.

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 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, 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.

Infigratinib

In August 2021, we announced that we began treating patients in a Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 ("FGFR2") gene amplification and other advanced solid tumors with FGFR genomic alterations.

In December 2021, we announced that infigratinib has been 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 cholangiocarcinoma with a FGFR2 fusion or other rearrangement. The approval enables early commercial access to infigratinib in the Bo'ao Lecheng International Medical Tourism Pilot Zone based on the drug's approval in other global jurisdictions.

TP-03

In November 2021, our partner Tarsus Pharmaceuticals, Inc. ("Tarsus") presented data from two studies on the prevalence and impact of Demodex blepharitis ("DB") at the American Academy of Optometry 2021 Annual Meeting. Data from the Titan real-world prevalence study demonstrated that DB accounts for 69% of all blepharitis cases and that current management tools for this disease are largely ineffective. Data from the multi-center observational Atlas impact study demonstrated that DB is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients.

In February 2022, Tarsus announced that the second pivotal trial of TP-03 in DB, Saturn-2, has completed enrollment and that they expect to announce topline results in April 2022.

NBTXR3

In October 2021, our partner Nanobiotix S.A. ("Nanobiotix") presented data at the 2021 Annual Meeting of the American Society for Radiation Oncology. The first analysis of overall survival ("OS") and progression-free survival ("PFS") from the ongoing Phase 1 trial of NBTXR3 in elderly and frail locally advanced head and neck squamous cell carcinoma patients ineligible for cisplatin and intolerant to cetuximab (Study 102) demonstrated median OS of 18.1 months and median PFS of 10.6 months in the evaluable population (n=41) from the dose expansion part of the study. NBTXR3 administration was feasible and well-tolerated overall. A total of eight Grade 3-4 NBTXR3-related adverse events ("AEs") were observed in eight patients. Of these AEs related to NBTXR3, five serious adverse events ("SAEs") were observed including dysphagia, sepsis, soft tissue necrosis, stomatitis, and tumor hemorrhage. Of the SAEs, one death from sepsis assessed by the investigator as possibly related to NBTXR3, radiotherapy, and cancer was observed.

In January 2022, Nanobiotix announced enrollment of the first patient in the NANORAY-312 global Phase 3 registrational study of NBTXR3 in head and neck cancer.

LYR-210

In October 2021, our partner Lyra Therapeutics, Inc. ("Lyra") presented new data from the Phase 2 LANTERN clinical trial of LYR-210 in surgically naïve chronic rhinosinusitis patients who had failed previous medical management at the 67th Annual Meeting of the American Rhinologic Society ("ARS"). The data presented at ARS demonstrated that 24 weeks after LYR-210 removal, 50% of treated patients continued to experience durable symptom improvement. LYR-210 continued to show strong safety during the 24-week follow up period with no increased incidence of treatment-related AEs.

In January 2022, 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 and that it plans to initiate ENLIGHTEN II, the second Phase 3 study by mid-year 2022.

Omilancor

In November 2021, our partner Landos BioPharma, Inc. ("Landos") announced that prior to initiating a pivotal Phase 3 study, the company plans to leverage the results of the prior Phase 2 study of omilancor in mild-to-moderate ulcerative colitis ("UC") patients to design and initiate a Phase 2b study in 2022. The Phase 2b study is expected to provide additional data to inform the pivotal Phase 3 study design. Accordingly, we are evaluating our clinical development strategy within our territories.

In October 2021, Landos presented positive translational data from the Phase 2 trial of omilancor in mild-to-moderate UC at United European Gastroenterology Week. Patients remaining on omilancor after the induction phase of the trial maintained low Mayo scores, an assessment of disease severity in UC, and nearly 90% of patients achieved remission thresholds in stool frequency and rectal bleeding after 36 weeks of open-label treatment.

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 (such as current resurgences in certain locations in China, including locations in which we are conducting clinical trials), which have caused and could further cause business disruptions in the future.

Efforts to contain the spread of the COVID-19 pandemic in the United States (including in New Jersey, where our U.S. headquarters is located) have included quarantines, shelter-in-place orders and various other government restrictions in order to control the spread of this virus.

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, 2021	Year Ended December 31, 2020
Research and development expenses (in thousands):		
Licensing fees	$ 136,915	$ 114,375
Employee related expense	7,601	3,003
CRO costs	11,117	1,187
Other costs	3,059	2,320
Total	$ 158,692	$ 120,885

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 $136.9 million and $114.4 million, for the years ended December 31, 2021 and 2020, respectively.

The following table sets forth a breakdown of licensing fees by program for the years indicated:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Licensing fees (in thousands):		
Mavacamten	$ —	$ 106,375
BBP-398	8,500	8,000
Sisunatovir	14,000	—
TP-03	64,415	—
Omilancor and NX-13	18,000	—
NBTXR3	20,000	—
LYR-210	12,000	—
Total	$ 136,915	$ 114,375

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 (expense) income, net

Interest (expense) income, net consists of interest expense from the payment made upon reaching the financing milestone under the exclusive license agreement with MyoKardia ("the MyoKardia Agreement"), offset by interest income received on our cash balances.

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 and bank fees incurred on our cash balances.

Income taxes

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 of December 31, 2021, we had U.S. federal net operating losses ("NOLs") of approximately $11.2 million, which are available to reduce future taxable income. U.S. federal NOLs can be carried forward indefinitely. Additionally, we carried forward foreign NOLs of approximately $20.1 million, some of which will begin to expire in 2025. Our carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

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 $9.6 million was recorded as of December 31, 2021.

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%). Tax losses incurred 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. Payments of dividend 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 withholding tax.

Results of operations

Comparison of the years ended December 31, 2021 and December 31, 2020

The following table sets forth a summary of our consolidated results of operations for the periods indicated.

	Year ended December 31, 2021	Year ended December 31, 2020
Operating expenses (in thousands):		
Research and development	$ 158,692	$ 120,885
General and administrative	36,878	13,984
Total operating expenses	195,570	134,869
Loss from operations	(195,570)	(134,869)
Other income (expense):		
Interest income (expense), net	243	(4,854)
Other (expense) income, net	(455)	123
Net loss before income taxes	(195,782)	(139,600)
Income taxes	518	4
Net loss	$ (196,300)	$ (139,604)

Research and development expenses

Research and development expenses increased by $37.8 million from $120.9 million for the year ended December 31, 2020 to $158.7 million for the year ended December 31, 2021. 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 our development and license agreement with Tarsus (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 our license and collaboration agreement with Lyra (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 higher personnel-related expenses, including share-based compensation expense, as a result of increased employee headcount, development activities to support our clinical trials and professional fees.

For the year ended December 31, 2020, research and development cost was primarily attributable to (i) $72.7 million in upfront and milestone payments and $33.8 million of expenses related to the warrant issued in connection with the MyoKardia Agreement and (ii) the $8.0 million upfront payment related to the Navire Agreement.

General and administrative expenses

General and administrative expenses increased by $22.9 million from $14.0 million for the year ended December 31, 2020 to $36.9 million for the year ended December 30, 2021. The increase was primarily attributable to a $11.3 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount, a $8.9 million increase, primarily attributable to legal service costs, consulting costs and accounting services, and a $2.8 million increase related to other expenses.

Interest income (expense), net

Interest income (expense) decreased by $5.1 million from $(4.9) million for the year ended December 31, 2020 to $0.2 million for the year ended December 31, 2021. The decrease was primarily attributable to interest expense of $2.3 million in 2020 related to imputed interest related to the achievement of the financing milestone under the MyoKardia Agreement that did not exist in 2021 and $2.5 million interest expense related to the conversion in 2020 of the $15.0 million convertible promissory notes due June 29, 2021 issued to Perceptive (the "2020 Convertible Notes").

Other (expense) income, net

Other (expense) income, net decreased by $(0.6) million from $0.1 million for the year ended December 31, 2020 to $(0.5) million for the year ended December 31, 2021. The decrease was primarily attributable to unrealized loss on foreign currencies held in our China subsidiary, Shanghai LianBio Development Co., Ltd., unrealized foreign exchange loss from the remeasurement of our intercompany payables, and by bank fees incurred on our cash balances.

Income taxes

Our income tax expense was $0.5 million for the year ended December 31, 2021, resulting in an effective income tax rate of 0.27% for the year ended December 31, 2021, as compared to $0.0 million, or an effective income tax rate of 0.00%, for the same period in 2020. A reconciliation of the statutory federal income tax rate to the effective income tax rate for each period is included in "Note 12: 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, 2021, we had cash and cash equivalents and marketable securities of $383.2 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, 2021	Year Ended December 31, 2020
Net cash (used in) provided by (in thousands):		
Operating activities	$ (163,953)	$ (98,142)
Investing activities	(155,937)	(886)
Financing activities	313,273	309,753

Net cash used in operating activities

During the year ended December, 2021, operating activities used approximately $164.0 million of cash, 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.

During the year ended December 31, 2020, operating activities used approximately $98.1 million, primarily due to our net loss of $139.6 million, partially offset by non-cash items of $33.8 million related to the MyoKardia Warrant, $2.5 million related to the amortization of the beneficial conversion feature on the 2020 Convertible Notes, $5.2 million related to share-based compensation expense, and due to changes related to operating assets and liabilities.

Net cash used in investing activities

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.

During the year ended December 31, 2020, investing activities used approximately $0.9 million, primarily resulting from the purchases of property and equipment.

Net cash provided by financing activities

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.

During the year ended December 31, 2020, financing activities provided approximately $309.8 million in net proceeds, primarily resulting from the net proceeds from our issuance of Series A Preferred shares and the 2020 Convertible Notes.

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. Our share-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes-Merton option pricing model. This model utilizes 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 $8.7 million and $5.2 million for the years ended December 31, 2021 and December 31, 2020, 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., China 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.

As of December 31, 2021, we had U.S. federal NOLs of approximately $11.2 million, which are available to reduce future taxable income. U.S. federal NOLs can be carried forward indefinitely. Additionally, we carried forward foreign NOLs of approximately $20.1 million, some of which will begin to expire in 2025. Our carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

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, 2021.

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 risk, credit risk and cash flow interest rate risk.

Foreign currency exchange rate 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 State Administration of Foreign Exchange ("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.

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, 2021. At December 31, 2021, we held $383.2 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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 31, 2022

LianBio
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 228,182	$ 254,350
Marketable securities	155,067	—
Prepaid expenses and other current assets	10,354	2,396
Other receivable	6,044	20,000
Total current assets	399,647	276,746
Restricted cash, non-current	20,000	—
Property and equipment, net	1,882	822
Operating lease right-of-use assets	4,763	1,706
Other non-current assets	51	12
Total assets	$ 426,343	$ 279,286
Liabilities, Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,231	$ 4,329
Accrued expenses	9,976	998
Current portion of operating lease liabilities	1,125	539
Other current liabilities	760	360
Total current liabilities	15,092	6,226
Operating lease liabilities	3,709	1,341
Other liabilities	206	—
Nonrefundable research deposit	20,000	20,000
Total liabilities	39,007	27,567
Commitments and contingencies (Note 8)		
Redeemable convertible preferred shares, $0.0001 par value. No shares authorized, issued and outstanding at December 31, 2021; 10,971,231 shares authorized, issued, and outstanding as of December 31, 2020	—	349,789
Shareholders' equity (deficit):		
Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of December 31, 2021; 107,275,458 shares issued and outstanding at December 31, 2021; Authorized 2,859,742,435 shares as of December 31, 2020; 20,477,338 shares issued and outstanding at December 31, 2020	2	—
Additional paid-in capital	713,269	31,132
Accumulated other comprehensive income (loss)	526	(40)
Accumulated deficit	(360,235)	(163,935)
Total LianBio shareholders' equity (deficit)	353,562	(132,843)
Non-controlling interest	33,774	34,773
Total shareholders' equity (deficit)	387,336	(98,070)
Total liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)	$ 426,343	$ 279,286

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating expenses:		
Research and development	$ 158,692	$ 120,885
General and administrative	36,878	13,984
Total operating expenses	195,570	134,869
Loss from operations	(195,570)	(134,869)
Other income (expense):		
Interest income (expense), net	243	(4,854)
Other (expense) income, net	(455)	123
Net loss before income taxes	(195,782)	(139,600)
Income taxes	518	4
Net loss	(196,300)	(139,604)
Other comprehensive income (loss):		
Foreign currency translation income (loss), net of tax	512	(40)
Unrealized gain on marketable securities, net of tax	54	—
Comprehensive loss	$ (195,734)	$ (139,644)
Net loss per share attributable to ordinary shareholders, basic and diluted	$ (5.71)	$ (11.58)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	34,394,622	12,051,433

See accompanying notes to the consolidated financial statements

LianBio
Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholders' Equity (Deficit)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Shares		Ordinary 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						
Balance, December 31, 2019	5,500,000	$ 55,000	10,265,811	$ —	$ 8,516	$ —	$ (24,331)	$ (15,815)	$ 999	$ (14,816)
Share-based compensation expense	—	—	—	—	5,177	—	—	5,177	—	5,177
Issuance of Series A Preferred Shares at $56.66, net of issuance costs	5,471,231	294,789	—	—	—	—	—	—	—	—
Beneficial conversion feature on issuance of convertible notes	—	—	—	—	2,439	—	—	2,439	—	2,439
Conversion of convertible notes into ordinary shares	—	—	10,211,527	—	15,000	—	—	15,000	—	15,000
Warrants issued in license agreement	—	—	—	—	—	—	—	—	33,774	33,774
Net Loss	—	—	—	—	—	—	(139,604)	(139,604)	—	(139,604)
Comprehensive Loss	—	—	—	—	—	(40)	—	(40)	—	(40)
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

LianBio
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2021	Year Ended December 31, 2020
Net loss	$ (196,300)	$ (139,604)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash share consideration, issued in acquisition of IPR&D	9,415	33,774
Amortization of beneficial conversion feature	—	2,475
Non-cash operating lease (benefit) expense	(106)	169
Depreciation expense	525	76
Share based compensation expense	8,664	5,177
Amortization of discounts on investments, net	(23)	—
Unrealized foreign currency transaction losses (gain), net	87	(380)
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other current assets	(8,176)	(2,327)
Decrease (increase) in other receivable	14,216	(20,000)
Increase in other non-current assets	(40)	(7)
(Decrease) increase in accounts payable	(1,708)	4,164
Increase in accrued expenses	8,761	811
Increase in nonrefundable research deposit	—	20,000
Increase in other current liabilities	732	375
Decrease in related party payable	—	(2,845)
Net cash used in operating activities	(163,953)	(98,142)
Cash flows from investing activities:		
Purchase of property and equipment	(947)	(886)
Purchase of marketable securities	(154,990)	—
Net cash used for investing activities	(155,937)	(886)
Cash flows from financing activities:		
Proceeds from exercise of share options	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	310,000
Issuance costs related to redeemable convertible preferred shares	(60)	(15,211)
Issuance of convertible notes	—	15,000
Debt issuance costs related to convertible notes	—	(36)
Net cash provided by financing activities	313,273	309,753
Effect of exchange rate changes on cash and cash equivalents	449	325
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (6,168)	$ 211,050
Cash and cash equivalents, and restricted cash—beginning of period	254,350	43,300
Cash and cash equivalents, and restricted cash—ending of period	$ 248,182	$ 254,350
Cash and cash equivalents—end of period	$ 228,182	$ 254,350
Restricted cash—end of period	$ 20,000	$ —
Cash and cash equivalents, and restricted cash—ending of period	$ 248,182	$ 254,350
Supplemental disclosure of non-cash financing and investing activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 5,160	$ 1,375
Seller financing related to the MyoKardia license	—	35,000
Issuance costs in accounts payable and other accrued liabilities	1,496	1,152

Beneficial conversion feature related to convertible notes	—	2,439
Purchase of property and equipment in accounts payable	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 global, science-driven biopharmaceutical company dedicated to developing and commercializing innovative medicines for patients with unmet medical needs, with an initial focus on in-licensing assets for 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 are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy continue to be 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 $360.2 million as of December 31, 2021 and $163.9 million as of December 31, 2020. The Company's cash and cash equivalents and marketable securities were $383.2 million and $254.4 million as of December 31, 2021 and December 31, 2020, 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 excludes the potential impact of convertible preferred shares, options to purchase ordinary shares, restricted share units and unexercised warrants, because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per ordinary share are the same.

(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, 2021 and December 31, 2020.

(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 will remain restricted until such time as the upfront payment is utilized for specified in-licensing and co-development activities or until the agreement terminates.

A summary of cash, cash equivalents and restricted cash is as follows:

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 228,182	$ 254,350
Restricted cash, non-current	20,000	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 248,182	$ 254,350

(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. 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 period ended December 31, 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, available-for-sale marketable securities and accounts receivable. 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.

The Company is subject to credit risk from its accounts receivable related to its product sales. The payment terms are predetermined and the Company evaluates the creditworthiness of each customer or distributor on a regular basis. The Company reserves all uninsured amounts billed directly to a patient until the time of cash receipt as collectability is not reasonably assured at the time the product is received. To date, the Company has not incurred any material credit losses.

(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' 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' 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, 2021, 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) Deferred Offering Costs

Costs directly related to the Company's IPO were deferred for expense recognition. These deferred offering costs are temporarily capitalized and consist of legal fees, accounting fees, and other applicable professional services. As of December 31, 2021 and December 31, 2020, $0.0 million and $1.1 million of these deferred offering costs are reported on the accompanying balance sheets within "prepaid expenses and other current assets." With the completion of the Company's IPO on November 3, 2021, these deferred offering costs were concurrently reclassified to additional paid in capital.

(S) 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.

(T) Other Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 enhances and simplifies multiple aspects of the income tax accounting guidance in ASC 740. The standard will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, with early adoption permitted. The guidance is generally effective as of January 1, 2021, with early adoption permitted. The Company adopted ASU 2019-12 in the first quarter of 2021 and the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which introduces a new accounting model known as Credit Expected Credit Losses ("CECL"). CECL requires earlier recognition of credit losses on financial assets, while also providing additional transparency about credit risk. The Company adopted ASU 2016-13 in the third quarter of 2021 and applied the guidance prospectively. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

(U) 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.

(V) Reclassification

Certain reclassifications of prior year information have been made to conform to the current year's presentation.

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. The QED License Agreement also required the Company to refund QED for costs incurred on the study through the execution date which was determined to be $2.8 million and was recorded as a related party payable as of December 31, 2019 on the consolidated balance sheet. 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).

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.

Navire License

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. As of December 31, 2021, the Company had recorded and paid the first development milestone of $8.5 million for IND acceptance in the PRC.

Pfizer Strategic Collaboration

In November 2020, the Company entered into a strategic collaboration agreement (the "Pfizer 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 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 as the services are performed. Additionally, as the upfront payment of the $20.0 million was received subsequent to December 31, 2020, the Company recognized a receivable for this amount on the consolidated balance sheet as of December 31, 2020. Upon receipt in 2021, the upfront payment was recorded as restricted cash within 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 Agreement terminates. Under the Pfizer 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.

ReViral License

In March 2021, the Company entered into an exclusive license agreement (the "ReViral License Agreement") with ReViral Ltd. ("ReViral"). 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 respiratory syncytial virus 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.

Tarsus License

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. 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 2021, the Company was notified that Tarsus had achieved certain development milestones. The Company paid $30.0 million to Tarsus during the twelve months ended December 31, 2021 as a result of the achievement of these milestones.

Landos License

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.

Nanobiotix License

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.

Lyra License

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.

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, 2021 and 2020:

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

As of December 31, 2020 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ —	$ —	$ —	$ —
Corporate debt securities	—	—	—	—
Government obligations	—	—	—	—
Total	$ —	$ —	$ —	$ —

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, 2021 are as follows:

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

As of December 31, 2020 (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	—	—	—	—	—	—
Total	$ —	$ —	$ —	$ —	$ —	$ —

Marketable securities on the balance sheet at December 31, 2021 and 2020 mature as follows:

	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

	December 31, 2020	
	Less than 12 Months	More Than 12 Months
Commercial paper	$ —	$ —
Corporate debt securities	—	—
Government obligations	—	—
Total Marketable securities	$ —	$ —

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, 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**

As of December 31, 2020, the Company's financial assets were all measured and recognized at a fair value of Level 1.

5. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2021	December 31, 2020
Leasehold improvements	$ 807	$ 693
Furniture and fixtures	65	7
Computer equipment and software	471	180
Construction in progress	1,145	18
	2,488	898
Accumulated depreciation	(606)	(76)
Total property and equipment, net	$ 1,882	$ 822

Total depreciation related to property and equipment for the years ended December 31, 2021 and 2020 was $0.5 million and $0.1 million, respectively.

6. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	December 31, 2021	December 31, 2020
Advance payments to suppliers and rent deposit	$ 1,499	$ 1,070
Prepaid insurance	7,378	74
Deferred costs	3	970
VAT receivable	1,176	261
Other prepaid expenses	298	21
Total prepaid expenses and other current assets	$ 10,354	$ 2,396

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2021	December 31, 2020
Employee compensation and related benefits	$ 2,309	$ 236
Professional fees	3,625	683
Consulting and contracted research	3,925	49
Other	117	30
Total accrued expenses	$ 9,976	$ 998

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 initial lease term ends on April 6, 2022 with an option to renew for one additional period of 24 months.

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 does not plan to 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.

On November 4, 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.

The components of total lease costs were as follows:

	December 31, 2021	December 31, 2020
Operating lease cost	$ 1,148	$ 425
Short-term lease cost	181	132
Total lease cost	$ 1,329	$ 557

Supplemental lease term and discount rate information related to leases was as follows:

	December 31, 2021	December 31, 2020
Weighted-average remaining lease terms—operating leases (years)	3.11	3.28
Weighted-average discount rate—operating leases	9.37 %	11.57 %

Supplemental cash flow information related to leases was as follows:

	December 31, 2021	December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,117	$ 274
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 5,160	$ 1,375

Commitments

As of December 31, 2021, future minimum lease payments, were as follows:

	Operating Leases
2022	$ 1,510
2023	1,862
2024	1,828
2025	399
Total	$ 5,599
Less imputed interest	(765)
Present value of lease liabilities	$ 4,834

(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, 2021, and December 31, 2020, 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 2019, 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, 2021, there were awards issued for approximately 9.7 million ordinary shares under the 2019 Plan and approximately 5.0 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.

In January 2020, the Company issued options to purchase 2,999,920 ordinary shares to senior management at an exercise price of $1.71 per share. During December 2020, the Company issued options to purchase an aggregate of 5,374,114 ordinary shares to employees, senior management and non-employee directors at an exercise price of $6.49 per share.

During the year ended December 31, 2021, the Company issued 7,426,136 options to purchase ordinary shares to employees, senior management and non-employee directors 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, 2021	Year Ended December 31, 2020
Expected Dividend Yield	— %	— %
Expected Volatility	60.00%—76.65%	60.00% —75.00%
Expected Term (years)	0.50—6.25	5.39—6.25
Risk Free Interest Rate	0.09%—1.36%	0.41%—1.73%
Exercise Price	$ 6.16—16.00	$ 1.71—6.49
Weighted Average grant date fair value per stock option	$ 6.44	$ 2.67

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, 2020	8,374,034	$ 4.78	9.62	$ 14,323
Granted	7,426,136	$ 10.48		
Exercised	(1,346,455)	$ 4.12		
Expired or forfeited	(3,075,938)	$ 5.97		
Outstanding at December 31, 2021	11,377,777	$ 8.25	9.19	$ 8,900
Vested or expected to vest at December 31, 2021	2,657,584	$ 2.92	8.24	$ 8,900
Exercisable at December 31, 2021	2,657,584	$ 2.92	8.24	$ 8,900

As of December 31, 2021, $49.8 million of total unrecognized expense related to non-vested share options is expected to be recognized over a weighted average period of 3.65 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

In May 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 (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	—	—	—	—
Granted	1,938,615	$ 6.90	9.37	
Vested	—	—		
Exercised	—	—		
Expired or forfeited	—	—		
Outstanding at December 31, 2021	1,938,615	$ 6.90	9.37	—
Non-vested options as of December 31, 2021	1,938,615	$ 6.90	9.37	—

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:

	Year Ended December 31, 2021
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, 2021, there was $7.7 million total unrecognized of compensation cost related to the performance share units.

In December 2021, 733,926 performance-based share units (“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 (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	—	—	0	—
Granted	733,926	$ 6.16	10.00	
Vested	—	—		
Exercised	—	—		
Expired or forfeited	—	—		
Outstanding at December 31, 2021	733,926	$ 6.16	10.00	—
Non-vested PSUs as of December 31, 2021	733,926	$ 6.16	10.00	—

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, 2021, there was $3.1 million of total unrecognized of compensation cost related to the PSUs.

Restricted Share Units

In December 2021, 479,673 restricted share units ("RSUs") were granted to certain employees. 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 2021:

	Numbers of nonvested RSUs	**Weighted average grant date fair value $**
Non-vested as of January 1, 2020	—	—
Granted	—	—
Vested	—	—
Non-vested as of December 31, 2020	—	—
Granted	479,673	6.16
Vested	—	—
Non-vested as of December 31, 2021	479,673	6.16

As of December 31, 2021, there was $3.0 million of total unrecognized compensation expense related to non-vested RSUs. The Company recorded compensation expense related to the RSUs of $0.0 million for the years ended December 31, 2021 and 2020, respectively.

In December 2021, 146,786 performance-based RSUs were granted to certain management. 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 2021:

	Numbers of nonvested restricted shares	Weighted average grant date fair value $
Non-vested as of January 1, 2020	—	—
Granted	—	—
Vested	—	—
Non-vested as of December 31, 2020	—	—
Granted	146,786	6.16
Vested	—	—
Non-vested as of December 31, 2021	146,786	6.16

As of December 31, 2021, 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 $0.0 million for the years ended December 31, 2021 and 2020, respectively.

10. Equity

Ordinary Shares

As of December 31, 2021, the Company was authorized to issue up to 2,923,900,005 ordinary shares, each with a par value of $0.000017100448.

As of December 31, 2020, the Company was authorized to issue up to 2,923,900,005 ordinary shares, of which 2,859,742,435 were authorized as ordinary shares with a par value of $0.000017100448, 5,500,000 were authorized Series Seed Preferred Shares with a par value of $0.0001, and 5,471,231 were authorized Series A Preferred Shares with a par value of $0.0001.

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.

The table below describes the preferred shares outstanding as of December 31, 2020.

	December 31, 2020					
	Shares Authorized	Shares Issued and Outstanding	Issue Price	Per Share Conversion Price	Liquidation Preference	Carrying Value
Series Seed Preferred Shares	5,500,000	5,500,000	$ 10.00	$ 1.72	$ 55,000	$ 55,000
Series A Preferred Shares	5,471,231	5,471,231	$ 56.66	$ 9.69	294,789	294,789
					$ 349,789	$ 349,789

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, 2021 and December 31, 2020, 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 and December 31, 2020, 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 and December 31, 2020, 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 August 2020, the Company issued a warrant exercisable for 170,000 ordinary shares of Lian Cardiovascular (the "MyoKardia Warrant"). The warrant is equity classified and was issued by Lian Cardiovascular, a wholly owned subsidiary of the Company, as partial consideration to MyoKardia for the MyoKardia License Agreement. The MyoKardia Warrant, if exercised, represents 17% of the fully diluted equity of Lian Cardiovascular. The MyoKardia Warrant is accounted for under ASC 718 Compensation – Stock Compensation and is fair valued on the grant date using the Black-Scholes Model based on the following weighted average assumptions:

Current Price of the Underlying Share	$	275.00
Exercise Price	$	275.00
Expected Term		10 years
Risk Free Interest Rate		0.60 %
Dividend Yield		0 %
Expected Volatility		70 %

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.

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, 2021, the MyoKardia Warrant was unexercised and no earnings were attributed to the non-controlling interest. As of December 31, 2020, the MyoKardia Warrant and the QED Warrants 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, 2021 and 2020, 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, 2021		Year Ended December 31, 2020
Numerator				
Net Loss attributable to ordinary shareholders	$	(196,300)	$	(139,604)
Denominator				
Weighted-average shares – basic and diluted		34,394,622		12,051,433
Net loss per ordinary share – basic and diluted	$	(5.71)	$	(11.58)

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, 2021	Year Ended December 31, 2020
Redeemable Convertible Preferred Shares	11,024,178	10,971,231
Convertible Notes	—	10,211,527
Employee Share Options	14,050,317	8,374,034
Non-vested restricted shares	626,459	—
QED Warrants	100,000	100,000
MyoKardia Warrant	170,000	170,000
Tarsus Warrants	125,000	—
Warrants in LianBio issued to QED and Tarsus	504,315	—

11. Convertible Notes

In June 2020, the Company issued $15.0 million aggregate principal non-interest bearing convertible promissory notes due June 29, 2021 (the "2020 Convertible Notes") to Perceptive. The 2020 Convertible Notes become convertible into the Company's ordinary shares at a conversion price of $1.47, at the option of the holder, upon the occurrence of the next preferred equity financing.

The fair value of the Company's ordinary shares as of the issuance date was $1.71 per share compared to the conversion rate of $1.47 per share and therefore the 2020 Convertible Notes contain a beneficial conversion feature ("BCF"). The Company measured the BCF at $2.4 million as the intrinsic value of the conversion option at the commitment date, representing the difference between the conversion price and the Company's share price on the commitment date. The BCF was recorded in additional paid-in capital as a discount to the carrying value of the 2020 Convertible Notes and amortized to interest expense using the effective interest method.

In October 2020, as part of the Series A preferred issuance, the 2020 Convertible Notes were subsequently converted into 10,211,527 ordinary shares, in accordance with their terms and at their conversion price of $1.47 per share, and following such conversion, the 2020 Convertible Notes were cancelled.

The Company accounted for the conversion of the 2020 Convertible Notes as interest expense of $1.6 million within interest expense in the consolidated statement of operations and comprehensive loss as of the year ended December 31, 2020. The interest expense upon conversion was calculated as the difference between (i) the 2020 Convertible Note principal amount of $15.0 million and (ii) the carrying value of the 2020 Convertible Notes, including the principal balance of the 2020 Convertible Notes of $13.4 million.

The Company recognized interest expense of $2.5 million related to the BCF during the year ended December 31, 2020, in connection with the 2020 Convertible Notes.

12. Income Taxes

The components of pre-tax income (loss) before income taxes are as follows:

	December 31, 2021	December 31, 2020
Domestic	$ (24,006)	$ (125,138)
Foreign	(171,776)	(14,462)
Total	$ (195,782)	$ (139,600)

The components of income tax expense are as follows:

	December 31, 2021	December 31, 2020
Federal	$ 461	$ —
State and local	57	4
Foreign	—	—
Total current tax expense	$ 518	$ 4

	December 31, 2021	December 31, 2020
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
Total deferred tax expense	$ —	$ —

	December 31, 2021	December 31, 2020
Total Provision	$ 518	$ 4

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, 2021	December 31, 2020
Income tax provision (benefit) at the statutory rate of 0%	— %	— %
State income tax (benefit), net of federal benefit	(0.03)%	— %
Foreign Rate Differential	3.25 %	21.06 %
License transfers	(15.85)%	— %
Other	(0.41)%	— %
Valuation Allowance	12.77 %	(21.06)%
Effective Tax Rate	(0.27)%	— %

The effective income tax rate is (0.27)% and 0.00% for the years ended December 31, 2021 and December 31, 2020, 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, 2021	December 31, 2020
Deferred tax assets:		
Accrued expenses	$ 568	$ 475
Net operating loss carryforwards	6,354	6,328
Share based compensation	1,773	1,327
Right of use liability	975	426
Intangible Assets	785	34,900
Other	87	—
Total Gross Deferred Tax Asset	10,542	43,456
Less: Valuation Allowance	(9,579)	(43,062)
Total Deferred Tax Asset	$ 963	$ 394
Deferred tax liabilities:		
Property and equipment	$ (37)	$ (11)
Right of use asset	(926)	(383)
Total gross deferred tax liabilities	(963)	(394)
Net deferred tax assets (liabilities)	$ —	$ —

The net change in the total valuation allowance resulted in a decrease of $33.5 million in 2021. 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, 2021. 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 $(9.6) million at December 31, 2021.

At December 31, 2021, the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $11.2 million which do not expire. The Company had foreign net operating loss carryforwards of $20.1 million which will begin to expire if unused in 2025.

Foreign undistributed earnings were considered permanently invested, therefore no provision for U.S. income taxes was accrued as of December 31, 2021 and 2020. The Company has not identified nor recorded any reserves for uncertain tax positions as of December 31, 2021 and December 31, 2020. As of December 31, 2021, 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").

13. Accumulated other comprehensive income (loss)

Other comprehensive income (loss) 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 income (loss) and the changes in accumulated other comprehensive items, by component, for the years ended December 31, 2021, and 2020, respectively.

	Unrealized Gains on Marketable Securities, net of tax	Foreign Currency Translation	Total Accumulated Other Comprehensive Items
Balance at December 31, 2019	$ —	$ —	$ —
Other comprehensive loss before reclassifications	—	(40)	(40)
Amounts reclassified from other comprehensive items	—	—	—
Other comprehensive loss	—	(40)	(40)
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

14. Subsequent Events

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 milestone payment due in April 2022.

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. Our 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, 2021, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

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 quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 23, 2022, the Company determined that it plans to hold its annual meeting of shareholders (the "Annual Meeting") on June 8, 2022. The record date for the determination of shareholders entitled to receive notice of, and to attend and vote at the Annual Meeting or any adjournment thereof shall be on or about April 12, 2022. Because the Company did not hold an annual meeting of shareholders in 2021, the Company is providing the due date for the submission of any qualified shareholder proposals or qualified shareholder nominations. The time, location and matters to be voted on at the Annual Meeting will be as set forth in the Company's proxy statement for the Annual Meeting, to be filed prior to the Annual Meeting with the Securities and Exchange Commission.

In accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), any shareholder proposal intended to be considered for inclusion in the Company's proxy materials for the Annual Meeting must comply with the requirements of Rule 14a-8 of the Exchange Act and be delivered to, or mailed to and received at, the Company's principal executive offices located at 103 Carnegie Center Drive, Suite 309, Princeton, New Jersey 08540, Attention: Investor Relations, on or before the close of business on April 20, 2022, which the Company believes is a reasonable time before it expects to begin to print and distribute its proxy materials for the Annual Meeting.

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, 2021.

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, 2021.

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, 2021.

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, 2021.

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, 2021.

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 Statements of Operations and Comprehensive Loss*
- *Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholders' Deficit*
- *Consolidated Statements 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.
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
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)
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)

Exhibit No.	Description
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
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)

Exhibit No.	Description
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
10.42*#	Form of Performance Based Restricted Share Unit Agreement
10.43*#	Form of Non-Performance Based Share Option Agreement (Employees)
10.44*#	Form of Performance Based Share Option Agreement
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)
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.
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 quarterly 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 would likely cause competitive harm to the registrant if disclosed.

# 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 31, 2022

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 31, 2022
/s/ Yi Larson **Yi Larson**	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2022
/s/ Konstantin Poukalov **Konstantin Poukalov**	Chairman of the Board	March 31, 2022
/s/ Adam Stone **Adam Stone**	Director	March 31, 2022
/s/ Neil Kumar **Neil Kumar**	Director	March 31, 2022
/s/ Tassos Gianakakos **Tassos Gianakakos**	Director	March 31, 2022
/s/ Susan Silbermann **Susan Silbermann**	Director	March 31, 2022
/s/ Jesse Wu **Jesse Wu**	Director	March 31, 2022

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.

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

SECOND AMENDMENT TO THE EXCLUSIVE LICENSE AGREEMENT

This SECOND AMENDMENT TO THE EXCLUSIVE LICENSE AGREEMENT (this "Amendment"), entered into as of December 14, 2021 (the "Amendment Effective Date"), is entered into by and between Lian Oncology Limited, a limited company incorporated under the laws of Hong Kong ("Lian Oncology HK"), LianBio Licensing, LLC, a Delaware limited liability company and an Affiliate of LianBio ("LianBio Licensing"), Lian Oncology, an exempted company organized under the laws of the Cayman Islands ("Lian Oncology") (together, "Licensee"), and QED Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware ("Company"). Licensee and Company are each referred to herein individually as a "Party", and collectively as the "Parties."

INTRODUCTION

WHEREAS, LianBio, an exempted company organized under the laws of the Cayman Islands ("LianBio") and Company entered into an Exclusive License Agreement, dated October 16, 2019 (the "Original License Agreement") for the Development, Manufacture, and Commercialization of Licensed Products in the Field in the Territory;

WHEREAS, LianBio and Company amended the License Agreement through an Amendment to the Exclusive License Agreement, dated September 26, 2020 (the "First Amendment", and together with the Original License Agreement, the "License Agreement");

WHEREAS, on October 11, 2020, LianBio novated to LianBio Licensing all of its rights, title, interest, liabilities, duties, and obligations under the License Agreement, Company agreed to such novation, and LianBio Licensing accepted such novation;

WHEREAS, on September 28, 2021, LianBio Licensing assigned to its Affiliate, Lian Oncology, all of its rights, title, interest, liabilities, duties, and obligations under the License Agreement, and Lian Oncology accepted such assignment;

WHEREAS, on September 28, 2021, LianBio Oncology assigned to its Affiliate, Lian Oncology HK, all of its rights, title, interest, liabilities, duties, and obligations under the License Agreement and Lian Oncology HK accepted such assignment;

WHEREAS, the Parties wish to amend the License Agreement to amend certain of Licensee's and Company's Development commitments under the License Agreement, as provided herein;

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:

1. Capitalized Terms. Any capitalized term used in this Amendment but not otherwise defined will have the meaning as defined in the License Agreement.

2. Development Diligence. Section 3.1(a) of the License Agreement is hereby amended and replaced in its entirety as follows:

Development Diligence. Licensee (directly, or through its Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and Commercialize the Licensed Products in the Field in the Territory in accordance with the Development Plan; provided, however, notwithstanding the foregoing and anything to the contrary in this Agreement or in the Development Plan, [***]. Notwithstanding the foregoing and anything to the contrary in this Agreement, Licensee shall not be deemed to be in breach of its obligations under this Section 3.1(a), (i) to the extent it is prevented from or delayed in using Commercially Reasonable Efforts to Develop the Licensed Product in the Field in the Territory as a result of the acts or omissions of Company, including Company's breach of any of its obligations under this Agreement or failure to timely perform its activities under the Development Plan, or (ii) for any failure by Licensee to enroll the number of patients in the [***] Trial (as defined below) specified in the Development Plan, provided that Licensee has used Commercially Reasonable Efforts to enroll patients in the [***] Trial (as defined below) after taking into consideration the Development Plan in good faith. Company (directly, or through its Affiliated Entities (to the extent applicable), Sublicensees and contractors) will use Commercially Reasonable Efforts to perform the activities assigned to it in the Development Plan.

3. Development Responsibilities. The last sentence of Section 3.1(b) of the License Agreement is hereby amended and replaced in its entirety as follows:

Subject to Section 3.1(a), Licensee 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 Plan), and will keep Company reasonably informed as to the progress of such activities.

4. Development Plan. The first sentence of Section 3.2 of the License Agreement is hereby amended and replaced in its entirety as follows:

Subject to Section 3.1(a), the Development of the Licensed Products in the Field in the Territory will be conducted by the Parties pursuant to the Development and regulatory plan and regulatory strategy (the "Development Plan"), an initial draft of which will be prepared by Licensee and delivered to the JSC within [***] after the Effective Date (or such later time as the Parties may mutually agree).

5. Specific Clinical Studies. Section 3.2(a) of the License Agreement is hereby amended and replaced in its entirety as follows:

Specific Clinical Studies. The Development Plan shall provide that, among other things, Licensee will (i) fund Clinical Studies in the Field in the Territory of the Licensed Product for [***] (such Clinical Studies, the "[***]Trials"); (ii) enroll [***] patients in the Territory in the [***] Trial (the "[***] Trial") (such patients, the "[***] Trial Patients"), provided that [***], ([***], the "[***] Patients"), (iii) initiate a proof-of-concept Phase 2 Study in the Territory of the Licensed Product use as a treatment for [***] in accordance with the Development Plan (the "[***] Phase 2 Trial"); and (iv) upon successful completion of the [***] Phase 2 Trial, subject to the approval of the JSC, conduct a registrational Clinical Study in the Territory of the Licensed Product for [***]. The Parties hereby acknowledge, confirm, and agree that Licensee has already reimbursed Company for [***].

6. Regulatory Filings and Approvals. The last sentence of Section 3.4(a) of the License Agreement is hereby amended and replaced in its entirety as follows:

Subject to the terms and conditions of this Agreement, Licensee will be responsible, at its sole cost and expense, for all regulatory activities for Licensed Products in the Field in the Territory, provided, that, Licensee will conduct such activities (and any and all regulatory activities delegated to Licensee in this Agreement) (1) in its own name, if Licensee is the legal and beneficial owner of the Regulatory Approvals for the Licensed Products in the Field in the Territory, or (2) as the express and authorized regulatory agent of record for Company in the Field in the Territory, if Company is the legal and beneficial owner of the Regulatory Approvals for the Licensed Products in the Field in the Territory, under which situation such actions will be taken on behalf of Company and for the benefit of Licensee in the Field in the Territory.

7. Development of the Licensed Products outside the Territory.

a) The second sentence of Section 3.6 is hereby amended and replaced in its entirety as follows:

Company will oversee, monitor and manage all interactions and communications with Regulatory Authorities with respect to such Licensed Products outside of the Territory.

b) The third sentence of Section 3.6 is hereby amended and replaced in its entirety as follows:

Company will have final decision-making authority regarding all regulatory activities outside of the Territory, including the labeling strategy and the content of Regulatory Filings with respect to such Licensed Products outside of the Territory.

8. Cost of [***] Patients. A new Section 3.8 is hereby added as follows:

Cost of [***] Patients in the Territory. Except as otherwise provided under this Agreement, Licensee will be responsible for all costs and expenses incurred by or on behalf of it or its Affiliates or Sublicensees in relation to patients enrolled by Licensee or its Affiliates or Sublicensees in the Clinical Studies of the Licensed Product in the Territory for [***] indications. Company will be responsible for any costs and expenses incurred by or on behalf of it or its Affiliates or Sublicensees to support or otherwise in relation to the Development of the Compound or Licensed Products in the Field [***]. Notwithstanding the foregoing, for costs and expenses incurred by or on behalf of Licensees or its Affiliates or Sublicensees in relation to patients enrolled by Licensee or its Affiliates or Sublicensees in the [***] Trial, the Parties agree to the following terms, [***]:

a) [***].

b) [***].

c) [***].

For purposes of this Section 3.8, "Out-of-Pocket Costs" means external costs paid by or on behalf of Licensee or its Affiliates or Sublicensees, including by a contract research organization engaged by or on behalf of Licensee or its Affiliates or Sublicensees, to a Third Party or QED or its Affiliates, including clinical trial expenses such as investigator payments, contract research organization management fees, third party monitoring costs and comparator drugs.

Notwithstanding the foregoing and anything to the contrary, (x) [***], and (y) [***] (i) [***] or (ii) [***], [***].

9. Decision-Making; Escalation to Senior Officers. The fourth sentence of Section 5.5 of the License Agreement is hereby amended and replaced in its entirety as follows:

If the Senior Officers fail to resolve such matter within [***] after the date on which matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then, [***].

10. Development Milestone Payment. The table in Section 6.1(c) of the License Agreement is hereby deleted and replaced in its entirety with the following table:

Development Milestone Event	Development Milestone Payment (in Dollars)
1. [***]	[***]
1. [***]	[***]
Total	[***]

11. Royalty Rate. The table in Section 6.2(a) of the License Agreement is hereby deleted and replaced in its entirety with the following table:

Portion of the Annual Net Sales of the Licensed Products	Royalty Rate
1. [***]	[***]
1. [***]	[***]
1. [***]	[***]

12. Dispute Resolution; Escalation. The last sentence of Section 13.1 is hereby amended and replaced in its entirety as follows:

> If the Senior Officers fail to resolve such matter within [***] after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then, subject to [***] under Section 5.5, either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 13.2.

13. No Other Changes. All other original terms and conditions of the License Agreement, except as specifically amended herein, shall remain in full force and effect. To the extent there is a conflict between this Amendment and the License Agreement, the provisions of this Amendment shall control.

14. Execution in Counterparts; Facsimile Signatures. This Amendment 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 Amendment Effective Date.

QED THERAPEUTICS, INC.

/s/ Michael Henderson

Name: Michael Henderson

Title: Chief Executive Officer

LIAN ONCOLOGY LIMITED

/s/ Raphael Ho

Name: Raphael Ho

Title: Authorized Signatory

LIANBIO LICENSING, LLC

/s/ Yizhe Wang

Name: Yizhe Wang

Title: Sole Manager

LIAN ONCOLOGY

/s/ Yizhe Wang

Name: Yizhe Wang

Title: Sole Director

ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT (this "Agreement") is made on December 15, 2021 (the "Effective Date") by and among LianBio, an exempted company organized and existing under the laws of the Cayman Islands ("LianBio") and LianBio Development (HK) Limited, a limited liability company organized under the laws of the Hong Kong Special Administrative Region ("LianBio Development"). Each of LianBio and LianBio Development is referred to herein as a "Party" and, collectively, as the "Parties".

INTRODUCTION

WHEREAS, LianBio and Pfizer Inc. ("Pfizer") are parties to a certain Strategic Collaboration Agreement dated November 17, 2020 (the "Collaboration Agreement"), attached hereto as Exhibit A, pursuant to which LianBio has agreed to enter into a strategic collaborative arrangement with Pfizer in the in-license, Development and Commercialization of the Products in the Territory (each of the capitalized terms in the preceding sentence is as defined under the Collaboration Agreement);

WHEREAS, LianBio Development is a wholly-owned subsidiary of LianBio; and

WHEREAS, pursuant to Section 11.4 of the Collaboration Agreement, (A) LianBio desires to assign and transfer, and effect an assignment of, the Collaboration Agreement to LianBio Development, including all of LianBio's rights and obligations thereunder, such that LianBio Development assumes all of LianBio's rights and obligations thereunder as if the original party thereto in place of LianBio, and (B) LianBio Development desires to accept and agree to such assignment.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Parties hereto agree as follows:

1. Assignment and Assumption.

1.1. Effective as of the Effective Date, LianBio hereby irrevocably assigns and transfers to LianBio Development all rights, licenses, title, interest, claims, demands, liabilities, duties, and obligations of LianBio under the Collaboration Agreement, including, without limitation, all rights, interests, claims, and demands recoverable in law or equity that LianBio has or may have under the Collaboration Agreement (a) for past, present, and future breaches by Pfizer of the Collaboration Agreement, (b) for past, present, and future tort or fraud claims, and (c) for compromising, settling, suing for, and collecting any profits and damages in connection with any of the foregoing, all of the foregoing to be held and enjoyed by LianBio Development, its successors and assigns or their legal representatives, as fully and entirely as if LianBio Development had at all times been a party to the Collaboration Agreement in place of LianBio (such assignment, the "Assignment").

1.2. LianBio Development hereby (a) irrevocably accepts the Assignment, and (b) (i) agrees to be bound by the Collaboration Agreement in accordance with its terms, (ii) assumes all liabilities, duties, and obligations of LianBio under the Collaboration Agreement, and (iii) acquires all rights, licenses, title, interest, claims, and demands of LianBio under the Collaboration Agreement, in each case, as if LianBio Development had at all times been a party to the Collaboration Agreement in place of LianBio.

1.3. LianBio Development shall assume all liability for any breach, non-observance or failure by LianBio to perform any performance, covenants, agreements, duties, and obligations expressed to be undertaken by LianBio under the Collaboration Agreement, irrespective of whether or not any such breach, non-observance or failure is known to any of the Parties.

2. Release. All actions prior to the Effective Date taken by LianBio in fulfillment of its obligations and duties under the Collaboration Agreement shall be considered to have discharged those parts of LianBio's obligations and duties under the Collaboration Agreement. All payments, obligations and duties of LianBio under the Collaboration Agreement due and payable or due to be performed on or prior to the Effective Date shall be paid or performed by LianBio Development in accordance with the terms of the Collaboration Agreement.

3. Further Assurances. Each Party shall 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 to effect the intent and purposes of this Agreement.

4. Interpretation; Successors. It is the clear intent of all Parties that the Assignment will be interpreted as an assignment and not a novation. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Collaboration Agreement. This Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns, and shall not be construed as conferring any rights on any other person.

5. Notice. The contact information of LianBio under Article 11.6 (Notices) of the Collaboration Agreement shall be deleted in its entirety and replaced with the following language:

LianBio Development:

LianBio Development (HK) Limited

Address:	RM 1901, 19/F Lee Garden One 33 Hysan Avenue, Causeway Bay HK
Attention:	Yizhe Wang, Chief Executive Officer
With copies to:	Ropes & Gray LLP 36F Park Place 1601 Nanjing Road West Shanghai, China 200040 Attention: Eric Wu Fax: 86-21-6157-5299 Email: Eric.Wu@ropesgray.com

6. Dispute Resolution; Governing Law. Sections 11.1, 11.2 and 11.3 of the Collaboration Agreement shall apply to this Agreement *mutatis mutandis*.

7. 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 6. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

8. Counterparts. 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 all 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 Page Intentionally Left Blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative on the Effective Date.

LIANBIO

By: /s/ Yizhe Wang

Name: Yizhe Wang

Title: Chief Executive Officer

[*Signature Page to Assignment and Assumption Agreement*]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative on the Effective Date.

LIANBIO DEVELOPMENT (HK) LIMITED

By: /s/ Wan Hing Raphael HO

Name: Wan Hing Raphael HO

Title: Director

[*Signature Page to Assignment and Assumption Agreement*]

Exhibit A

Collaboration Agreement

[Exhibit A to Assignment and Assumption Agreement]

Exhibit 10.37

Execution Version

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT (this "**Agreement**") is made and entered into as of September 14, 2021 by and between LianBio, LLC, a limited liability company organized under the laws of the State of Delaware, the United States of America (the "**US**") (the "**Company**"), and Yizhe Wang, an American citizen whose passport number is [***] (the "**Employee**").

WHEREAS, the Company and the Employee entered into an employment agreement on April 19, 2021 (the "**Original Agreement**") under which the Company employs the Employee as its Chief Executive Officer subject to the terms and conditions of the Original Agreement.

WHEREAS, the Company and the Employee agree to amend and restate the Original Agreement by entering into this Agreement as hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual covenants and obligations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Employment. The Company hereby agrees to employ the Employee and the Employee hereby accepts employment with the Company upon the terms and conditions hereinafter set forth.

2. Term. Subject to the provisions of Sections 8, 9, 10 and 11 hereof, the term of the Employee's employment with the Company, which commenced on May 17, 2021 (the "**Commencement Date**"), shall end on January 1, 2024 (the "**Initial Term**"). Unless earlier terminated by the Company or the Employee in accordance with the terms and conditions set forth herein, 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 8, 9, 10 or 11 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 service under Sections 8, 9, 10 and 11 hereof.

3. Location. The Employee will be initially based in the State of Florida, the US. For the avoidance of doubt, the Employee may need to travel to other locations as required by the Company or the board of directors (the "**Board**") of LianBio (the parent of the Company) from time to time, with the understanding that the Employee is required to perform certain of his duties at the offices of the affiliates of the Company in Shanghai, the People's Republic of China (the "**PRC**") and shall spend significant time in Shanghai, the PRC, every year as may be reasonably determined by the Board. The Employee hereby agrees to sign such other agreements or documents as may reasonably be requested by the Company (or its relevant affiliate(s)) in order to obtain the relevant work permit and residence permits issued by the PRC government and other regulators for the Employee to legally work and reside in Shanghai. For the avoidance of doubt, the Employee agrees that the requirements set forth in this Section 3 are material terms of this Agreement.

4. Duties and Responsibilities. The Employee will serve as the Chief Executive Officer (the "**CEO**") of the Company, reporting to the chairman ("**Chairman**") of the Board. The Employee will perform such duties and services as are customary for the positions of CEO in similarly situated enterprises in the biopharmaceutical industry and such other duties as may be reasonably assigned to him from time to time by the Chairman or the Board. In furtherance of the foregoing, the Employee hereby agrees to perform faithfully such duties and responsibilities and the other reasonable duties and responsibilities assigned to him from time to time by the Chairman or the Board. Additionally, the Employee hereby agrees to cooperate with the Company during and after the Employment Period with respect to all matters arising during or related to the Employee's employment.

5. Time to be Devoted to Service. Except for reasonable vacations, absences due to temporary illness, and activities that may be mutually agreed to by the parties, the Employee shall devote his entire time, attention and energies during normal business hours and such evenings and weekends as may be reasonably required for the discharge of his duties to the business of the Company while the Employee is employed by the Company during the Employment Period. During the Employment Period, the Employee will not be engaged in any other business activity that, in the reasonable judgment of the Board, conflicts with the duties of the Employee hereunder (including without limitation, any activities that present a conflict of interest) without the prior written consent of the Company. The Employee and the Company agree that, subject to receiving prior written consent from the Board, the Employee may serve as a director of other corporations and/or non-profit organizations, provided that such directorships do not, individually or in the aggregate, conflict with the duties of the Employee hereunder (including without limitation, any directorships that present a conflict of interest).

6. Conflict of Interest. The Employee has reviewed with the Board (i) the present directorships and other positions or roles held by the Employee or his associate(s) in all such business organizations or arrangements that may be directly competitive or directly in conflict with the Company and (ii) ownership interests (legal or beneficial, direct or indirect) in another company held by the Employee or his associate(s) comprising more than two percent (2%) of such company, schedules of which are listed on Schedule 1 hereto. During the Employment Period, the Employee agrees to review with the Board any potential directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles with business organizations or arrangements that may be directly competitive or directly in conflict with the Company. Except as set forth in Schedule 1 hereto, during the Employment Period, the Employee or his associate(s) is precluded from owning an interest (legal and beneficial, direct and indirect) in another company comprising more than two percent (2%) of such company or serving as an employee, director, consultant, advisor or member of such other company that may be directly competitive or directly in conflict with the Company until such interest is presented to the Board and the Board consents to such interest or employment.

7. Compensation; Benefits; Reimbursement.

7.1 Base Salary. During the Employment Period, the Employee shall receive as compensation an initial annual base salary of US$500,000 (the "**Base Salary**"), less any payroll taxes or withholdings legally required or properly requested by the Employee. This Base Salary and all other compensation and reimbursement under the Agreement will be payable in such installments as are applicable to employees of the Company at substantially the same service level as the Employee. The Board will review the Base Salary on an annual basis and may, in its sole discretion, increase the amount to adjust for inflations and/or market changes.

7.2 Stock Options. Subject to (i) the Board's approval of any grant, (ii) the Employee's continued employment with the Company and (iii) the Employee's execution and delivery of an Option Agreement in the form provided by the Company, following the Commencement Date, the Company shall grant the Employee non-statutory stock options ("**Options**") to purchase up to 663,023 ordinary shares of LianBio (representing approximately four percent (4%) of the fully-diluted share capital of LianBio as of the Commencement Date) at a price per share equal to the fair market value of such ordinary shares on the date of grant by way of participation in LianBio's 2019 Equity Incentive Plan or any other long-term incentive plan of LianBio (the "**ESOP**"). The Options shall be subject to the terms and conditions of the ESOP (as amended from time to time) and shall vest in accordance with following conditions, and subject, in each case, to the Employee remaining in "active working status" with the Company from the date of grant through each such vesting date:

(a) Options Subject to Time-Based Vesting: Fifty percent (50%) of the Options shall vest as to one-fourth (1/4) on the first anniversary of the Commencement Date, another one-fourth (1/4) on the second anniversary of the Commencement Date, another one-fourth (1/4) on the third anniversary of the Commencement Date and the final one-fourth (1/4) on the fourth anniversary of the Commencement Date.

(b) Options Subject to Performance Criteria and Time-Based Vesting:

i. First Tranche: Twenty-five percent (25%) of the Options (the "**First Tranche Performance Options**") shall become vested upon the satisfaction of each of the following vesting conditions:

(i) LianBio achieves an Enterprise Value (as defined below) of not less than US$2 billion at any time after the Commencement Date ("**First Tranche Performance Criteria**"); and

(ii) One-fourth (1/4) of the First Tranche Performance Options shall vest on the first anniversary of the Commencement Date, another one-fourth (1/4) shall vest on the second anniversary of the Commencement Date, another one-fourth (1/4) shall vest on the third anniversary of the Commencement Date and the final one-fourth (1/4) shall vest on the fourth anniversary of the Commencement Date.

ii. Second Tranche: Twenty-five percent (25%) of the Options (the "**Second Tranche Performance Options**", together with the First Tranche Performance Options, the "**Performance Options**") shall become vested upon the satisfaction of each of the following vesting conditions:

(i) LianBio achieves an Enterprise Value (as defined below) of not less than US$4 billion at any time after the Commencement Date ("**Second Tranche Performance Criteria**", together with the First Tranche Performance Criteria, "**Performance Criteria**"); and

(ii) One-fourth (1/4) of the Second Tranche Performance Options shall vest on the first anniversary of the Commencement Date, another one-fourth (1/4) shall vest on the second anniversary of the Commencement Date, another one-fourth (1/4) shall vest on the third anniversary of the Commencement Date and the final one-fourth (1/4) shall vest on the fourth anniversary of the Commencement Date.

iii. Performance Criteria: The performance criteria applicable to the Performance Options shall be the enterprise value of LianBio and its subsidiaries (the "**Enterprise Value**"). The parties agree that the Enterprise Value shall be determined in accordance with the following:

(i) Prior to the initial public offering of LianBio's ordinary shares (the "**IPO**"), any instance where Enterprise Value is determined in connection with the assessment of Performance Criteria for Performance Option vesting purposes, the Enterprise Value shall be the fair market value of all the shares of LianBio, as determined in connection with a Qualified Financing. For the purposes hereof, a "**Qualified Financing**" shall mean any subsequent round of equity financing of LianBio after the Commencement Date (which shall include any convertible debt, convertible preferred share or other equity-linked derivative security financing), in a single or series of related transactions which raises gross proceeds to LianBio of at least US$50,000,000 in the aggregate; and

(ii) Following the IPO, any instance where the Enterprise Value is determined in connection with the assessment of Performance Criteria for Performance Option vesting purposes, the Enterprise Value shall be equal to the number of outstanding ordinary shares of LianBio multiplied by the volume weighted average price of a single ordinary share averaged over a period of thirty (30) days ending one (1) day prior to the date of the valuation. For purposes hereof, the closing price shall be reported by Bloomberg Financial Markets or if Bloomberg Financial Markets is not then reporting such prices, by a comparable reporting service of national reputation selected by the Board.

7.3 Bonus. At the conclusion of the first calendar year which includes the Commencement Date, the Employee will be entitled to receive an annual bonus of one hundred percent (100%) of the Base Salary (the "**First Year Annual Bonus**"), calculated on a *pro rata* basis commencing from the Commencement Date to December 31, 2021. Commencing from January 1, 2022, at the conclusion of each calendar year during the Employment Period, the Employee may be entitled to receive a discretionary performance-based annual bonus with a target equal to one hundred percent (100%) of the Base Salary (the "**Performance Bonus**"), the actual amount of which shall be determined by the Board in its sole and exclusive discretion based on the Board's evaluation of the Employee's performance and other pre-agreed parameters reflecting the Company's business plan. Except as otherwise expressly provided in Section 5 hereof, the Employee must be employed and in "active working status" through the date the First Year Annual Bonus or a Performance Bonus is paid in order to be eligible for the bonus. For purposes of this Agreement, "**active working status**" means that the Employee has not resigned (or given notice of his resignation) or been terminated (or been given notice of his termination).

7.4 Fringe Benefits. During the Employment Period, the Employee will be entitled to the fringe benefits that are made available to officers of the Company and such other benefits as are determined by the Board or a committee thereof, in its sole and exclusive discretion (which, for the avoidance of doubt, shall include expenses and benefits in relation to the Employee's performance of his duties in the PRC).

7.5 Reimbursements. During the Employment Period, the Employee will be reimbursed, in accordance with the Company's expense reimbursement policy as in effect from time to time, for all reasonable traveling expenses and other disbursements incurred by him for or on behalf of the Company in the performance of his duties hereunder upon presentation by the Employee of appropriate vouchers.

7.6 Special Sign-On Bonus. The Employee acknowledges he has received a lump sum cash payment of US$240,000 (the "**Sign-On Bonus**"), which was offered by the Company to the Employee as compensation for the amount of retention bonuses the Employee is required to return to his prior employer. In the event the Employees resigns without Good Reason (as defined below) or a Termination with Cause (as defined below) by the Company within one (1) year after the Commencement Date, the Employee shall repay to the Company within thirty (30) days following the date of termination a prorated portion of the Sign-On Bonus based on the number of full and partial months remaining in such one (1) year period as of the date of such termination of employment.

7.7 Deductions. Recognizing that the Employee is an employee for all purposes, the Company or an affiliate of the Company shall deduct from any compensation payable to the Employee the sums which the Company or such affiliate is required by law to deduct, including, but not limited to, government state withholding taxes, social security taxes and state disability insurance and mandatory provident funds, and the Company or such subsidiary shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

8. Involuntary Termination.

8.1 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 him mentally or physically incapable of performing the services required to be performed by him under this Agreement, 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 Agreement immediately upon giving him notice to that effect. In the case of a Disability, until the Company shall have terminated the Employee's service in accordance with the foregoing, the Employee will be entitled to receive compensation, at the rate and in the manner provided in Section 7, notwithstanding any such physical or mental disability. Termination pursuant to this Section 8 is hereinafter referred to as an "**Involuntary Termination**".

8.2 Substitution. 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 7 of this Agreement 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.

8.3 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 7.1, but shall continue to participate in all other compensation and benefits in accordance with Section 7.4 until the date of the Employee's termination of employment.

8.4 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 Agreement 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.

9. 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 Agreement, "**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 Agreement or the Compliance Agreement (as defined below), 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; or (v) 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.

10. 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). In the event of termination of the Employee's employment in accordance with this Section 10, the Company may elect to waive the period of notice, or any portion thereof, and, if the Company so elects, the Company will pay the Employee the Base Salary for the period so waived.

11. Termination by the Employee.

11.1 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.

11.2 With Good Reason. The Employee may terminate the services 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 his 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 Agreement, 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 8.2) 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 Agreement by the Company.

12. Effect of Termination on Services.

12.1 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates, or its subsidiaries under this Agreement except to receive:

(i) the unpaid portion of the Base Salary provided for in Section 7.1, computed on a *pro rata* basis to the date of such termination;

(ii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 7.5; and

(iii) any other benefits as required by applicable law.

12.2 Involuntary Termination. Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

(i) a termination payment equal to that provided for in Section 12.1(i) hereto;

(ii) an aggregate amount equal to the Base Salary and fringe benefits for twelve (12) months (the "**Severance Payment**"), payable from the date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 7.1 and 7.4 hereof, plus any additional compensation as may be expressly required under applicable law;

(iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 7.5; and

(iv) any other benefits as required by applicable law.

12.3 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

(i) a termination payment equal to that provided for in Section 12.1(i) hereto;

(ii) one hundred percent (100%) of the Severance Payment, payable from the date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 7.1 and 7.4 hereof, plus any additional compensation as may be expressly required under applicable law;

(iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 7.5; and

(iv) any other benefits as required by applicable law.

12.4 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

(i) a termination payment equal to that provided for in Section 12.1(i) hereto;

(ii) the Severance Payment, payable from the date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 7.1 and 7.4 hereof, plus any additional compensation as may be expressly required under applicable law;

(iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 7.5;

(iv) subject to the Employee's satisfaction of the Severance Bonus Milestone, a maximum aggregate amount equal to fifty percent (50%) of the First Year Annual Bonus or the target amount of the Performance Bonus (as applicable) (such aggregate amount, the "**Severance Bonus**"), payable simultaneously with the final batch of the Severance Payment, which will be paid no later than twelve (12) months following the date of termination. "**Severance Bonus Milestone**" means the Employee being employed and in "active working status" for no less than six (6) consecutive months in the applicable calendar year of a Termination without Cause or a Termination for Good Reason. For the avoidance of doubt, the Employee shall not be eligible to receive any portion of the Severance Bonus unless and until the Employee has satisfied the Severance Bonus Milestone; and

(v) any other benefits as required by applicable law.

12.5 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

(i) a termination payment equal to that provided for in Section 12.1(i) hereto;

(ii) an aggregate amount equal to (x) the Severance Payment and (y) an additional six (6) months of fringe benefits (for an aggregate of eighteen (18) months of fringe benefits from the date of termination) (the "**Additional Fringe Benefits**"), payable from the date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 7.1 and 7.4 hereof, plus any additional compensation as may be expressly required under applicable law;

(iii) an aggregate amount equal to three (3) times the First Year Annual Bonus or the target amount of the Performance Bonus (as applicable) (such aggregate amount, the "**CIC Separation Bonus**", and together with the Severance Payment and the Additional Fringe Benefits, "**CIC Severance Payment**"). Payment of the CIC Separation Bonus shall be made simultaneously with the final batch of Severance Payment, which will be paid no later than twelve (12) months following the date of termination;

(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. For the avoidance of doubt, any outstanding unvested stock options or other equity-based incentives subject to the Performance Criteria shall no longer be subject to such Performance Criteria and one hundred percent (100%) of such stock options or other equity-based incentives subject to the Performance Criteria shall vest in accordance with the accelerated vesting described in the preceding sentence;

(v) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 7.5; and

(vi) any other benefits as required by applicable law.

For purposes of this Agreement, "**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.

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.

12.6 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 Agreement by the Company shall be extremely difficult or impossible to establish or prove, and agree that the Severance Payment or the CIC Severance Payment, as applicable, shall constitute liquidated damages for any breach of this Agreement 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 Agreement 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 his employment or any such breach of this Agreement and that, as a condition to receiving the Severance Payment or the CIC Severance Payment, as applicable, the Employee will execute a separation agreement containing a release of claims and other customary terms 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 or the CIC Severance Payment, as applicable, 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.

12.7 Resignations. Upon the termination of the Employee's employment hereunder for any reason, the Employee will be deemed to have resigned from any and all positions, offices, or memberships that the Employee held with the Company or on any boards of directors or other governing boards of the Company or its affiliates, including but not limited to the general managers, authorized signatories, legal representatives and other similar positions of any affiliates of the Company, the Board, and any and all memberships the Employee 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 date of termination (the "**Resignation Date**"), and the Employee agrees to sign and return such documents confirming the Resignations as the Company or any of its affiliates may reasonably require. For the avoidance of doubt, the Employee agrees to (i) execute any such forms, letters, certificates, powers of attorney, instruments and documents necessary or reasonable to effect such Resignations, including, without limitation, registration forms to be submitted to the PRC State Administration for Market Regulation or any other applicable governmental and regulatory authorities with respect to the Resignations (collectively, the "**Removal Documents**"); (ii) deliver the Removal Documents to the designee of the Company; (iii) use the Employee's best efforts to cause the employees of the Company or any of its affiliates to provide assistance that may reasonably require with respect to the Resignations, including, without limitation, execution and delivery of the Removal Documents; (iv) upon request of the Company, but in any event no later than the Resignation Date, return all confidential information, Company intellectual property and all originals and copies of documents, records, files, drawings, blueprints, manuals, reports, notebooks, notes, photographs and any other recorded, written or printed matter relating to the research, manufacturing operations or business of the Company made, accessed or received by the Employee during the Employment Period. Similarly, upon request of the Company, but in any event no later than the Resignation Date, the Employee will return all other property of the Company, such as equipment, models, samples and biological cultures, as well as any 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. The Employee also agree to disclose to the Company, upon request of the Company, but in any event no later than the Resignation Date, all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, any information which the Employee has password-protected on any computer equipment, network or system of the Company; and (v) provide all other necessary assistance to effect the Resignations. It is understood and agreed that the Company and its affiliates have taken and will take actions in reliance on the Resignations and that the Resignations will become irrevocable on the Resignation Date.

13. Indemnification of Employee.

13.1 Indemnification. In the event that (a) the Employee was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Employee's Corporate Status (as defined below) or (b) the Employee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Employee's Corporate Status, the Employee shall be indemnified by the Company against all Expenses (as defined below) and Liabilities (as defined below) incurred or paid by the Employee in connection with such Proceeding (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Employee as an employee and/or director of the Company, as applicable, (iii) "**Expenses**" means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

13.2 Advancement of Expenses. The Company agrees that the Company shall pay to the Employee all Indemnifiable Amounts incurred by the Employee in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Employee provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Employee is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

13.3 Limitation on Indemnification. The Employee shall not be entitled to any indemnification under this Section 13 if the Employee knowingly violated any duty, responsibility or obligation of the Employee imposed under this Agreement, the Compliance Agreement or any Company policy.

13.4 Change in Law. To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Employee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

14. Compliance Agreement. The Employee agrees to continue to be bound by the Employee Confidentiality, IP Assignment and Non-Competition Agreement executed by the Company and the Employee on April 19, 2021 (the "**Compliance Agreement**", attached hereto as Exhibit A), the terms and conditions of which are specifically incorporated herein by reference. Notwithstanding the foregoing, the parties hereto hereby agree that Section 12(a) of the Compliance Agreement shall not apply to the Employee following the date of termination if the Employee's employment is terminated as a result of (a) a Non-Renewal by the Company or (b) a Change in Control Termination. The obligation of the Company to make payments to or on behalf of the Employee under Section 12.2(ii), Section 12.3(ii), Section 12.4(ii) or Section 12.5(ii) above is expressly conditioned upon the Employee's continued performance of the Employee's obligations under the Compliance Agreement.

15. Compliance with Anti-Bribery, Anti-Corruption, Etc. 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 PRC Criminal Law, the PRC 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, its affiliates or its subsidiaries. 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, its affiliates or its subsidiaries 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, its affiliates or its subsidiaries by any person or entity, or (d) the using of any assets of the Company, its affiliates or its subsidiaries for the establishment of any unlawful or unrecorded fund of monies or other assets, or the making of any unlawful or undisclosed payment.

16. Enforcement. It is the desire and intent of the parties hereto that the provisions of this Agreement will be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, to the extent that a restriction contained in this Agreement is more restrictive than permitted by the laws of any jurisdiction whose law may be deemed to govern the review and interpretation of this Agreement, the terms of such restriction, for the purpose only of the operation of such restriction in such jurisdiction, will be the maximum restriction allowed by the laws of such jurisdiction and such restriction will be deemed to have been revised accordingly herein. A court having jurisdiction over an action arising out of or seeking enforcement of any restriction contained in this Agreement may modify the terms of such restriction in accordance with this Section 16.

17. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) two (2) business days after deposit with an internationally recognized overnight courier, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their address as set forth on the signature page, or to such e-mail address, facsimile number or address as subsequently modified by written notice given in accordance with this Section 17.

18. Survival. The provisions set forth in Sections 12, 16, 18, 20, 24, 26 and 29 of this Agreement shall survive the termination of this Agreement.

19. Binding Agreement; Benefit. The provisions of this Agreement will be binding upon and will inure to the benefit of, the respective heirs, legal representatives and successors of the parties hereto.

20. Governing Law. For so long as the Employee primarily resides and works in Florida, the US, this Agreement shall be governed by and construed under the laws of the State of Florida, the US; for as long as the Employee primarily resides and works in Shanghai, the PRC, this Agreement shall be governed by and construed under the laws of Hong Kong Special Administrative Region of the PRC ("**Hong Kong**"), in each case, without giving effect to any choice of law rule that would cause the application of the laws of any other jurisdiction.

21. Waiver of Breach. The waiver by either party of a breach of any provision of this Agreement by the other party must be in writing and will not operate or be construed as a waiver of any subsequent breach by such other party.

22. Entire Agreement; Amendments. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements or understanding among the parties with respect thereto. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

23. Headings. The Section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

24. Severability. Subject to the provisions of Section 16 above, any provision of this Agreement that is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction.

25. Assignment. This Agreement is personal in its nature and the parties hereto shall not, without the consent of the other party hereto, assign or transfer this Agreement or any rights or obligations hereunder, provided, however, that the rights and obligations of the Company hereunder shall be assignable and delegable in connection with any subsequent merger, consolidation, sale of all or substantially all of the assets or shares of the Company or similar transaction involving the Company or a successor corporation.

26. Confidentiality. The Employee agrees not to disclose this Agreement or its terms to any person or entity, other than the Employee's agents, advisors or representatives, except as consented to by the Company in writing or as may be required by law.

27. Further Assurances. The Employee agrees to execute, acknowledge, seal and deliver such further assurances, documents, applications, agreements and instruments, and to take such further actions, as the Company may reasonably request in order to accomplish the purposes of this Agreement.

28. Counterparts. The parties may execute this Agreement in any number of counterparts and, as so delivered, the counterparts shall together constitute one and the same document. The parties agree that each such counterpart is an original and shall be binding upon all of the parties, even though all of the parties are not signatories to the same counterpart.

29. Dispute Resolution.

29.1 Any dispute, controversy or claim (each, a "**Dispute**") arising out of or relating to this Agreement, or the interpretation, breach, termination, validity or invalidity thereof, shall be referred to and conclusively determined by arbitration upon the demand of any party to the dispute with notice (the "**Arbitration Notice**") to the other party or parties. The only claims not covered by this agreement to arbitrate are claims for benefits under U.S. workers' compensation or unemployment insurance statutes and other claims that cannot be arbitrated as a matter of law. Any Dispute must be brought to arbitration within the statute of limitations for bringing such Dispute in court or before the appropriate administrative agency, as applicable.

29.2 For so long as the Employee primarily resides and works in Florida, the Dispute shall be settled by arbitration in Miami, Florida administered by JAMS in accordance with its Employment Arbitration Rules & Procedures; for so long as the Employee primarily resides and works in Shanghai, any Dispute shall be settled by arbitration in Hong Kong by the Hong Kong International Arbitration Centre (the "**HKIAC**") in accordance with the Hong Kong International Arbitration Centre Administered Arbitration Rules (the "**HKIAC Rules**") in force when the Arbitration Notice is submitted in accordance with the HKIAC Rules.

29.3 The disputing parties may jointly select one (1) arbitrator who is a retired judge, or, as applicable, agree that the Chairman of HKIAC shall select the arbitrator. In the absence of such agreement, there shall be three (3) arbitrators, the claimant to the Dispute, or in the case of multiple claimants, all such claimants acting collectively (the "**Claimant**") shall select one (1) arbitrator and the respondent to the Dispute, or in the case of more than one respondent, the respondents acting collectively (the "**Respondent**") shall select one (1) arbitrator. All selections shall be made within thirty (30) days after the selecting party gives or receives the demand for arbitration. Such arbitrators shall be freely selected, and neither the Claimant nor the Respondent shall be limited in their selection to any prescribed list. As applicable, the Chairman of HKIAC shall select the third arbitrator who will act as chairman of the arbitration board. In such case, if any arbitrator to be appointed by a party has not been appointed and consented to participate within thirty (30) days after the selection of the first arbitrator, the relevant appointment shall be made by the Chairman of HKIAC.

29.4 The arbitral proceedings shall be conducted in English. To the extent that the Employment Arbitration Rules & Procedures of JAMS or the HKIAC Rules, as applicable, are in conflict with the provisions of this Section, including the provisions concerning the appointment of the arbitrators, the provisions of this Section shall prevail.

29.5 Each party to the arbitration shall cooperate with each other party to the arbitration in making full disclosure of and providing complete access to all information and documents requested by such other party in connection with such arbitral proceedings, subject only to any confidentiality obligations binding on such party. If the arbitration is conducted in Florida, the arbitrator shall permit adequate discovery, shall issue a written award, and is authorized to award any type of relief recoverable in court.

29.6 The decision of the arbitral tribunal shall be final and binding upon the parties thereto, and the prevailing party may apply to a court of competent jurisdiction for enforcement thereof.

29.7 For so long as the Employee primarily resides and works in Florida, the arbitral tribunal shall decide any Dispute submitted by the parties to the arbitration strictly in accordance with the substantive laws of the State of Florida; for as long as the Employee primarily resides and works in Shanghai, the arbitral tribunal shall decide any Dispute submitted by the parties to arbitration strictly in accordance with the substantive laws of Hong Kong, in each case, without regard to principles of conflict of laws thereunder, and the arbitral tribunal shall not apply any other substantive law.

29.8 Any party to the Dispute shall be entitled, without posting any bond, to seek preliminary injunctive relief, temporary restraining order or other temporary relief (if applicable), from any court of competent jurisdiction pending the constitution of the arbitral tribunal.

29.9 During the course of the arbitral tribunal's adjudication of the Dispute, this Agreement shall continue to be performed except with respect to the part in dispute and under adjudication.

29.10 If the Dispute is arbitrated in Florida, (i) the Employee acknowledges and agrees that no claims will be arbitrated on a class action or collective action basis, (ii) the arbitration costs incurred by the Employee shall not exceed the cost of filing a complaint in a court of law or equity, and (iii) the parties expressly waive all rights to a jury trial in court on all statutory or other claims.

30. Timing of Payments and Section 409A.

30.1 Notwithstanding anything to the contrary in this Agreement, 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 Agreement 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**").

30.2 For purposes of this Agreement, 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)

30.3 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.

30.4 In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

[The remainder of this page has been left intentionally blank]

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the date first above written.

COMPANY:

LianBio, LLC

Address: 103 Carnegie Center Drive, Suite 215, Princeton, New Jersey 08540

By: /s/ Konstantin Poukalov
Name: Konstantin Poukalov
Title: Authorized Representative

Attn: Konstantin Poukalov
Email: [***]

EMPLOYEE:

Address:

/s/ Yizhe Wang
Yizhe Wang

Attn: Yizhe Wang
Email: [***]

[Signature Page to Executive Employment Agreement]

SCHEDULE 1

CONFLICT OF INTEREST

102868158_9

EXHIBIT A

EMPLOYEE CONFIDENTIALITY, IP ASSIGNMENT AND NON-COMPETITION AGREEMENT

Name:	[_____]
Number of Restricted Share Units:	[_____]
Date of Grant:	[_____]
Vesting Commencement Date:	[_____]

LIANBIO
2021 EQUITY INCENTIVE PLAN

Restricted Share Unit Agreement

This agreement (this "**Agreement**") evidences a grant (the "**Award**") of Restricted Share Units ("**RSUs**") by LianBio, an exempted company organized under the laws of the Cayman Islands (the "**Company**"), to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the LianBio 2021 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. Grant of RSUs. On the date of grant set forth above (the "**Date of Grant**"), the Company granted to the Participant the number of RSUs set forth above, giving the Participant the conditional right to receive, without payment and pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, one Share with respect to each RSU subject to this Award, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The RSUs are granted to the Participant in connection with the Participant's Employment with the Company.

2. Vesting. [ ]

3. Cessation of Service. If the Participant's Employment ceases for any reason, except as expressly provided in a written employment, change of control or severance-benefit agreement between the Participant and the Company or one of its affiliates that is in effect at the time of such cessation of Employment, the RSUs, to the extent not then vested, will be immediately forfeited for no consideration.

4. Delivery of Shares. The Company shall, as soon as practicable upon the vesting of any RSUs (but in no event later than thirty (30) days following the date on which such RSUs vest), effect delivery of the Shares with respect to such vested RSUs to the Participant (or, in the event the RSUs have passed to the estate or beneficiary of the Participant or a permitted transferee, to such estate or beneficiary or permitted transferee).

5. Nontransferability. The RSUs may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Forfeiture; Recovery of Compensation. By accepting, or being deemed to have accepted, the RSUs, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to the RSUs, including the right to any Shares acquired in respect of the RSUs and any amounts received in respect thereof, are subject to

Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any applicable clawback or recoupment policy of the Company. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7. Taxes. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon settlement of the Award, are subject to the Participant promptly satisfying all taxes and other amounts required to be withheld.

(a) The number of shares of Stock necessary to satisfy the minimum statutory withholding tax obligations on the vesting date or settlement date, as applicable, will automatically be released by the Participant from the Shares otherwise deliverable to the Participant hereunder on such date to a broker or other third-party intermediary acceptable to the Company (the "**Broker**") and sold in order to satisfy such withholding tax obligations ("**Sell to Cover**"). The Participant will be responsible for all third-party administration processing fees in connection with such Sell to Cover. In addition, the Participant may be subject to and taxed in respect of short-term capital gains or losses that reflect the difference in the withholding tax liability determined on the date that the Award vests and/or settles hereunder and the sales price actually achieved.

(b) In connection with the implementation of the Sell to Cover provision described in Section 7(a) above, the Participant hereby authorizes the Company to instruct the Broker to sell a number of Shares to be issued upon the vesting or settlement of the Award to satisfy the minimum statutory withholding tax obligations, as described in Section 7(a) above.

(c) Notwithstanding anything in this Agreement to the contrary, the Participant acknowledges and agrees that the Sell to Cover provision may not cover the Participant's full tax liability as it relates to the vesting and settlement of the Award and that the Participant shall remain fully responsible for his or her tax obligations in respect of the Award in all cases.

(d) The Participant further acknowledges and agrees as follows:

(i) The instruction to the Broker to sell in connection with the Sell to Cover provision is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Securities Exchange Act of 1934 (the "**Exchange Act**"), and is to be interpreted to comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act.

(ii) The Participant is not aware of any material, nonpublic information with respect to the Company or any securities of the Company as of the date of this Agreement.

(iii) The Sell to Cover contemplated by this Agreement is adopted to (A) be effective as of the Date of Grant and (B) permit the Participant to sell a number of Shares issued upon the vesting or settlement of the Award

sufficient to pay the statutory minimum amount of withholding taxes that become due as a result of the vesting or settlement of the Award.

(iv) The Broker is under no obligation to arrange for any sale in connection with the Sell to Cover provision at any particular price.

(v) The Participant hereby authorizes the Broker to remit directly to the Company the proceeds necessary to cover the Participant's tax liability as it relates to the vesting and settlement of the Award as provided in Section 7(a) above, and to retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Broker relating to the Sell to Cover.

(vi) The Participant hereby appoints the Company as his or her agent and attorney-in-fact to instruct the Broker with respect to the number of Shares to be sold under the Sell to Cover contemplated by this Agreement.

(vii) The Participant hereby waives any claims he or she may have against the Company and its directors, officers or employees now or in the future related to the Company's instructions to a Broker or any actions taken by the Broker in effecting sales or otherwise and shall indemnify and hold the Company and its directors, officers, employees and agents harmless from any losses, costs, damages, or expenses relating to any sale under the Sell to Cover contemplated by this Agreement.

(viii) It may not be possible to sell Shares due to, among other reasons, (A) a legal or contractual restriction applicable to the Participant or to the Broker, (B) a market disruption, (C) rules governing order execution priority on the Nasdaq Global Market or (D) if the Company determines that sales may not be effected hereunder.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, the Award, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Acknowledgements. The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement.

LIANBIO

By: _____
Name: _____
Title: _____

Agreed and Accepted:

By_____
[Participant's Name]

Name: [_____]
Number of PSUs: [_____]
Date of Grant: [_____]

LIANBIO
2021 EQUITY INCENTIVE PLAN
RESTRICTED SHARE UNIT AWARD AGREEMENT

This agreement (this "**Agreement**") evidences a grant (the "**Award**") of performance-based Restricted Share Units granted by LianBio, an exempted company organized under the laws of the Cayman Islands (the "**Company**"), to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the LianBio 2021 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. Grant of PSUs. On the date of grant set forth above (the "**Date of Grant**"), the Company granted to the Participant the target number of performance-based Restricted Stock Units (the "**PSUs**") set forth above, giving the Participant the conditional right to receive, without payment and pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, one Share with respect to each PSU forming part of the Award, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof. The number of PSUs that may be earned by the Participant will be determined in accordance with Exhibit A hereto.

The PSUs are granted to the Participant in connection with the Participant's Employment with the Company.

2. Earning; Vesting.

(a) Earned PSUs. The PSUs shall become "**Earned PSUs**" to the extent earned in accordance with the performance criteria set forth on Exhibit A hereto.

(b) Vesting of Earned PSUs. The Earned PSUs shall become vested on the dates set forth in Exhibit A hereto, subject to the Participant remaining in continuous employment from the Date of Grant through the applicable vesting date.

3. Cessation of Service. If the Participant's Employment ceases for any reason, except as expressly provided in a written employment, change of control or severance-benefit agreement between the Participant and the Company or one of its affiliates that is in effect at the time of such cessation of Employment, the PSUs or Earned PSUs, as applicable, to the extent not then vested, will be immediately forfeited for no consideration.

4. Delivery of Shares. The Company shall, as soon as practicable upon the vesting of any Earned PSUs (but in no event later than thirty (30) days following the date on which such Earned PSUs vest), effect delivery of the Shares with respect to such vested Earned PSUs to the Participant (or, in the event the PSUs have passed to the estate or beneficiary of the Participant or a permitted transferee, to such estate or beneficiary or permitted transferee).

5. Nontransferability. The PSUs may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Forfeiture; Recovery of Compensation. By accepting, or being deemed to have accepted, the PSUs, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to the PSUs, including the right to any Shares acquired in respect of the PSUs and any amounts received in respect thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any applicable clawback or recoupment policy of the Company. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7. Taxes. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon settlement of the Award, are subject to the Participant promptly satisfying all taxes and other amounts required to be withheld.

(a) The number of Shares necessary to satisfy the minimum statutory withholding tax obligations on the vesting date or settlement date, as applicable, will automatically be released by the Participant from the Shares otherwise deliverable to the Participant hereunder on such date to a broker or other third-party intermediary acceptable to the Company (the "**Broker**") and sold in order to satisfy such withholding tax obligations ("**Sell to Cover**"). The Participant will be responsible for all third-party administration processing fees in connection with such Sell to Cover. In addition, the Participant may be subject to and taxed in respect of short-term capital gains or losses that reflect the difference in the withholding tax liability determined on the date that the Award vests and/or settles hereunder and the sales price actually achieved.

(b) In connection with the implementation of the Sell to Cover provision described in Section 7(a) above, the Participant hereby authorizes the Company to instruct the Broker to sell a number of Shares to be issued upon the vesting or settlement of the Award to satisfy the minimum statutory withholding tax obligations, as described in Section 7(a) above.

(c) Notwithstanding anything in this Agreement to the contrary, the Participant acknowledges and agrees that the Sell to Cover provision may not cover the Participant's full tax liability as it relates to the vesting and settlement of the Award and that the Participant shall remain fully responsible for his or her tax obligations in respect of the Award in all cases.

(d) The Participant further acknowledges and agrees as follows:

(i) The instruction to the Broker to sell in connection with the Sell to Cover provision is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Securities Exchange Act of 1934 (the "**Exchange Act**"), and is to be interpreted to comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act.

(ii) The Participant is not aware of any material, nonpublic information with respect to the Company or any securities of the Company as of the date of this Agreement.

(iii) The Sell to Cover contemplated by this Agreement is adopted to (A) be effective as of the Date of Grant and (B) permit the Participant to sell a number of Shares issued upon the vesting or settlement of the Award sufficient to pay the statutory minimum amount of withholding taxes that become due as a result of the vesting or settlement of the Award.

(iv) The Broker is under no obligation to arrange for any sale in connection with the Sell to Cover provision at any particular price.

(v) The Participant hereby authorizes the Broker to remit directly to the Company the proceeds necessary to cover the Participant's tax liability as it relates to the vesting and settlement of the Award as provided in Section 7(a) above, and to retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Broker relating to the Sell to Cover.

(vi) The Participant hereby appoints the Company as his or her agent and attorney-in-fact to instruct the Broker with respect to the number of Shares to be sold under the Sell to Cover contemplated by this Agreement.

(vii) The Participant hereby waives any claims he or she may have against the Company and its directors, officers, or employees now or in the future related to Company's instructions to a Broker or any actions taken by the Broker in effecting sales or otherwise and shall indemnify and hold the Company and its directors, officers, employees and agents harmless from any losses, costs, damages, or expenses relating to any sale under the Sell to Cover contemplated by this Agreement.

(viii) It may not be possible to sell Shares due to, among other reasons, (A) a legal or contractual restriction applicable to the Participant or to the Broker, (B) a market disruption, (C) rules governing order execution priority on the Nasdaq Global Market or (D) if the Company determines that sales may not be effected hereunder.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, the Award, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Acknowledgements. The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement.

LIANBIO

By: _____
Name: _____
Title: _____

[*Signature Page to Performance Based Restricted Share Unit Agreement*]

Agreed and Accepted:

By _____
[Participant's Name]

Name:	
Number of Shares subject to the Share Option:	
Exercise Price Per Share:	$
Date of Grant:	
Vesting Commencement Date	

LianBio
2021 Equity Incentive Plan

Non-Statutory Share Option Agreement

This agreement (this "**Agreement**") evidences a share option granted by LianBio, an exempted company organized under the laws of the Cayman Islands (the "**Company**") to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the LianBio 2021 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. Grant of Share Option. The Company grants to the Participant on the date set forth above (the "**Date of Grant**") an option (the "**Share Option**") to purchase, pursuant to and subject to the terms set forth in this Agreement and in the Plan, up to the number of Shares set forth above (the "**Shares**") with an exercise price per Share as set forth above, in each case subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Share Option evidenced by this Agreement is a non-statutory option (that is, an option that is not intended to qualify as an ISO) and is granted to the Participant in connection with the Participant's Employment.

2. Vesting. The term "**vest**" as used herein with respect to the Share Option or any portion thereof means to become exercisable and the term "**vested**" with respect to the Share Option (or any portion thereof) means that the Share Option (or portion thereof) is then exercisable. Unless earlier terminated, forfeited, relinquished or expired, the Share Option will vest as follows:

[ ]

3. Exercise of the Share Option. No portion of the Share Option may be exercised until such portion vests. Each election to exercise any vested portion of the Share Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the Administrator, signed (including by electronic signature) by the Participant or, if at the relevant time the Share Option has passed to the estate or beneficiary of the Participant or a permitted transferee, by such estate or beneficiary or permitted transferee. Each such written or electronic exercise election must be received by the Company at its principal office or at such other place or by such other party as the Administrator may prescribe and must be accompanied by payment in full of the exercise price (i) in cash, by wire transfer of immediately available funds or by check, (ii) through a broker-assisted exercise program, as described in Section 6(b)(3) of the Plan and otherwise acceptable to the Administrator, or (iii) as otherwise provided in the Plan. Subject to earlier termination as set forth herein or in the Plan (including Section 6(a)(4) of the Plan), the latest date on which the Share Option or any portion thereof may be exercised is the tenth (10^{th}) anniversary of the Date of Grant (the "**Final Exercise Date**") and, if not exercised by such date, the Share Option or any remaining portion thereof will thereupon immediately terminate.

4. Cessation of Employment. If the Participant's Employment ceases, except as expressly provided for in an employment or other agreement between the Participant and the Company that is in effect at the time of such termination, the Share Option, to the extent not then vested, will be immediately forfeited for no consideration, and any vested portion of the Share Option that is then outstanding will be treated as follows:

(a) Subject to (b) and (c) below, each vested and unexercised Share Option (or portion thereof) held by the Participant or the Participant's permitted transferees, if any, immediately prior to such termination of employment, to the extent then exercisable, will remain exercisable for the lesser of (i) a period of ninety (90) days following such termination of employment or (ii) the period ending on the latest date on which such Share Option could have been exercised without regard to this Section 4(a), and will thereupon immediately terminate.

(b) Subject to (c) below, each vested and unexercised Share Option (or portion thereof) held by the Participant or the Participant's permitted transferees, if any, immediately prior to such termination of employment as a result of the Participant's death or disability, to the extent then exercisable, will remain exercisable for the lesser (i) the one-year period ending on the first anniversary of the date of such termination of employment or (ii) the period ending on the latest date on which such Share Option could have been exercised without regard to this Section 4(b), and will thereupon immediately terminate.

(c) All Share Options (whether or not vested or exercisable) held by a Participant or the Participant's permitted transferees, if any, immediately prior to the termination of the Participant's employment will immediately terminate upon such termination if the termination is for Cause, as defined in the Plan, or occurs in circumstances that in the determination of the Administrator would have constituted grounds for the Participant's employment to be terminated for Cause (in each case, without regard to the lapsing of any required notice or cure periods in connection therewith).

5. Restrictions on Transfer. The Share Option may not be transferred except as expressly permitted Section 6(a)(3) of the Plan.

6. Forfeiture; Recovery of Compensation. By accepting, or being deemed to have accepted, the Share Option, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to the Share Option, including the right to any Shares acquired under the Share Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any applicable clawback or recoupment policy of the Company. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7. Taxes. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon exercise of the Share Option, are subject to the Participant promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes and other amounts required to be withheld. No Shares will be issued pursuant to the exercise of the Share Option unless and until the person exercising the Share Option has remitted to the Company an amount in cash sufficient to satisfy any withholding requirements, or has made other arrangements satisfactory to the Company with respect to such amounts. The Participant authorizes the Company and its subsidiaries to withhold any amounts due in respect of any required withholdings from any amounts otherwise owed to the Participant, but nothing in this sentence will be construed as relieving the Participant from any liability for satisfying his or her obligation under the preceding provisions of this Section.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, the Share Option, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Effect on Employment. Neither the grant of the Share Option, nor the issuance of Shares upon exercise of the Share Option, will give the Participant any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to discharge the Participant at any time, or affect any right of the Participant to terminate his or her Employment at any time.

10. Acknowledgements.

(a) The grant of the Share Option is considered a one-time benefit and does not create a contractual or other right to receive any other award under the Plan, benefits in lieu of such awards or any other benefits in the future.

(b) The Plan is a voluntary program of the Company and future awards, if any, will be at the sole discretion of the Company, including, but not limited to, the timing of any award, the amount of any award, vesting provisions and purchase price, if any.

(c) The value of the Share Option is an extraordinary item of compensation outside of the scope of the Participant's Employment. As such, the Share Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-term service awards, pension or retirement benefits or similar payments. The future value of the Shares covered by the Share Option is unknown and cannot be predicted with certainty.

(d) The Participant authorizes the Company to use and disclose to any agent administering the Plan or providing recordkeeping services with respect to the Plan such information and data as the Company shall request in order to facilitate the grant of the Share Option, the administration of the Share Option and the administration of the Plan.

(e) The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

LIANBIO

By: _____

Name: _____

Title: _____

Agreed and Accepted:

By_____
[Participant's Name]

Name:
Number of Shares subject to the Share Option:
Exercise Price Per Share: $
Date of Grant:

LIANBIO
2021 EQUITY INCENTIVE PLAN

PERFORMANCE-BASED NON-STATUTORY SHARE OPTION AGREEMENT

This agreement (this "**Agreement**") evidences a performance-based share option granted by LianBio, an exempted company organized under the laws of the Cayman Islands (the "**Company**") to the individual named above (the "**Participant**"), pursuant to and subject to the terms of the LianBio 2021 Equity Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan.

1. Grant of Share Option. The Company grants to the Participant on the date set forth above (the "**Date of Grant**") an option (the "**Share Option**") to purchase, pursuant to and subject to the terms set forth in this Agreement and in the Plan, up to the number of Shares set forth above (the "**Shares**") with an exercise price per Share as set forth above, in each case subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof. The percentage of the Share Option that may be earned by the Participant will be determined in accordance with Section 2 below.

The Share Option evidenced by this Agreement is a non-statutory option (that is, an option that is not intended to qualify as an ISO) and is granted to the Participant in connection with the Participant's Employment.

2.Vesting. The term "**vest**" as used herein with respect to the Share Option or any portion thereof means to become earned and vested and the term "**vested**" with respect to the Share Option (or any portion thereof) means that the Share Option (or portion thereof) is then earned and vested. Unless earlier terminated, forfeited, relinquished or expired, the Share Option will be earned and will vest as set forth on Exhibit A attached hereto.

3. Exercise of the Share Option. No portion of the Share Option may be exercised until such portion vests as provided for in Exhibit A attached hereto. Each election to exercise any vested portion of the Share Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the Administrator, signed (including by electronic signature) by the Participant or, if at the relevant time the Share Option has passed to the estate or beneficiary of the Participant or a permitted transferee, by such estate or beneficiary or permitted transferee. Each such written or electronic exercise election must be received by the Company at its principal office or at such other place or by such other party as the Administrator may prescribe and must be accompanied by payment in full of the exercise price (i) in cash, by wire transfer of immediately available funds or by check, (ii) through a broker-assisted exercise program, as described in Section 6(b)(3) of the Plan and otherwise acceptable to the Administrator, or (iii) as otherwise provided in the Plan. Subject to earlier termination as set forth herein, including Exhibit A attached hereto, or in the Plan (including Section 6(a)(4) of the Plan), the latest date on which the Share Option or any portion thereof may be exercised is the tenth (10th) anniversary of the Date of Grant (the "**Final Exercise Date**") and, if not exercised by such date, the Share Option or any remaining portion thereof will thereupon immediately terminate.

4. Cessation of Employment. If the Participant's Employment ceases, except as expressly provided for in an employment or other agreement between the Participant and the Company that is in effect at the time of such termination, the Share Option, to the extent not then vested, will be immediately forfeited for no consideration, and any vested portion of the Share Option that is then outstanding will be treated as follows:

(a) Subject to (b) and (c) below, each vested and unexercised Share Option (or portion thereof) held by the Participant or the Participant's permitted transferees, if any, immediately prior to such termination of employment, to the extent then exercisable, will remain exercisable for the lesser of (i) a period of ninety (90) days following such termination of employment or (ii) the period ending on the latest date on which such Share Option could have been exercised without regard to this Section 4(a), and will thereupon immediately terminate.

(b) Subject to (c) below, each vested and unexercised Share Option (or portion thereof) held by the Participant or the Participant's permitted transferees, if any, immediately prior to such termination of employment as a result of the Participant's death or disability, to the extent then exercisable, will remain exercisable for the lesser (i) the one-year period ending on the first anniversary of the date of such termination of employment or (ii) the period ending on the latest date on which such Share Option could have been exercised without regard to this Section 4(b), and will thereupon immediately terminate.

(c) All Share Options (whether or not vested or exercisable) held by a Participant or the Participant's permitted transferees, if any, immediately prior to the termination of the Participant's employment will immediately terminate upon such termination if the termination is for Cause, as defined in the Plan, or occurs in circumstances that in the determination of the Administrator would have constituted grounds for the Participant's employment to be terminated for Cause (in each case, without regard to the lapsing of any required notice or cure periods in connection therewith).

5. Restrictions on Transfer. The Share Option may not be transferred except as expressly permitted Section 6(a)(3) of the Plan.

6. Forfeiture; Recovery of Compensation. By accepting, or being deemed to have accepted, the Share Option, the Participant expressly acknowledges and agrees that his or her rights, and those of any permitted transferee, with respect to the Share Option, including the right to any Shares acquired under the Share Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). The Participant further agrees to be bound by the terms of any applicable clawback or recoupment policy of the Company. Nothing in the preceding sentence will be construed as limiting the general application of Section 8 of this Agreement.

7. Taxes. The Participant expressly acknowledges and agrees that the Participant's rights hereunder, including the right to be issued Shares upon exercise of the Share Option, are subject to the Participant promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes and other amounts required to be withheld. No Shares will be issued pursuant to the exercise of the Share Option unless and until the person exercising the Share Option has remitted to the Company an amount in cash sufficient to satisfy any withholding requirements, or has made other arrangements satisfactory to the Company with respect to such amounts. The Participant authorizes the Company and its subsidiaries to withhold any amounts due in respect of any required withholdings from any amounts otherwise owed to the Participant, but nothing in this sentence will be construed as relieving the Participant from any liability for satisfying his or her obligation under the preceding provisions of this Section.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been made available to the Participant. By accepting, or being deemed to have accepted, the Share Option, the Participant agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Effect on Employment. Neither the grant of the Share Option, nor the issuance of Shares upon exercise of the Share Option, will give the Participant any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to discharge the Participant at any time, or affect any right of the Participant to terminate his or her Employment at any time.

10. Acknowledgements.

(a) The grant of the Share Option is considered a one-time benefit and does not create a contractual or other right to receive any other award under the Plan, benefits in lieu of such awards or any other benefits in the future.

(b) The Plan is a voluntary program of the Company and future awards, if any, will be at the sole discretion of the Company, including, but not limited to, the timing of any award, the amount of any award, vesting provisions and purchase price, if any.

(c) The value of the Share Option is an extraordinary item of compensation outside of the scope of the Participant's Employment. As such, the Share Option is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-term service awards, pension or retirement benefits or similar payments. The future value of the Shares covered by the Share Option is unknown and cannot be predicted with certainty.

(d) The Participant authorizes the Company to use and disclose to any agent administering the Plan or providing recordkeeping services with respect to the Plan such information and data as the Company shall request in order to facilitate the grant of the Share Option, the administration of the Share Option and the administration of the Plan.

(e) The Participant acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Participant.

[Signature page follows.]

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

LIANBIO

By: _____

Name: _____

Title: _____

[*Signature page to Performance Based Share Option Agreement*]

Agreed and Accepted:

By _____
[Participant's Name]

[*Signature page to Performance Based Share Option Agreement*]

Exhibit 21.1

Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation or Organization
LianBio Development (Cayman) Limited	Cayman Islands
LianBio, LLC	Delaware
Lian Oncology	Cayman Islands
Lian Cardiovascular	Cayman Islands
LianBio Respiratory	Cayman Islands
LianBio Ophthalmology	Cayman Islands
LianBio Inflammatory	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 statement (No. 333-260732) on Form S-8 of our report dated March 31, 2022, with respect to the consolidated financial statements of LianBio and subsidiaries.

/s/ KPMG LLP

New York, New York

March 31, 2022

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, 2021 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)) 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) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (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 31, 2022

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, 2021 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)) 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) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (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 31, 2022

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, 2021 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 31, 2022

By: /s/ Yizhe Wang

Yizhe Wang
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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, 2021 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 31, 2022

By: /s/ Yi Larson

Yi Larson
Chief Financial Officer
(Principal Financial and Accounting Officer)