

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

**AMENDMENT NO. 4  
to  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**LianBio**

(Exact name of registrant as specified in its charter)

**Cayman Islands**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**98-1594670**  
(I.R.S. Employer  
Identification Number)

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Telephone: (609) 486-2308**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Approximate date of commencement of proposed sale to the public:**

As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

## [Table of Contents](#)

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated October 28, 2021.

## 20,312,500 American Depositary Shares

## Representing 20,312,500 Ordinary Shares



**LianBio**

We are offering 20,312,500 American depositary shares ("ADSs"). Each ADS represents one Ordinary Share, par value \$0.000017100448 per share.

This is the initial public offering in the United States of LianBio, a Cayman Islands exempted holding company with headquarters and operations in both the United States and China. As a holding company, we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements. If any of our Chinese subsidiaries incurs 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 prospectus, 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 prospectus, 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 and \$5,000,000 in equity financing via capital contributions from its shareholder outside of China in February 2020, September 2020, December 2020 and October 2021, respectively, to fund its business operations in China. In the future, cash proceeds raised from overseas financing activities, including this offering, may be transferred by us to our Chinese subsidiaries via capital contribution or shareholder loans, as the case may be.

Throughout this prospectus, unless the context indicates otherwise, references to "LianBio" refer to LianBio, a holding company, together as a group with our subsidiaries, including our operating company subsidiaries. LianBio, LLC and Shanghai LianBio Development Co., Ltd., our U.S. and China-based operating subsidiaries, respectively, conduct our daily operations. Investors purchasing our ADSs in this initial public offering are purchasing equity securities of our Cayman Islands exempt holding company and are not purchasing equity securities of our subsidiaries that have business operations in the United States and China. No public market currently exists for our ADSs or Ordinary Shares.

We currently expect the initial public offering price to be between \$15.00 and \$17.00 per ADS. See "Underwriting" for a discussion of the factors to be considered in determining the initial offering price. We have applied to list the ADSs on the Nasdaq Global Market under the symbol "LIAN."

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), and a "smaller reporting company" as defined in the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings. See "Prospectus Summary—Implications of being an emerging growth company and a smaller reporting company."

*There are significant legal and operational risks associated with having the majority of our operations in China, including that changes in the legal, political and economic policies of the Chinese government, the relations between China and the United States, or Chinese or United States regulations may materially and adversely affect our business, financial condition, results of operations and the market price of our ADSs. Any such changes could significantly limit or completely hinder our ability to offer or continue to offer our ADSs to investors, and could cause the value of our ADSs to significantly decline or become worthless. Recent statements made and regulatory actions undertaken by China's government, including the recent enactment of China's new Data Security Law, as well as our obligations to comply with China's Cybersecurity Review Measures (revised draft for public consultation), regulations and guidelines relating to the multi-level protection scheme, Personal Information Protection Law 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 or list on a U.S. or foreign exchange. For more information on these risks and other risks you should consider before buying our ADSs, see "Risk Factors" beginning on page 21.*

**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

	Per ADS	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds before expenses, to us	\$	\$

(1) We have agreed to reimburse the underwriters for certain expenses. See "Underwriting."

To the extent that the underwriters sell more than 20,312,500 ADSs, the underwriters have the option to purchase up to an additional 3,046,875 ADSs from us at the initial public offering price less underwriting discounts and commissions.

The underwriters expect to deliver the ADSs against payment in New York, New York on or about , 2021.

*Joint Book-Running Managers*

**Goldman Sachs & Co. LLC**

**Jefferies**

**BofA Securities**

*Lead Manager*

**Raymond James**

Prospectus dated , 2021.

TABLE OF CONTENTS

	<b>Page</b>
<a href="#">Prospectus Summary</a>	1
<a href="#">Risk Factors</a>	21
<a href="#">Cautionary Note Regarding Forward-Looking Statements</a>	108
<a href="#">Use of Proceeds</a>	111
<a href="#">Dividend Policy</a>	113
<a href="#">Capitalization</a>	114
<a href="#">Dilution</a>	116
<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	119
<a href="#">Business</a>	134
<a href="#">Regulation</a>	189
<a href="#">Management</a>	227
<a href="#">Executive and Director Compensation</a>	237
<a href="#">Security Ownership of Beneficial Owners and Management</a>	250
<a href="#">Certain Relationships and Related Party Transactions</a>	253
<a href="#">Description of Share Capital</a>	258
<a href="#">Description of American Depositary Shares</a>	269
<a href="#">Ordinary Shares and American Depositary Shares Eligible for Future Sale</a>	281
<a href="#">Taxation</a>	286
<a href="#">Underwriting</a>	296
<a href="#">Legal Matters</a>	302
<a href="#">Experts</a>	302
<a href="#">Enforcement of Civil Liabilities</a>	302
<a href="#">Where You Can Find More Information</a>	305
<a href="#">Index to Consolidated Financial Statements</a>	F-1

## **ABOUT THIS PROSPECTUS**

We are responsible for the information contained in this prospectus and in any free writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide you with different information, and we and the underwriters take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date.

## **INDUSTRY AND MARKET DATA**

Although we are responsible for all disclosure contained in this prospectus, 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 prospectus 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 headings “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” in this prospectus.

## **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 prospectus 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 prospectus 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.

## **PRESENTATION OF FINANCIAL INFORMATION**

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

## **THE CONVERSIONS**

Immediately prior to the completion of this offering and after giving effect to the 5.8478-for-1 stock split effected on October 14, 2021, we will (i) convert all of our outstanding series seed preferred shares, par value \$0.0001 per share (the “Series Seed Preferred Shares”) into an aggregate of 32,162,900 of our Ordinary Shares, par value \$0.000017100448 per share (the “Ordinary Shares”) and (ii) convert all of our outstanding series A preferred shares, par value \$0.0001 per share (the “Series A Preferred Shares”) into an aggregate of 32,304,277 Ordinary Shares.

References to the “Conversions” throughout this prospectus refer to (i) the conversion of our Series Seed Preferred Shares into Ordinary Shares and (ii) the conversion of our Series A Preferred Shares into Ordinary Shares.

## PROSPECTUS SUMMARY

*This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our ADSs, and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes appearing elsewhere in this prospectus, before deciding to buy our ADSs. Unless the context requires otherwise, references in this prospectus to the "Company," "LianBio," "we," "us" and "our" refer to LianBio and its consolidated subsidiaries.*

### 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 preferential access to an innovative pipeline of more than 20 product candidates in development. In less than three years, 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 plan to initiate four registrational studies over the next 12 to 18 months to advance our product candidates towards regulatory approval in China.

### The China opportunity

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.

## Our pipeline

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.

### Global Development Status<sup>1</sup>

Therapeutic Area	Program	Indication	Phase 1	Phase 2	Phase 3/ Pivotal	Approved	Next step in China	Partner
Cardiovascular	Mavacamten	Obstructive Hypertrophic Cardiomyopathy (oHCM)					Initiate China bridging Phase 3 trial and PK study (conducted in parallel)	Bristol Myers Squibb
		Non-obstructive Hypertrophic Cardiomyopathy (nHCM)					Join BMS future global Phase 3 trial	
		Heart Failure with Preserved Ejection Fraction (HFpEF)					Join BMS future global Phase 3 trial	
Ophthalmology	TP-03	Demodex Blepharitis					Conduct China standalone Phase 3 trial	Tarsus
Oncology	NBTXR3 <sup>2</sup>	Head and Neck Squamous Cell Carcinoma (HNSCC)					Join NANORAY-312 global Phase 3 trial	NANOBIOTIX
		Solid Tumor IO Combinations					Join future global Phase 3 trial	
	Infigratinib <sup>3</sup>	Second-line Cholangiocarcinoma with FGFR2 Fusions					Explore development and patient access strategies	bridgebio
		First-line Cholangiocarcinoma with FGFR2 Fusions					Join ongoing PROOF-301 Phase 3 trial	
		Gastric Cancer with FGFR2 Amplification; Other Solid Tumors w FGFR Alterations <sup>4</sup>					Conduct China Phase 2a proof of concept trial	
	BBP-398	Solid Tumors Driven by Mutations in MAPK					Conduct China Phase 1 dose escalation trial	bridgebio navire
Inflammatory Disease	Omilancor	Ulcerative Colitis					Join future global Phase 3 trial	LANDOS
		Crohn's Disease					Join future global Phase 3 trial	
	NX-13	Ulcerative Colitis					Join future global Phase 3 trial	LYRA
	LYR-210	Chronic Rhinosinusitis (CRS)					Join future global Phase 3 trial	
Respiratory	Sisunatovir	Respiratory Syncytial Virus (RSV)					Join future global Phase 3 trial	REVIRAL

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 the Company. For more information regarding the risks related to our business operations and clinical and regulatory strategies, please see "Risk Factors—Risks related to our business and industry."
2. NBTXR3 has received European market approval (CE mark) in the European Union, which is not a part of our licensed territory, for the treatment of locally advanced soft tissue sarcoma. At present, we are not pursuing NBTXR3 in relation to this soft tissue sarcoma 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 gastric cancer and other FGFR-driven tumor standalone clinical trial in China. Separate investigator-sponsored Phase 2 clinical trial of infigratinib in FGFR-driven tumors is ongoing in the United States.

Our late-stage development pipeline is led by mavacamten, TP-03 and NBTXR3, each of which we intend to develop in our licensed territories in Greater China and other Asian markets. We have partnered with MyoKardia, Inc. ("MyoKardia," now a wholly-owned subsidiary of Bristol-Myers Squibb,

or “BMS”) to develop and commercialize mavacamten, an oral therapy for the treatment of obstructive hypertrophic cardiomyopathy (“oHCM”). Mavacamten met all primary and secondary endpoints in its pivotal Phase 3 clinical trial, demonstrating statistically significant and clinically meaningful improvements in symptoms, functional status and key aspects of quality of life. We intend to evaluate mavacamten in a Phase 3 registrational clinical trial in patients with oHCM, called EXPLORER-CN, in China and a simultaneous pharmacokinetics (“PK”) clinical trial in China and, if the data are consistent with the data generated in global trials, use the China data in combination with data generated in global trials conducted by MyoKardia to seek regulatory approval in China. We received clearance from the China National Medical Products Administration (the “NMPA”) to initiate the Phase 3 and PK trials and we anticipate initiating these trials in the first quarter of 2022.

We also plan to develop mavacamten in non-obstructive hypertrophic cardiomyopathy (“nHCM”) and heart failure with preserved ejection fraction (“HFpEF”).

We have partnered with Tarsus Pharmaceuticals, Inc. (“Tarsus”) to develop and commercialize TP-03 (lotilaner ophthalmic solution), an eye solution for the treatment of Demodex blepharitis (“DB”). DB is caused by an infestation of Demodex mites triggering inflammation and affecting approximately 43 million patients in China. There are currently no approved therapies for DB. 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, is ongoing. We plan to generate data in China to be used in combination with clinical data generated from the Saturn-1 and Saturn-2 pivotal trials conducted by Tarsus and, if such data are positive, to seek regulatory approval in Greater China. We anticipate initiating a Phase 3 clinical trial of TP-03 in China in the second half of 2022. We also plan to develop TP-03 for the treatment of Meibomian Gland Disease (“MGD”).

We have partnered with Nanobiotix S.A. (“Nanobiotix”) to develop and commercialize NBTXR3, a radiosensitizer 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. NBTXR3 is designed to enhance the effect of radiotherapy without resulting in additional side effects on surrounding healthy tissue. NBTXR3 may also prime the body’s immune response against cancer, and clinical activity has been observed across a number of different solid tumor types and in combination with immuno-oncology agents. 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 recently reported an 82.5% primary tumor objective response rate and 62.5% complete response rate from an ongoing Phase 1b extension clinical trial in head and neck (“H&N”) cancer. We plan to join the NBTXR3 development program by enrolling patients in China in five of Nanobiotix’s potential future global pivotal trials across certain indications and therapeutic combinations including immunotherapy, beginning with Nanobiotix’s announced planned Phase 3 NANORAY-312 clinical trial in locally advanced H&N cancer. We anticipate initiating the China portion of the NBTXR3 Phase 3 clinical trial in H&N cancer in the second half of 2022.

Our pipeline also includes six clinical-stage assets across oncology, inflammatory disease and respiratory indications:

- **Infigratinib (FGFR-selective TKI):** Infigratinib is approved in the United States for the treatment of patients with previously-treated locally advanced or metastatic unresectable cholangiocarcinoma (“CCA”) harboring a fibroblast growth factor receptor (“FGFR”) 2 fusion or rearrangement. We initiated a Phase 2a proof of concept clinical trial in China for FGFR2-amplified gastric cancer and other solid tumors with FGFR alterations in August 2021.



Additionally, we plan to join QED Therapeutics, Inc.'s ("QED") 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 are also exploring development and patient access strategies in our territories for infigratinib in previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or other rearrangement (second-line CCA).

- **BBP-398 (SHP2 inhibitor):** We received clearance from the NMPA to enroll patients in China in a Phase 1 monotherapy clinical trial of BBP-398 in advanced solid tumors. We also plan to advance BBP-398 into combination trials with targeted therapies, including potentially epidermal growth factor receptor ("EGFR") tyrosine kinase inhibitors ("TKI") and programmed cell death protein 1 ("PD-1") inhibitors, in the future.
- **LYR-210 (implantable drug matrix):** Based on its successful Phase 2 LANTERN clinical trial, Lyra Therapeutics, Inc. ("Lyra") has announced plans to advance LYR-210 into pivotal Phase 3 clinical trials, which we intend to join by enrolling patients in China.
- **Omilancor (LANCL2 agonist):** Based on supportive data from a Phase 2 clinical trial in ulcerative colitis ("UC"), Landos Biopharma, Inc. ("Landos") has announced plans to initiate two global Phase 3 clinical trials of omilancor in UC, PACIFY I and PACIFY II. We intend to participate in these trials by enrolling patients in China. Omilancor is also being studied by Landos for Crohn's disease ("CD"), currently in a Phase 2 clinical trial, and, should the program advance into Phase 3, we intend to participate in this future trial by enrolling patients in China.
- **NX-13 (NLRX1 agonist):** In April 2021, Landos initiated a Phase 1b clinical trial of NX-13 in patients with UC. Landos has also announced plans to study NX-13 in CD. If this program advances to Phase 3, we plan to participate in these future Phase 3 clinical trials of NX-13 in UC and CD by enrolling patients in China.
- **Sisunatovir (RSV fusion inhibitor):** ReViral Ltd. ("ReViral") is currently conducting Phase 2 clinical trials of sisunatovir in pediatric patients hospitalized due to respiratory syncytial virus ("RSV") infection and in immunocompromised patients. ReViral has also announced plans to study sisunatovir in elderly RSV patients. Should ReViral advance sisunatovir into pivotal Phase 3 clinical trials in pediatric and elderly patients, we plan to join these Phase 3 clinical trials by enrolling patients in China.

### Our strengths

Our goal is to become a leading global biopharmaceutical company focused on addressing critical unmet patient needs, initially in Greater China and other Asian markets. We leverage the following strengths to accomplish this goal.

***Diversified portfolio of clinically validated late-stage and highly innovative early- to mid-stage product candidates, providing multiple avenues of value creation for us and our partners.*** Our pipeline currently consists of nine compelling product candidates across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications, a majority of which are late-stage and have been clinically validated. Our late-stage, clinically validated pipeline is comprised of five product candidates: mavacamten, TP-03, NBTXR3, infigratinib and LYR-210, all of which have either obtained regulatory approval in certain jurisdictions and indications or have demonstrated achievement of statistically significant endpoints in controlled clinical trials. These product candidates are complemented by our earlier stage product candidates, BBP-398, omilancor, NX-13 and sisunatovir.



**Strategic and selective asset sourcing.** We have leveraged our deep scientific understanding, combined with region-specific development, regulatory and commercial insights, to select and in-license promising assets for development in our target markets. We were founded by Perceptive, a leading life science-focused investment firm with deep experience investing in biopharmaceutical companies and a global network within the biotechnology universe. In less than three years since our incorporation, we have in-licensed nine assets across five therapeutic areas, establishing a foundation for our platform. We continue to build momentum, including through our strategic partnership with BridgeBio, which provides us with preferential access to more than 20 current and future product candidates for development and commercialization in Greater China and other Asian markets.

**Execution capabilities across development and regulatory functions and strong commercial leadership.** Our clinical development, regulatory affairs and market access teams have deep experience and proven track records of bringing medicines to patients in China. We drive regional initiatives that work synergistically with our partners' global development strategies. We carry out development plans designed to both maximize value to our stakeholders and prioritize the needs of local patients, in some cases by leading local indication expansion studies and pursuing new combination approaches. Our team in aggregate has contributed to the development of more than 100 drugs that have been approved in China across multiple therapeutic areas.

**Asset-centric, cross-border partnership model.** We have built an asset-centric, cross-border platform to provide our partners with access to our regulatory and development expertise in our licensed territories. We seek to serve as an extension of our partners' global development strategies in order to maximize the value potential of our assets both in our licensed territories and globally. We have implemented both a partner and asset centric model that drives our execution, with project leadership at the asset level overlaying functional roles. We believe this fundamental cross-border, partner and asset centric approach differentiates us from our competitors operating in these markets.

**Highly experienced global management team.** Our management team consists of experienced industry leaders who have deep knowledge of the development, regulatory and commercial landscape in China and the United States, in addition to strong transactional and business development track records. We are led by Yizhe Wang, Ph.D., our Chief Executive Officer, who has significant experience leading organizations and designing and executing clinical development and commercialization strategies in the United States, Europe and China, with past roles at Eli Lilly and Company, GlaxoSmithKline plc and BMS. Debra Yu, M.D., our President and Chief Strategy Officer, is a recognized leader in cross-border U.S.-China life sciences transactions with 30 years of experience, including previous roles at Pfizer, WuXi AppTec Co., Ltd. and McKinsey & Company. Yi Larson, our Chief Financial Officer, has an extensive track record of successfully guiding biopharma corporate strategy across both operational and investment banking roles, with previous experience at Turning Point Therapeutics, Inc. and Goldman Sachs & Co. LLC.

**Broad network of institutional investors with deep sector knowledge.** We have raised over \$380 million in equity financing from a leading syndicate of investors based in the United States and China. We believe our relationships with these investors will contribute to our success in sourcing value-creating partnerships. Our investor base is comprised of leading firms in the United States, including our founder, Perceptive, and in Greater China.

## Our vision and strategy

Our vision is to bring novel therapies with the ability to address critical unmet needs to historically underserved patients in Greater China and other Asian markets. We plan to do so by continuing to pursue the following strategies:

**Advance our lead product candidates, mavacamten, TP-03 and NBTXR3, to seek regulatory approval and commercialization in our licensed territories, while advancing our additional product candidates, infgratinib, BBP-398, LYR-210, omilancor, NX-13 and sisunatovir, toward regulatory approval via bespoke development strategies.** We have designed development and regulatory strategies that we believe will enable us to leverage data generated in our partners' global registrational trials, as applicable, and we are executing clinical development programs that account for considerations specific to our licensed territories, including local clinical practice, patient preferences and diagnostic equipment availability, with the goal of obtaining regulatory approval and maximizing patient reach for each therapeutic candidate. In addition, we believe we can capture additional value from our other territories in Asia through a fit-for-purpose development, registration and commercialization approach.

**Establish integrated launch capabilities and strategically build commercial infrastructure customized to each of our assets.** Our commercial strategy aims to efficiently maximize patient reach for each of our assets. For therapies we plan to commercialize on our own, we intend to build and utilize a focused salesforce in China in order to promote our products, if approved. We believe we will be able to leverage the commercial infrastructure we create for our lead programs to lay the groundwork for the future launch of programs across our portfolio. For other therapies, we may pursue a co-commercialization strategy such as through our Pfizer collaboration, which will position us to access Pfizer's extensive sales network and established commercial organization in the region.

**Continue to deepen our pipeline in existing therapeutic areas with potentially transformative medicines that fit with our expertise, portfolio and strategy.** We seek to anchor each therapeutic focus area with a core asset and then build around these core areas. We intend to collaborate with world-class partners, selecting programs with a strong scientific basis and compelling clinical data to continue building our portfolio with innovative medicines that have the potential to become new standards of care in Greater China and other Asian markets.

## Risk factors summary

There are a number of risks that you should understand before making an investment decision regarding this offering. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth in the section titled "Risk Factors" before deciding whether to invest in our ADSs. These risks include, but are not limited to:

- 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 prospectus 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 inspected by the PCAOB and, as such, in the future investors may be deprived of the benefits of such inspection. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act (the "HFCA Act") if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely, and as a

result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable 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 instead of three.

- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.
- The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs. For additional information regarding the risks associated with having the majority of our operations in China, please see "Risk Factors—Risks Related to Doing Business in China and Our International Operations" beginning on page 21.
- Both recent and future economic, political and social conditions, as well as governmental policies and regulatory actions implemented in China, could affect our ability to operate our business. The Chinese government has provided new guidance on China-based companies raising capital outside of China. 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.
- Changes in the legal, political and economic policies of the Chinese government, the relations between China and the United States, or Chinese or United States regulations may materially and adversely affect our business, financial condition, results of operations and the market price of our ADSs, which could cause the value of our ADSs to significantly decline or to become worthless. Any such changes may take place quickly and with very little notice. Recent statements made and regulatory actions undertaken by China's government, including the recent enactment of China's new Data Security Law, as well as our obligations to comply with China's Cybersecurity Review Measures (revised draft for public consultation), regulations and guidelines relating to the multi-level protection scheme, Personal Information Protection Law 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 or list on a U.S. or foreign exchange. For additional information, see "Risk Factors—Risks Related to Doing Business in China and Our International Operations" beginning on page 21.
- As of the date of this prospectus, we are not required to obtain approval or prior permission of this offering from the China Securities Regulatory Commission (the "CSRC") or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect. As of the date of this prospectus, neither we nor any of our subsidiaries, including but not limited to our operating company subsidiaries, have been informed by the CSRC, Cybersecurity Administration of China (the "CAC") or any other Chinese regulatory authority of any requirements, approvals or permissions that we should obtain prior to this offering. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future.
- The CSRC has announced its intention to implement new rules for China-based companies seeking to conduct initial public offerings in foreign markets. While such rules have not yet

gone into effect, the Chinese government may exert more oversight and control over offerings that are conducted overseas and foreign investment in China-based issuers, which could significantly limit or completely hinder our ability to offer or continue to offer our ADSs to investors and could cause the value of our ADSs to significantly decline or become worthless.

- 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.
- Even if we consummate this offering, 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 for you 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 harmed.
- 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.
- Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.
- 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.
- 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, 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. Additionally, Perceptive and its affiliates will continue to exercise significant influence over our Company after this offering, which may limit your ability to influence corporate matters and could delay or prevent a change in corporate control. Perceptive and its affiliates beneficially own 62.4% of our ordinary shares prior to this offering, based on the number of shares outstanding as of September 30, 2021. Two of our current non-employee directors are affiliated with Perceptive. In connection with this offering, we have 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 owns as of the completion of this offering. See “Certain Relationships and Related Party Transactions—Director Nomination Agreement” for additional information. 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 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.

## **Regulatory Developments**

### Proposed Cybersecurity Measures

On July 10, 2021, the Cyberspace Administration of China published the draft amendment to the Cybersecurity Review Measures (Revised Draft for Public Consultation), which is expected to replace the current Cybersecurity Review Measures after it is adopted and becomes effective. The draft measures stipulate that, among other items, if an issuer is classified as a “critical information infrastructure operator” or a “data processing operator” as defined therein and such issuer possesses the personal information of more than one million users and intends to be listed on a securities exchange in a foreign country, it must complete a cybersecurity review. Alternatively, relevant governmental authorities in China may initiate a cybersecurity review if such governmental authorities determine an operator’s cyber products or services, data processing or potential listing in a foreign country affect or may affect national security. The draft measures were released for public comment only, and the draft provisions and anticipated adoption or effective date are subject to changes and thus its interpretation and implementation remain substantially uncertain. We cannot predict the impact of the draft measures, 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.

The exact scope of “critical information infrastructure operators” and “data processing operators” under the draft measures and the current regulatory regime remains unclear, and the Chinese government authorities may have wide discretion in the interpretation and enforcement of these laws. Currently, the draft 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 or may be interpreted to affect national security. As of the date of this prospectus, we have not been informed by any relevant Chinese government authorities that we are identified as or considered a “critical information infrastructure operator” or “data processing operator.” We are also not aware of any requirement that we should file for a cybersecurity review, nor have we received any inquiry, notice, warning, sanction in such respect or any regulatory objections to this offering. 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 data processing operator under the Chinese cybersecurity laws and regulations in the future, or that the draft 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 “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, and adversely impact our operating results,” “Risk Factors—Risks Related to Doing Business in China and Our International Operations—Compliance with China’s new Data Security Law, Cybersecurity Review Measures (revised draft for public consultation), Personal Information Protection Law, 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 “Risk Factors—Risks Related to Doing Business in China and Our International Operations—The approval of the China Securities Regulatory Commission or other Chinese regulatory agencies may be required in connection with this offering under Chinese law.”

#### Potential CSRC Approval Required for This Offering

On July 6, 2021, the relevant Chinese government authorities published the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities and increased supervision of overseas listings by China-based companies, and propose to take effective measures, such as promoting the construction of relevant regulatory systems to regulate the risks and incidents faced by China-based overseas-listed companies. As of the date of this prospectus, no official guidance or related implementation rules have been issued in relation to these recently issued opinions and the interpretation and implementation of these opinions remain unclear at this stage. We could be subject to additional requirements that we obtain pre-approval to pursue this offering or any future offerings from the CSRC and potentially other regulatory authorities. Based on existing Chinese laws and regulations, we are not required to obtain any pre-approval from the CSRC to conduct this offering, subject to interpretation of the existing Chinese laws and regulations by the Chinese government authorities. As of the date of this prospectus, we have not received any inquiry, notice, warning, sanction or any regulatory objections to this offering from the CSRC. For additional information, see “Risk Factors—Risks Related to Doing Business in China and Our International Operations—The approval of the China Securities Regulatory Commission or other Chinese regulatory agencies may be required in connection with this offering under Chinese law.”

#### 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 9<sup>th</sup> Floor, Kerry Parkside, 1155 Fangdian Road, Unit 901-902, Shanghai, People's Republic of China 201204. Our telephone number at this address is (021) 6132 9798. 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 215, Princeton, New Jersey 08540 and our telephone number is (609) 486-2308.

Our website is [www.lianbio.com](http://www.lianbio.com). Information contained on our website or that can be accessed through our website is not a part of, and is not incorporated by reference in, this prospectus.

### **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 prospectus, 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 prospectus, 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 and \$5,000,000 in equity financing via capital contributions from its shareholder outside of China in February 2020, September 2020, December 2020 and October 2021, respectively, to fund its business operations in China. In the future, cash proceeds raised from overseas financing activities, including this offering, 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 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.

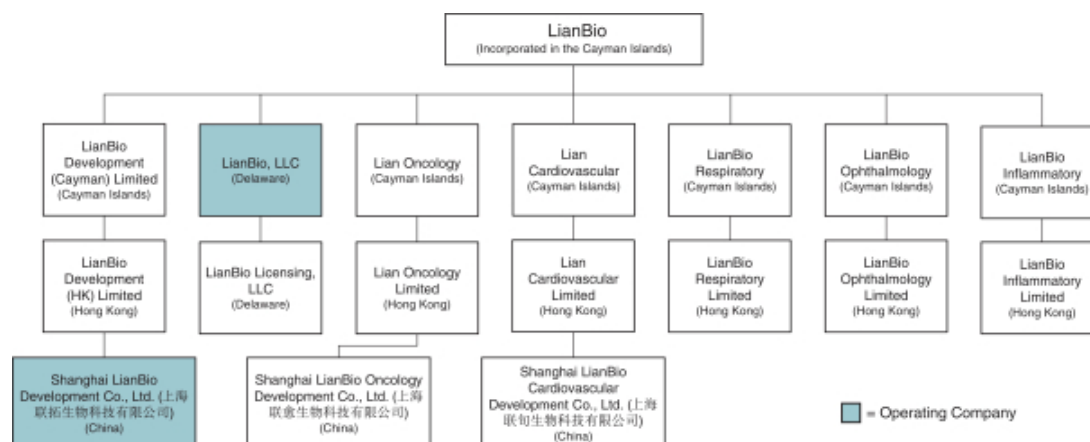
Renminbi is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use their potential future renminbi revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of renminbi 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 “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 “Taxation—China taxation” for more details.

## Organizational structure

The following diagram depicts our corporate structure. As of the date of this prospectus, 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 under “Certain Relationships and Related Party Transactions.” 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.

### Implications of being an emerging growth company and a smaller reporting company

As a company with less than \$1.07 billion in total annual gross revenues during our most recently completed fiscal year, we qualify as an “emerging growth company” as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding shareholder advisory votes on executive compensation;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- reduced disclosure of financial information in this prospectus, including only two years of audited financial information and two years of selected financial information.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We will remain an emerging growth company until the earlier

to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer,” under the rules of the U.S. Securities and Exchange Commission (the “SEC”), which means the market value of our equity securities that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

For so long as we remain an emerging growth company, we are permitted to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved and an exemption from compliance with the requirements regarding the communication of critical audit matters in the auditor’s report on financial statements. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise 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,” meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

The offering	
ADSs offered by us	20,312,500 ADSs, each ADS representing one Ordinary Share.
Underwriters' option to purchase additional ADSs	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an aggregate of 3,046,875 additional ADSs, less estimated underwriting discounts and commissions.
ADSs to be outstanding immediately after completion of this offering	20,312,500 ADSs (or 23,359,375 ADSs if the underwriters exercise their option to purchase additional ADSs in full).
Ordinary Shares to be outstanding immediately after completion of this offering	105,257,014 Ordinary Shares (or 108,303,889 Ordinary Shares if the underwriters exercise their option to purchase additional ADSs in full). Immediately after completion of this offering and assuming the underwriters do not exercise their option to purchase additional ADSs, approximately 19.3% of our Ordinary Shares represented by ADSs will be held by our public shareholders.
The ADSs	<p>Each ADS represents one Ordinary Share. The ADSs may be evidenced by ADRs.</p> <p>The depositary or its nominee will hold the Ordinary Shares underlying your ADSs, and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and the holders and beneficial owners of ADSs.</p> <p>If we declare dividends on our Ordinary Shares, the depositary will pay you the cash dividends and other distributions it receives on our Ordinary Shares, after deducting its fees and expenses.</p> <p>You may turn in your ADSs to the depositary for cancellation and receipt of the corresponding Ordinary Shares. The depositary will charge you fees for the cancellation of ADSs and delivery of the corresponding Ordinary Shares.</p>

	<p>We may amend or terminate the deposit agreement without your consent. If an amendment becomes effective and you continue to hold your ADSs, you will be bound by the deposit agreement as amended.</p> <p>To better understand the terms of the ADSs, you should carefully read “Description of American Depositary Shares” in this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement of which this prospectus forms a part.</p>
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$296.8 million, or approximately \$342.1 million if the underwriters exercise their option to purchase additional ADSs in full, at an assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from the sale of ADSs in this offering to advance the clinical development of our multiple product candidates, support commercial and launch preparation efforts, fund new business development and for working capital and other general corporate purposes. See “Use of Proceeds” for additional information.</p>
Dividend policy	<p>We do not expect to pay any dividends on our ADSs in the foreseeable future. See “Dividend Policy” for additional information.</p>
Risk factors	<p>You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our ADSs.</p>
Depository	<p>Citibank, N.A.</p>
Proposed Nasdaq Global Market trading symbol	<p>“LIAN”</p>
<p>Except as otherwise indicated, the number of Ordinary Shares to be outstanding after this offering is based on 84,944,514 Ordinary Shares outstanding as of June 30, 2021 after giving effect to the Conversions, and excludes:</p> <ul style="list-style-type: none"> <li>• 11,670,901 Ordinary Shares issuable upon the exercise of options outstanding as of June 30, 2021 pursuant to our 2019 Equity Incentive Plan (the “2019 Equity Incentive Plan”) at a weighted-average exercise price of \$5.58 per share, of which options to purchase 1,309,907 Ordinary Shares were exercised subsequent to June 30, 2021;</li> </ul>	

- 582,688 Ordinary Shares issuable upon the exercise of warrants outstanding at June 30, 2021 at a weighted-average exercise price of \$0.000017100448 per share;
- 14,174,972 Ordinary Shares reserved for future issuance under our 2021 Equity Incentive Plan (the “2021 Equity Incentive Plan”), which will become effective in connection with this offering; and
- 315,216 Ordinary Shares remaining available for issuance under the 2019 Equity Incentive Plan, which shares will be added to the shares available for issuance under our 2021 Equity Incentive Plan in connection with this offering.

Unless otherwise indicated or the context otherwise requires, all information in this prospectus assumes or gives effect to:

- a 5.8478-for-1 forward stock split of our Ordinary Shares effected on October 14, 2021;
- the Conversions;
- the effectiveness of our fifth amended and restated memorandum and articles of association, which will occur immediately upon the closing of this offering;
- no issuance or exercise of options or warrants on or after June 30, 2021; and
- no exercise by the underwriters of their option to purchase up to an additional 3,046,875 ADSs in this offering.

**Summary consolidated financial data**

The following summary consolidated statement of operations and comprehensive loss data for the period from July 17, 2019 (date of incorporation) through December 31, 2019 and the year ended December 31, 2020 have been derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary consolidated statements of operations data and comprehensive loss data for the six months ended June 30, 2020 and 2021 and the summary consolidated balance sheet data as of June 30, 2021 have been derived from our unaudited financial statements and related notes included elsewhere in this prospectus. Our consolidated financial statements appearing in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). In the opinion of management, the unaudited financial statements reflect all adjustments, which include only normal, recurring adjustments necessary for a fair presentation of such financial data.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our operating results for the six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the entire year ending December 31, 2021. The following information should be read in conjunction with the sections titled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with our consolidated financial statements and the related notes thereto, each included elsewhere in this prospectus.



[Table of Contents](#)

Consolidated statement of operations and comprehensive loss data (in thousands, except share and per share amounts):	Period from July 17, 2019 (date of incorporation) to December 31, 2019	Year ended December 31, 2020	Six months ended June 30, 2020 (unaudited)	Six months ended June 30, 2021 (unaudited)
<b>Operating expenses:</b>				
Research and development	\$ 22,624	\$ 120,885	\$ 1,258	\$ 146,383
General and administrative	1,713	13,984	5,363	13,607
Total operating expenses	24,337	134,869	6,621	159,990
<b>Operating loss</b>	(24,337)	(134,869)	(6,621)	(159,990)
Other income (expense):				
Interest income (expense), net	11	(4,854)	13	139
Other (expense) income, net	(1)	123	(18)	(192)
<b>Net loss before income taxes</b>	(24,327)	(139,600)	(6,626)	(160,043)
Income taxes	4	4	2	1,950
<b>Net loss</b>	(24,331)	(139,604)	(6,628)	(161,993)
Other comprehensive loss:				
Foreign currency transaction (loss), net of tax	—	(40)	(53)	130
<b>Comprehensive loss</b>	<u>\$ (24,331)</u>	<u>\$ (139,644)</u>	<u>\$ (6,681)</u>	<u>\$ (161,863)</u>
Net loss per share attributable to ordinary shareholders, basic and diluted <sup>(1)</sup>	<u>\$ (4.99)</u>	<u>\$ (11.58)</u>	<u>\$ (0.65)</u>	<u>\$ (7.91)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted <sup>(1)</sup>	<u>4,872,447</u>	<u>12,051,433</u>	<u>10,265,811</u>	<u>20,477,337</u>
Pro forma net loss per share attributable to ordinary shareholders, basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (1.45)</u>		<u>\$ (1.54)</u>
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to ordinary shareholders, basic and diluted (unaudited) <sup>(1)</sup>		<u>96,521,487</u>		<u>105,257,014</u>
<sup>(1)</sup> For the calculation of our basic and diluted net loss per share attributable to ordinary shareholders, unaudited basic and diluted pro forma net loss per share and weighted-average number of shares used in the computation of the per share amounts, see Note 8 and Note 9 to our financial statements included elsewhere in this prospectus.				

(in thousands)	As of June 30, 2021		
	Actual	Pro Forma <sup>(1)</sup>	Pro Forma, as Adjusted <sup>(2)(4)</sup>
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and restricted cash	\$ 162,624	\$ 162,624	\$ 459,424
Total assets	168,645	168,645	465,445
Working capital <sup>(3)</sup>	104,291	104,291	401,091
Total liabilities	63,317	63,317	63,317
Redeemable convertible preferred shares	352,729	—	—
Total shareholders' (deficit) equity	(247,401)	105,328	402,128

(1) The pro forma balance sheet data gives effect to the Conversions.

(2) The pro forma as adjusted balance sheet data reflects the pro forma adjustments described in footnote (1) as well as the receipt of \$296.8 million in net proceeds from the sale of 20,312,500 ADSs in this offering, based upon an assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus.

(3) We define working capital as current assets less current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

(4) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and restricted cash, total assets, working capital and total shareholders' equity (deficit) by approximately \$18.9 million, assuming that the number of ADSs offered, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 in the number of ADSs offered would increase (decrease) each of our pro forma cash, cash equivalents and restricted cash, total assets, working capital and total shareholders' equity (deficit) by approximately \$14.9 million, assuming the assumed initial public offering price per ADS as set forth on the cover of this prospectus remains the same and after deducting the estimated underwriting discounts and commissions. The pro forma information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

## RISK FACTORS

*Investing in our ADSs involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this prospectus, including our consolidated financial statements and their related notes appearing at the end of this prospectus, before deciding to invest in our ADSs. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Cautionary Note Regarding Forward-Looking Statements."*

### **Risks Related to Doing Business in China and Our International Operations**

***Changes in the political and economic policies of the Chinese government or in relations between China and the United States may materially and adversely affect our business, financial condition, results of operations 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 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 SEC has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. 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 United States, as well as 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.***

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

***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 conduct clinical activities and have business operations both in the United States and 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 drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, 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 drug products 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 has 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 by China. However, it is possible that the Company's periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and 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 U.S. 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," it 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 the recent U.S.-China tension 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.

***Compliance with China's new Data Security Law, Cybersecurity Review Measures (revised draft for public consultation), Personal Information Protection Law, 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.***

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new 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.

Additionally, China's Cyber Security Law 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 China adopt a multi-level protection scheme (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.

Recently, the Cyberspace Administration of China has taken action against several Chinese internet companies in connection with their initial public offerings 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, the Cyber Security Law and the Measures on Cybersecurity Review, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests." On July 10, 2021, the Cyberspace Administration of China published a revised draft of the Cybersecurity Review Measures, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

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 this could lead to us delisting from the U.S. stock market.

Also, recently, the National People's Congress released the Personal Information Protection Law, which will become effective on November 1, 2021. The Personal Information Protection Law 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 Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who 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 Personal Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or pseudonymized health data for clinical trials in compliance with local regulations.

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 and the Data Security Law 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, including engaging in follow-on offerings of our securities in the U.S. market once we are a public company.

***The approval of the CSRC or other Chinese regulatory agencies may be required in connection with this offering under Chinese law.***

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (the "M&A Rules") purport to require offshore special purpose vehicles that are controlled by Chinese companies or individuals and that have been formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of Chinese domestic companies or assets in exchange for the shares of the offshore special purpose vehicles shall obtain CSRC approval prior to publicly listing their securities on an overseas stock exchange.

Based on our understanding of the Chinese laws and regulations in effect at the time of this prospectus, we will not be required to submit an application to the CSRC for its approval of this offering

and the listing and trading of our ADSs on the Nasdaq under the M&A Rules. However, there remains some uncertainty as to how the M&A Rules will be interpreted or implemented, and its opinions summarized above are subject to any new laws, rules and regulations or detailed implementations and interpretations in any form relating to the M&A Rules. We cannot assure you that relevant Chinese government agencies, including the CSRC, would reach the same conclusion.

Furthermore, on July 6, 2021, the General Office of the Central Committee of the Communist Party of China 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 and Data Security Law. See “Regulation—Government regulation of pharmaceutical product development and approval—Data privacy and data protection” for more details. As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure you 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. Notwithstanding the foregoing, as of the date of this prospectus, we are not aware of any Chinese laws or regulations in effect requiring that we obtain permission from any Chinese authority to issue securities to foreign investors, and we have not received any inquiry, notice, warning, sanction or any regulatory objection to this offering from the CSRC, the CAC or any other Chinese authorities that have jurisdiction over our operations.

Based on the above and our understanding of the Chinese laws and regulations currently in effect as of the date of this prospectus, we are not required to submit an application to the CSRC or the CAC for the approval of this offering and the listing and trading of our ADSs on the Nasdaq. 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 the CSRC, CAC or any other regulatory authority is required for this offering, we may face sanctions by the CSRC, the CAC or other Chinese regulatory agencies. These regulatory agencies 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 the proceeds from this offering 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. The CSRC, the CAC or other Chinese regulatory agencies also may take actions requiring us, or making it advisable for us, to halt this offering before settlement and delivery of the ADSs. Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that settlement and delivery may not occur. In addition, if the CSRC, the CAC or other regulatory agencies later promulgate new rules requiring that we obtain their approvals for this offering, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such an approval requirement could have a material adverse effect on the trading price of the ADSs.

***Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, 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 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.

For further information regarding government regulation in China and other jurisdictions, see "Regulation—Government regulation of pharmaceutical product development and approval," "Regulation—Coverage and reimbursement" and "Regulation—Other healthcare laws."

***Although the audit report included in this prospectus 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, future investors may be deprived of such inspections, which could result in limitations or restrictions to our access of the U.S. capital markets. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act or the Accelerating Holding Foreign Companies Accountable Act if the SEC subsequently determines our audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely, and as a result, U.S. national securities exchanges, such as the Nasdaq, may determine to delist our securities. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable 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 instead of three.***

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 their 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 component 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.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress which, if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges ("EQUITABLE") Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges such as the Nasdaq of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted. Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act (the "HFCA Act"), which 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. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020. 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 department 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. On March 24, 2021, the SEC adopted interim final rules relating to the implementation of certain disclosure and documentation requirements of the HFCA Act. We will be required to comply with these rules if the SEC identifies us as having a "non-inspection" year (as defined in the interim final rules) under a process to be subsequently established by the SEC. The SEC is assessing how to implement other requirements of the HFCA Act, including the listing and trading prohibition requirements described above. Under the HFCA Act, 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 Accelerating Holding Foreign Companies Accountable 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 instead of three. On September 22, 2021, the PCAOB adopted a final rule implementing the HFCAA, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCAA, 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.

While we understand that there has been dialogue among the China Securities Regulatory Commission (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. 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 geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

***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 waste water, 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 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 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. 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. It 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 capital investments or changes in tax regulations that are currently 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 enjoy than 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. For further information regarding

healthcare reform and the changes in the drug review and approval process in China, see “Regulation—Government regulation of pharmaceutical product development and approval” and “Regulation—Coverage and reimbursement.”

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, including proceeds from this offering.***

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 State Administration for Market Regulation 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 you 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 use the proceeds we receive from this offering and to capitalize or otherwise 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 you 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 Companies 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 (the “Prior Reporting Rules”) 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 (the “Security Review Rules”) 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 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. To date, we have not received any financial incentives from local governments in China. 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. 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. To the extent we receive any financial incentives from local governments in China in the future, the 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 Chinese 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 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 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 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 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 have 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 buying and 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 current 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 is required on the basis that the current offering has commercial purposes and is 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 the current offering 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 stock incentive plan will be subject to such regulation. We plan to assist our employees to register their stock options or shares. However, any failure of our Chinese individual beneficial owners and holders of stock 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. 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 period from July 17, 2019 (date of incorporation) to December 31, 2019 and for the year ended December 31, 2020, our net losses were \$24.3 million and \$139.6 million, respectively. For the six months ended June 30, 2020 and 2021, our net losses were \$6.6 million and \$162.0 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 you to lose all or part of your investment.

***Our business model is designed to continue to in-license additional product candidates for development. Even if we consummate this offering, 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.***

To date, we have financed our activities primarily through private placements. Through September 30, 2021, we have raised over \$383 million in equity financing. Our operations have consumed substantial amounts of cash since our incorporation. The net cash used in our operating activities was \$11.7 million and \$98.1 million for the period from July 17, 2019 (date of incorporation) to December 31, 2019 and for the year ended December 31, 2020, respectively. The net cash used in our operating activities was \$6.7 million and \$94.8 million for the six months ended June 30, 2020 and 2021, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our current clinical-stage product candidates and seek regulatory approval for these and other future product candidates. Our business model is designed to continue to in-license additional product candidates for development, and we expect to make significant upfront payments, milestone payments, and/or royalty payments to our current and any future licensing partners as we continue to advance the development and commercialization of our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We have also incurred and may 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 and restricted cash as of June 30, 2021, combined with the net proceeds from this offering, 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.***

Even if we consummate this offering, we will need to continue to rely on additional financing to achieve our business objectives. 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our 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. 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 for you 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. We have not yet 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 harmed.***

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 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 other 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 National Medical Products Administration of China (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 need to 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, potentially having 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.

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 other of our product candidates, we will not be able to market our product candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our product candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials or development programs. In addition, if manufacturing or other issues result in a supply shortage of any treatments or any other combination therapeutics, we may not be able to complete clinical development of NBTXR3 or BBP-398 and/or another of our product candidates on our current timeline or at all.

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.

***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 and BeiGene, Ltd., 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. is developing a treatment for oHCM. 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 Limited 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. 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 have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Future 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 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, preclinical studies and clinical trials that could delay or terminate our clinical trials, or delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- 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, including 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 from the China Human Genetic Resources Administrative Office (“HGRAO”) 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 reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (“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;
- clinical trials may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide to abandon product development programs, or we may decide, or regulators may require us, to conduct additional clinical trials;
- 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 be unable to employ a companion diagnostic test to identify patients in a timely manner, or at all, who are likely to benefit from our product candidates;

## [Table of Contents](#)

- 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, HGRAO 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, 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 depends 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 Therapeutics, Inc. ("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. 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 would result in 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;



## [Table of Contents](#)

- 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, 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 after this offering.

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 you or others

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.

***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). The known adverse events for BBP-398 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;
- 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 create or revise a medication guide outlining the risks of such side effects for distribution to patients;
- 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 may 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. 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 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, 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 letter 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 will be 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 transition into operating 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 drug product 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 drug products.

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' 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' contract manufacturing organizations ("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), terrorist attacks 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, 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.

In addition, certain of our product candidates, including LYR-210, could be reviewed for regulatory approval via the medical device pathway as opposed to the pharmaceutical candidate pathway. The NMPA and comparable regulatory authorities in other jurisdictions could decide to classify these product candidates as either a medical device or a drug, and such classification could impact the regulatory framework of such product's clinical development. Our development and commercialization plan for these product candidates is based on the assumption that they will be approved and classified as drugs. If any of our product candidates are considered to be medical



devices in China, their development and commercialization process could potentially be longer and more costly than we anticipated. In addition, medical devices in China are not qualified for reimbursement under the NRDL, but are instead reimbursed either indirectly through reimbursement of medical service fees or directly by the Basic Medical Insurance if they are consumables/disposables. Our sales forecast for these product candidates may change if they were unable to be reimbursed separately by the Basic Medical Insurance.

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 or a related companion diagnostic is suitable to identify appropriate patient populations;
- 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 HGRAO or comparable regulatory authorities, or to obtain the HGRAO'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 ("ICH-GCP") and the requirements of China GCP imposed by the NMPA;

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

In addition, even if we were to obtain approval, regulatory authorities may revoke approval, may approve any of our product candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our drugs or indirectly limit our ability to charge or change the price of our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the NMPA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in China, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our product candidates, we may be subject to penalties.***

If the NMPA or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any such drug 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 drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials for the surveillance and monitoring the safety and efficacy of the drug.

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 drug products, 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 a 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, and 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 of the People's Republic of China (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. These 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 (as defined below), the Personal Information Protection Law (as defined below), and various implementing regulations and standards.

Under the Cyber Security Law and the Measures on Standard, Safety and Service of the National Medical Care Big Data (Tentative) (the "Measures on Health and Medical Big Data"), 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 Standing Committee of the National People's Congress of the People's Republic of China ("SCNPC") promulgated the Data Security Law of the People's Republic of China (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 Personal Information Protection Law (the "Personal Information Protection Law"), which was promulgated in August 2021 and will become 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, 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 in and outside of China.

Furthermore, in July 2021, the Cybersecurity Administration of China, China’s top cyberspace regulator, issued a proposed amendment to the Cybersecurity Review Measures (“Cybersecurity Review Measures”) which have been in effect since June 1, 2020. Under the proposed amendment, the scope of entities required to undergo cybersecurity review to assess national security risks that arise from data processing activities would be expanded to include all critical information infrastructure operators who purchase network products and services and all data processors carrying out data processing activities that affect or may affect national security. In addition, the draft amendment proposed that all such entities that maintain or store the personal information of more than 1 million users and undertake a public listing of securities in a foreign country would be required to pass cybersecurity review, which would focus on the potential risk of core data, important data, or a large amount of personal information being stolen, leaked, destroyed, illegally used or exported out of China, or critical information infrastructure being affected, controlled or maliciously used by foreign governments after such a listing.

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 of the People’s Republic of China (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 out 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 HGRAO 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 HGRAO 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 HGRAO to take rectification measures and was also banned by the HGRAO from submitting any clinical trial applications until the HGRAO 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 HGRAO 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 (the "MOST"), significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in 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. In December 2020, the NHSA organized a new round of price negotiation with drug companies and 119 new drugs were included in the 2020 NRDL, which resulted in an average price reduction of over 50.6%.

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 of 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, or "BMS"), TP-03 from Tarsus Pharmaceuticals, Inc. ("Tarsus"), infigratinib from 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 sub-licensed 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 sub-license. 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. Additionally, Perceptive and its affiliates will continue to exercise significant influence over us after this offering, which may limit your ability 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. Prior to this offering, entities affiliated with Perceptive beneficially owned approximately 62.4% of our Ordinary Shares, and after giving effect to this offering, entities affiliated with Perceptive will beneficially own approximately 50.5% of our Ordinary Shares (including Ordinary Shares represented by our ADSs), or approximately 49.1% if the underwriters exercise their option to purchase additional ADSs in full. Entities affiliated with Perceptive have indicated an interest in purchasing an aggregate of up to \$35.0 million of our ADSs in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to these entities, or these entities may determine to purchase more, less or no shares in this offering. Assuming (i) an initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) such entities purchase in full the \$35.0 million of our ADSs they have indicated an interest in purchasing, following this offering, such entities will beneficially own 52.6% of our Ordinary Shares (including Ordinary Shares represented by our ADSs), or approximately 51.1% if the underwriters exercise their option to purchase additional ADSs in full. If entities affiliated with Perceptive control a majority of the voting power of our outstanding Ordinary Shares after the completion of this offering, we would be a controlled company (within the meaning of the Nasdaq rules). If we qualify as a controlled company after this offering 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;

## [Table of Contents](#)

- 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. See "Management—Board Committees."

In addition, two of our non-employee directors are affiliated with Perceptive. As a result, even after this offering, whether or not Perceptive purchases ADSs in this offering, Perceptive will have 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 you 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 and BridgeBio, 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.

For additional information regarding the ownership of our outstanding Ordinary Shares by Perceptive and its affiliates, see the section titled "Security Ownership of Beneficial Owners and Management" included elsewhere in this prospectus.

***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 may 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 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 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. 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 Good Laboratory Practices ("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 you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with ICH-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 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 an 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 expect to source our clinical and commercial drug supply of mavacamten through a supply agreement with BMS, 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 expect to source 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 sub-licensors. 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 sub-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.

***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 drug products. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products 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 sub-licensors. 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 drug products 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 “Chinese 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 12 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 you 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 sub-licensed 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 ("NCE"). 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 Chinese 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 Chinese 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 materially 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 Chinese 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 Chinese 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. As of the date of this prospectus, no operational details have been published 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 September 30, 2021, we had eleven trademark applications pending in Mainland China, four trademarks registered in Hong Kong, two trademarks registered in Singapore, two trademark applications pending in the United States, four trademark applications pending in Taiwan, four trademark applications pending 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, regardless 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 drug products. 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 our ADSs and This Offering**

***We have broad discretion to determine how to use the net proceeds from this offering and may use the proceeds in ways that may not enhance our results of operations or the price of the ADSs.***

Although we currently intend to use the net proceeds from this offering in the manner described in the section titled “Use of Proceeds” in this prospectus, our management will have broad discretion over the use of net proceeds from this offering, and we could spend the net proceeds from this offering in ways the holders of the ADSs may not agree with or that do not yield a favorable return. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. You will not have the opportunity, as part of your investment decision, to assess whether proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of this offering.

***We are eligible to be treated as 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 eligible to be treated as an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and we may 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 for up to five years, 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 may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

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 will incur significantly increased costs as a result of operating as a U.S.-listed public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company in the United States, we will incur significant legal, accounting and other expenses globally that we did not incur previously. These expenses will likely be even more significant 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance, 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 will be 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 will be 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, potentially 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. 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.

***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. In particular, the China legal system is based on written statutes and prior court decisions have limited value as precedents. 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 Central Committee of the Communist Party of China 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. It is especially difficult for us to accurately predict the potential impact to the Company of new legal requirements in China because the China legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

***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, United States-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.

***We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our 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, you are not likely to receive any dividends on your ADSs at least in the near term, and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our investors purchased their ADSs.

***There has been no public market in the United States for our Ordinary Shares or ADSs prior to this offering and an active trading market may not develop, and you may not be able to resell our ADSs at or above the price you paid, or at all.***

Prior to this offering, there has been no public market in the United States for our Ordinary Shares or ADSs. We have applied to have our ADSs listed on the Nasdaq. Our Ordinary Shares will not be listed on any other exchange, or quoted for trading on any over-the-counter trading system, in the United States.

The initial public offering price for our ADSs will be determined by negotiations between us and the underwriters and may bear no relationship to the market price for our ADSs after this initial public offering. Among the factors considered in determining the initial public offering price will be our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. We cannot assure you that an active trading market for our ADSs will develop or that the market price of our ADSs will not decline below the initial public offering price. If an active trading market for our ADSs does not develop after this offering, the market price and liquidity of our ADSs will be materially and adversely affected.

***The market price for our ADSs may be volatile which could result in substantial loss to you.***

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 expiry 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, as recently as 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. 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 your investment.***

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 your investment. 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.

***Since the initial public offering price is substantially higher than our net tangible book value per share, you will incur immediate and substantial dilution.***

If you purchase our ADSs in this offering, you will pay more for your ADSs than the amount paid by our existing shareholders for their Ordinary Shares on a per ADS basis. As a result, you will experience immediate and substantial dilution of approximately \$12.20 per ADS, representing the difference between our net tangible book value per ADS as of June 30, 2021, after giving effect to this offering and an assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus. In addition, you may experience further dilution to the extent that our Ordinary Shares are issued upon the exercise of stock options or warrants. See “Dilution” for a more complete description of how the value of your investment in our ADSs will be diluted upon completion of this offering.

***Substantial future sales or perceived sales of our ADSs in the public market could cause the price of our ADSs to decline, even if our business is doing well.***

Sales of our ADSs in the public market after this offering, or the perception that these sales could occur, could cause the market price of our ADSs to decline. Based on the number of shares outstanding as of September 30, 2021, upon completion of this offering, we will have 106,566,921 Ordinary Shares outstanding, including Ordinary Shares represented by ADSs. All ADSs sold in this offering will be freely transferable without restriction or additional registration under the Securities Act. The remaining Ordinary Shares outstanding after this offering will be available for sale, subject to restrictions as applicable under Rule 144 under the Securities Act, upon the expiration of the 180-day lock-up arrangements entered into by our executive officers, directors and shareholders in connection with the offering. There are certain exceptions to these lock-up arrangements. See “Underwriting” and “Ordinary Shares and American Depositary Shares Eligible for Future Sale” for additional information. We cannot predict what effect, if any, market sales of securities held by our significant shareholders or any other shareholder or the availability of these securities for future sale will have on the market price of our ADSs.

In addition, promptly following the completion of this offering, we intend to file one or more registration statements 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, which will be effective immediately upon completion of this offering, 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, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the Ordinary Shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, 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 to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all

commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the Ordinary Shares underlying your 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. As a holder or beneficial owner of ADSs, you may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if you wish us or the depositary to participate in legal proceedings. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

***You 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 you.***

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to you 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. You will receive these distributions in proportion to the number of Ordinary Shares your 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 you 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 to you. 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, in connection with this offering, we have entered into a 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 owns as of the completion of this offering. See "Certain Relationships and Related Party Transactions—Director Nomination Agreement" for additional information. Perceptive may exercise its voting and other rights in a manner in which you 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 intend to adopt, 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.

***Your right to participate in any future rights offerings may be limited, which may cause dilution to your 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 you 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 depository will not make rights available to you 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 depository does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your 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 U.S. Holder (as defined below under “Material United States Federal Income Tax Considerations”) holds our ADSs, such U.S. Holder may suffer adverse U.S. federal income tax consequences, including having gains realized on the sale of our ADSs treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on our ADSs by individuals who are U.S. Holders, having interest charges apply to distributions by us and the proceeds of sales of our ADSs, and having additional reporting requirements. Additionally, if we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs, 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 (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, which would result in U.S. federal income tax consequences to holders of our ADSs 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 our most recently completed taxable year, and we do not expect to become a PFIC in the current taxable year though there can be no assurances, including because the determination of whether a corporation will be a PFIC for any taxable year generally can only be made after the close of such taxable year. Because we hold, and will continue to hold after this offering, 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, which may be especially volatile due to the early stage of our product candidates, and by how, and how quickly, we use the cash proceeds from the offering in our business, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year. 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, whether or not such U.S. Holder makes a timely “qualified electing fund” (“QEF election”) 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. Prospective investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ADSs. See “Material United States Federal Income Tax Considerations—Passive foreign investment company considerations.”

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

If a U.S. Holder (as defined below under “Material United States Federal Income Tax Considerations”) is treated as owning (directly, indirectly or constructively) at least 10% of either the total value or total combined voting power of our stock, such U.S. Holder may be treated as a “United States 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, 2019 and 2020. In addition, we believe that certain of our Subsidiaries were CFCs for the taxable years ended December 31, 2019 and 2020. We do not know whether we will be a CFC for the current tax year. 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). A United States 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 United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will 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 United States shareholder with respect to any such CFC. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. If you are a United States shareholder, failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

***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 tax in the United States. As of December 31, 2020 we had U.S. federal net operating losses ("NOLs") of approximately \$22.7 million that do not expire and state NOLs of approximately \$1.2 million, which, if not utilized, generally begin to expire in 2039. We also had foreign NOLs of approximately \$1.4 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. It is uncertain if and to what extent various states will confirm to the U.S. federal rules.

In addition, in general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), 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 have not performed an ownership change analysis as of December 31, 2020. We may experience ownership changes in the future as a result of this offering and/or subsequent changes in our stock 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 China, Hong Kong, the Cayman Islands 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. 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.

***You 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 you to effect service of process within the United States upon these persons. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors. In addition, there is uncertainty as to whether the courts of the Cayman Islands or 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 your 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 you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest. 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, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you 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 United States 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 you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your 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 you are successful in bringing an action, the laws of the Cayman Islands and China may render you 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.

***You may be subject to limitations on transfers of your ADSs.***

Your ADSs are transferable on the books of the depository. However, the depository 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 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 United States 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. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other 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, you or such other 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 your 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, you 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 your cost and limit your ability to bring a claim in a judicial forum that you 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 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 a man-made or natural disasters, public health epidemics, 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 has been impacted by the COVID-19 pandemic and could continue to experience negative impact to business operations. Although we have not been materially impacted by the COVID-19 pandemic to date, other outbreaks may occur, or there could be a resurgence of the COVID-19 pandemic, which could cause business disruptions in the future. Our or our partners' clinical development efforts could be delayed or otherwise negatively impacted, as patients may be 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, 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 temporarily implementing a work-from-home policy for many of our employees and limiting non-essential travel. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism or employee turnover, disrupt our operations or increase the 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. If we or any of the third parties with which we engage or on which we rely were to 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 you 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 will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our ADSs would likely decrease. Even if we do obtain analyst coverage, 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.

***After the completion of this offering, 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. 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.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements 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 fact contained in this prospectus, 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,” “potential,” “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 and other Asian markets;
- our plans to leverage data generated in our partners’ global registrational trials and clinical development programs to obtain regulatory approval and maximize patient reach for our product candidates;
- 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 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 initiate and complete any clinical trials to advance our product candidates, including mavacamten, TP-03, NBTXR3, infigratinib, BBP-398, LYR-210, omilancor, NX-13 and sisunatovir, and any future product candidates towards regulatory approval in China;
- our ability to conduct a Phase 3 registrational trial in China of mavacamten in patients with oHCM and to obtain potential regulatory approval of mavacamten in Greater China and other Asian markets by leveraging clinical data generated in MyoKardia’s global Phase 3 EXPLORER-HCM clinical trial;
- our plans to bring mavacamten to market in China for the treatment of oHCM patients by concurrently conducting a Phase 3 registrational trial and a PK clinical trial in China;
- our plans to pursue the development of mavacamten for the treatment of nHCM and HFpEF;

- our ability to bring TP-03 to market for patients in China by using the data we may generate from a local Phase 3 clinical trial in DB in China, together with data from two pivotal clinical trials conducted by Tarsus in the United States, to seek regulatory approval in Greater China;
- our plans to pursue the development of TP-03 in Greater China for the treatment of DB and MGD, as well as our plans to join any future global pivotal trial of TP-03 in MGD conducted by Tarsus;
- our ability to join the NBTXR3 global development program by enrolling patients in China in five of Nanobiotix's potential future global pivotal clinical trials across indications and therapeutic combinations including immunotherapy, beginning with Nanobiotix's announced planned Phase 3 NANORAY-312 clinical trial in locally advanced head and neck cancer;
- our ability to lead infigratinib's global development in connection with our local development strategy for the treatment FGFR2-amplified gastric and other FGFR-driven cancers, as well as our ability to join the ongoing global Phase 3 PROOF-301 clinical trial of QED in first-line locally advanced or metastatic CCA patients with FGFR2 gene fusions or translocations by enrolling patients in China in the clinical trial;
- the potential for infigratinib 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;
- our ability to pursue local development strategies for infigratinib in China with a focus on gastric cancer, and the possibility of leading infigratinib's global development in gastric cancer indications;
- our ability to develop BBP-398 in China as part of a global development plan in partnership with Navire, including our plans to initiate a Phase 1 monotherapy clinical trial and to advance BBP-398 into combination trials with targeted therapies;
- our ability to develop BBP-398 in combination with an 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 NSCLC;
- our plans to join the omilancor development program by enrolling patients in China in Landos's potential future global pivotal clinical trials in UC and CD;
- the potential for omilancor to have a more benign safety profile or result in a differentiated safety profile than currently available therapeutic options;
- our ability to join Landos's potential future global pivotal trials of NX-13 in UC and CD;
- our plans to join Lyra's clinical development program for LYR-210 by enrolling patients in China as part of Lyra's planned pivotal Phase 3 clinical trial;
- our plans to join ReViral in its clinical trials in potential future global pivotal clinical trials of sisunatovir in pediatric patients hospitalized due to RSV infection and in elderly RSV patients should ReViral advance sisunatovir into pivotal Phase 3 clinical trials in such patients;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- 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;

- 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 and the markets and communities in which we and our partners, collaborators and vendors operate;
- our use of proceeds from this offering, estimates of our expenses, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

Although we base these forward-looking statements on assumptions that we believe are reasonable when made, we caution you 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 prospectus. 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 prospectus, those results or developments may not be indicative of results or developments in subsequent periods.

Given these risks and uncertainties, you are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statement that we make in this prospectus 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. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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 prospectus, 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.

## USE OF PROCEEDS

We estimate that the net proceeds to us from our issuance and sale of 20,312,500 ADSs in this offering will be approximately \$296.8 million (or approximately \$342.1 million if the underwriters exercise in full their option to purchase additional ADSs), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. This estimate assumes an initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per ADS would increase (decrease) the net proceeds to us from this offering by approximately \$18.9 million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Each increase (decrease) of 1,000,000 ADSs from the expected number of ADSs to be sold by us in this offering, assuming no change in the assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) our net proceeds from this offering by approximately \$14.9 million.

We intend to use the net proceeds of this offering as follows:

- approximately \$55 million to further the clinical development of (i) mavacamten in local Phase 3 and PK clinical trials for oHCM, (ii) TP-03 in a local Phase 3 clinical trial for DB and (iii) NBTXR3 as part of a global Phase 3 clinical trial (NANORAY-312) for H&N cancer;
- approximately \$100 million to advance our additional pipeline candidates;
- approximately \$35 million to support our commercial and launch preparation efforts;
- approximately \$63 million to fund new business development and in-licensing opportunities; and
- the remainder for working capital and other general corporate purposes.

Based on our planned use of the net proceeds, we estimate such funds, together with our existing cash, cash equivalents and restricted cash, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least the next 24 months.

The specific allocation of the proceeds from this offering and our current cash, cash equivalents and restricted cash towards specific programs will depend on, among other things, results from our research and development efforts for each program, the timing and success of our clinical studies, the timing of patient enrollment, evolving regulatory requirements and the timing and outcome of regulatory submissions. As a result, and due to the number of our programs currently in clinical development, we currently are unable to specify with reasonable accuracy the stage of development to which the proceeds from this offering and our current cash, cash equivalents and restricted cash will enable us to progress the development of each program, other than with respect to our three lead programs, mavacamten, TP-03 and NBTXR3. With respect to mavacamten, TP-03 and NBTXR3, we expect the proceeds from this offering and our current cash, cash equivalents and restricted cash will be sufficient for us to complete the local Phase 3 and PK clinical trials of mavacamten for oHCM, the local Phase 3 clinical trial of TP-03 for DB and our part of the global Phase 3 clinical trial of NBTXR3 (NANORAY-312) for H&N cancer.

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which we could change in our discretion in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, such as any collaborations or licensing agreements we may enter into with third parties for any additional product

candidates we may in-license, the status of and results from the pre-clinical and clinical trials of our product candidates, and our operating costs and expenditures. As a result, our management will have broad discretion over the use of the net proceeds from this offering and may change the allocation of use of these proceeds among the uses described above. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

The expected net proceeds of this offering will not be sufficient for us to fund all our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

Pending the uses described above, we intend to invest the net proceeds from this offering 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, including guaranteed obligations of the U.S. government, including treasuries and government-sponsored enterprises.

## **DIVIDEND POLICY**

We have never declared or paid dividends on our Ordinary Shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration, amount 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, legal, tax and regulatory restrictions. If we elect to pay such dividends in the future, we may reduce or discontinue entirely the payment of such dividends at any time. If we pay any dividends, ADS holders will generally have the right to receive the dividends paid on the underlying Ordinary Shares, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. See “Description of American Depositary Shares.”



## CAPITALIZATION

The following table sets forth our cash, cash equivalents and restricted cash and capitalization as of June 30, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) the Conversions that will be completed immediately prior to this offering, as described under “The Conversions,” and (ii) the effectiveness of our fifth amended and restated memorandum and articles of association, which will occur immediately upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of 20,312,500 Ordinary Shares represented by ADSs by us in this offering at an assumed public offering price of \$16.00 per ADS, which is the midpoint of the offering price range set forth on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table should be read in conjunction with the information contained in “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as our consolidated financial statements and the related notes thereto, each included elsewhere in this prospectus.

(in thousands, except share and per share data)	As of June 30, 2021 (unaudited)		
	Actual	Pro Forma	Pro Forma as Adjusted
Cash, cash equivalents and restricted cash	<u>\$ 162,624</u>	<u>\$ 162,624</u>	<u>\$ 459,424</u>
Series Seed Preferred Shares, par value \$0.0001 per share; 5,500,000 shares authorized; 5,500,000 issued and outstanding on an actual basis; no shares authorized, issued or outstanding on a pro forma and pro forma as adjusted basis	\$ 55,000	\$ —	\$ —
Series A Preferred Shares, par value \$0.0001 per share, 5,524,178 shares authorized; 5,524,178 issued and outstanding on an actual basis; no shares authorized, issued or outstanding on a pro forma and pro forma as adjusted basis	297,729	—	—
Shareholders’ (deficit) equity:			
Ordinary Shares, par value \$0.000017100448 per share, 2,859,432,812 shares authorized; 20,477,338 shares issued and outstanding on an actual basis; 2,923,900,005 shares authorized, 84,944,514 issued and outstanding on a pro forma basis; 2,923,900,005 shares authorized, 105,257,014 shares issued and outstanding on a pro forma as adjusted basis	—	1	2
Additional paid-in capital	34,249	386,977	683,776
Accumulated other comprehensive income	90	90	90
Accumulated deficit	(325,928)	(325,928)	(325,928)
Total LianBio shareholders’ (deficit) equity	(291,589)	61,140	357,940
Non-controlling interest	44,188	44,188	44,188
Total shareholders’ (deficit) equity	(247,401)	105,328	402,128
Total capitalization	<u>\$ 105,328</u>	<u>\$ 105,328</u>	<u>\$ 402,128</u>

The information above is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. The table above does not include:

- 11,670,901 Ordinary Shares issuable upon the exercise of options outstanding as of June 30, 2021 pursuant to our 2019 Equity Incentive Plan at a weighted-average exercise price of \$5.58 per share, of which options to purchase 1,309,907 Ordinary Shares were exercised subsequent to June 30, 2021;
- 582,688 Ordinary Shares issuable upon the exercise of warrants outstanding at June 30, 2021 at a weighted-average exercise price of \$0.000017100448 per share;
- 14,174,972 Ordinary Shares reserved for future issuance under our 2021 Equity Incentive Plan, which will become effective in connection with this offering; and
- 315,216 Ordinary Shares remaining available for issuance under the 2019 Equity Incentive Plan, which shares will be added to the shares available for issuance under our 2021 Equity Incentive Plan in connection with this offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the offering price range set forth on the cover of this prospectus, would decrease (increase) the amount of cash, cash equivalents and restricted cash, additional paid-in capital, total LianBio shareholders' equity (deficit), total shareholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$18.9 million, assuming the number of ADSs offered by us as set forth on the cover page of this prospectus remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 ADSs offered by us would increase (decrease) cash, cash equivalents and restricted cash, additional paid-in capital, total LianBio shareholders' equity (deficit), total shareholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$14.9 million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information above is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

## DILUTION

If you invest in our ADSs, your investment will be diluted for each ADS you purchase to the extent of the difference between the initial public offering price per ADS and our pro forma as adjusted net tangible book value per ADS immediately after this offering. Dilution results from the fact that the initial public offering price per Ordinary Share represented by ADSs is substantially in excess of the book value per Ordinary Share attributable to the existing shareholders for our presently outstanding Ordinary Shares.

As of June 30, 2021, we had a negative net tangible book value of \$(249.9) million, or \$(12.20) per Ordinary Share and \$(12.20) per ADS. We calculate net tangible book value per Ordinary Share by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities and redeemable convertible preferred shares by the number of our Ordinary Shares outstanding. Pro forma net tangible book value per Ordinary Share is calculated after giving effect to the Conversions. Pro forma as adjusted net tangible book value per Ordinary Share is calculated after giving effect to (i) the pro forma adjustments described above and (ii) the issuance of 20,312,500 Ordinary Shares represented by ADSs by us in this offering at the assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus. Dilution is determined by subtracting pro forma as adjusted net tangible book value per Ordinary Share from the public offering price per Ordinary Share represented by ADSs.

Without taking into account any other changes in such net tangible book value after June 30, 2021, after giving effect to the receipt of the estimated net proceeds from our sale of ADSs in this offering (assuming the underwriters do not exercise their option to purchase additional ADSs), assuming an initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2021 would have been approximately \$399.6 million, or \$3.80 per Ordinary Share and \$3.80 per ADS. This represents an immediate increase in net tangible book value of \$2.59 per Ordinary Share and \$2.59 per ADS to existing shareholders and an immediate dilution in net tangible book value of \$12.20 per Ordinary Share and \$12.20 per ADS to you.

The following table illustrates this dilution:

Assumed initial public offering price	\$16.00
Historical net tangible book value per Ordinary Share as of June 30, 2021	\$(12.20)
Pro forma increase in net tangible book value per Ordinary Share as of June 30, 2021	<u>13.41</u>
Pro forma net tangible book value per Ordinary Share as of June 30, 2021	1.21
Increase in pro forma net tangible book value per Ordinary Share attributable to new investors	<u>2.59</u>
Pro forma as adjusted net tangible book value per Ordinary Share after this offering	3.80
Dilution per Ordinary Share to new investors in this offering	<u>\$12.20</u>

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover of this prospectus, would decrease (increase) the dilution to new investors by \$0.82 per Ordinary Share and \$0.82 per ADS, assuming no change to the number of ADSs offered by us as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us. We may also increase or decrease the number of ADSs we are offering.

## [Table of Contents](#)

Each increase of 1,000,000 ADSs offered by us would decrease the dilution to new investors by \$0.10 per Ordinary Share and \$0.10 per ADS, assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us. Each decrease of 1,000,000 ADSs offered by us would increase the dilution to new investors by \$0.11 per Ordinary Share and \$0.11 per ADS, assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriters exercise their option to purchase additional ADSs in full, the pro forma as adjusted net tangible book value would be \$4.11 per Ordinary Share and \$4.11 per ADS, and the dilution in pro forma as adjusted net tangible book value to investors in this offering would be \$11.89 per Ordinary Share and \$11.89 per ADS.

The following table sets forth, on a pro forma as adjusted basis as of June 30, 2021, the number of Ordinary Shares purchased from us, the total consideration paid to us and the average price per Ordinary Share/ADS paid by existing shareholders and to be paid by new investors purchasing ADSs in this offering at an assumed initial public offering price of \$16.00, which is the midpoint of the price range set forth on the cover of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Ordinary Shares Purchased		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
(in thousands, except per share amounts and percentages)						
Existing Shareholders	84,944,514	80.7%	\$391,516 <sup>(1)</sup>	54.6%	\$ 4.61	\$ 4.61
New Investors	20,312,500	19.3%	\$325,000	45.4%	\$ 16.00	\$ 16.00
Total	<u>105,257,014</u>	<u>100%</u>	<u>\$716,516</u>	<u>100%</u>		

(1) Includes \$8.5 million provided to BridgeBio in the form of Ordinary Shares in connection with the BridgeBio Exclusivity Agreement (as defined below).

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per ADS would decrease (increase) the total consideration paid by new investors by approximately \$20.3 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 1.5 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 1.6 percentage points, assuming no change to the number of ADSs offered by us as set forth on the cover page of this prospectus. Similarly, each increase (decrease) of 1,000,000 ADSs offered by us would increase (decrease) the total consideration paid by new investors by \$16.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 0.6 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 0.9 percentage points, assuming no change in the assumed initial public offering price per share.

The table assumes no exercise of the underwriters' option to purchase additional ADSs in this offering. If the underwriters were to fully exercise their option to purchase additional ADSs from us, the percentage of our Ordinary Shares held by existing shareholders would be reduced to 78.4%, and the percentage of our Ordinary Shares held by new investors would be increased to 21.6%.

The number of shares to be outstanding after this offering is based on 84,944,514 Ordinary Shares outstanding as of June 30, 2021 after giving effect to the Conversions and excludes:

- 11,670,901 Ordinary Shares issuable upon the exercise of options outstanding as of June 30, 2021 pursuant to our 2019 Equity Incentive Plan at a weighted-average exercise price of \$5.58 per share, of which options to purchase 1,309,907 Ordinary Shares were exercised subsequent to June 30, 2021;
- 582,688 Ordinary Shares issuable upon the exercise of warrants outstanding at June 30, 2021 at a weighted-average exercise price of \$0.000017100448 per share;
- 14,174,972 Ordinary Shares reserved for future issuance under our 2021 Equity Incentive Plan, which will become effective in connection with this offering; and
- 315,216 Ordinary Shares remaining available for issuance under the 2019 Equity Incentive Plan, which shares will be added to the shares available for issuance under our 2021 Equity Incentive Plan in connection with this offering.

The pro forma as adjusted information discussed above is illustrative only. Our net tangible book value following the closing of this offering is subject to adjustment based on the actual initial public offering price of the ADSs and other terms of this offering determined at pricing.

New investors will experience further dilution if new options or warrants are issued under our equity incentive plans or we issue additional Ordinary Shares, other equity securities or convertible debt securities in the future. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### 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. Refer to the section entitled "Business" for a summary of our clinical programs.

We have built an asset-centric, cross-border platform to provide our partners with access to our regulatory and development expertise in our licensed territories. We have created a diverse, balanced portfolio of highly differentiated assets that represent our broad program scope and significant potential market opportunity across various stages of development, providing multiple avenues for value creation for us and our partners.

### 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 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. Although we have not been materially impacted by the COVID-19 pandemic to date, other outbreaks may occur, or there could be a resurgence of the COVID-19 pandemic, which could 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 have also implemented an interim work-from-home policy and 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, in the future, 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 “Risk Factors” 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**

#### *Revenue*

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future.

#### *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.

#### *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 products. 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 expect 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.

#### *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 \$10.0 million, \$80.7 million, \$0.0 million, and \$127.5 million for the period from July 17, 2019 (date of incorporation) through December 31, 2019, for the year ended December 31, 2020, for the six months ended June 30, 2020, and for the six months ended June 30, 2021, respectively.

*Interest (expense) income, net*

Interest (expense) income, net consists of interest expense from the payment made upon reaching the financing milestone under the MyoKardia Agreement and the conversion in June 2020 of the \$15.0 million convertible promissory notes due June 29, 2021 issued to Perceptive (the “Perceptive Convertible Notes”), offset by interest income received on our cash balances.

*Other income (expense), net*

Other income (expense), net consists of unrealized gains on foreign currencies held in our China subsidiary, Shanghai LianBio Development Co., Ltd., offset by 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.

At December 31, 2020, we had net operating loss (“NOL”) carryforwards for federal income tax purposes of approximately \$22.7 million, which do not expire. We had NOL carryforwards for state income tax purposes of approximately \$1.2 million, which will expire if unused in years 2039 through 2040. We had foreign NOL carryforwards of \$1.4 million, which will expire if unused in 2025.

We recorded income tax expense of \$2.0 million for the six months ended June 30, 2021 and income tax expense of \$0.0 million for the six months ended June 30, 2020.

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, stock 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 \$43.1 million was recorded as of December 31, 2020. As of June 30, 2021, the valuation allowance remained unchanged from December 31, 2020.

*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. For more information, see “Taxation—Cayman Islands taxation.”

*People's Republic of China*

Our subsidiaries incorporated in 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. For more information, see "Taxation—People's Republic of China Taxation."

## Results of operations

*Comparison of the period from July 17, 2019 (date of incorporation) to December 31, 2019, and for the year ended December 31, 2020*

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

	Period from July 17, 2019 (date of incorporation) to December 31, 2019	Year ended December 31, 2020
<b>Operating expenses (in thousands):</b>		
Research and development	\$ 22,624	\$ 120,885
General and administrative	1,713	13,984
Total operating expenses	24,337	134,869
Operating loss	(24,337)	(134,869)
Other income (expense):		
Interest income (expense), net	11	(4,854)
Other (expense) income, net	(1)	123
Net loss before income taxes	(24,327)	(139,600)
Income taxes	4	4
Net loss	<u>\$ (24,331)</u>	<u>\$ (139,604)</u>

### Research and development expenses

Research and development expenses increased by \$98.3 million from \$22.6 million from July 17, 2019 to December 31, 2019 to \$120.9 million for the year ended December 31, 2020. During 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 warrants issued in connection with the MyoKardia Agreement and (ii) the \$8.0 million upfront payment for the Navire Agreement. The remaining increase is attributable to higher personnel-related expenses, including share-based compensation expense, as a result of increased employee headcount, development activities to support our clinical studies and professional fees. We expect that our research and development expenses will continue to increase in future periods with the advancement of our clinical programs and additional future clinical trials.

During 2019, research and development cost was primarily attributable to (i) the upfront payment of \$10.0 million related to the QED Agreement, (ii) \$8.5 million related to the Ordinary Shares issued to BridgeBio pursuant to an exclusivity agreement (the "BridgeBio Exclusivity Agreement"), (iii) \$2.8 million related to reimbursements provided to QED for research and development costs incurred prior to the execution of the QED License, (iv) \$1.0 million of expenses related to warrants granted to QED in consideration for the QED License, and (v) salaries and legal expenses.

### General and administrative expenses

General and administrative expenses increased by \$12.3 million from \$1.7 million from July 17, 2019 to December 31, 2019 to \$14.0 million for the year ended December 31, 2020. The increase was primarily attributable to a \$9.7 million increase in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and a \$1.5 million increase, primarily attributable to legal service costs, consulting costs and accounting services.

### *Interest income (expense)*

Interest income (expense) decreased by \$4.9 million from \$0.0 million from July 17, 2019 to December 31, 2019 to (\$4.9) million for the year ended December 31, 2020. The decrease was primarily attributable to \$2.3 million of imputed interest related to the achievement of the financing milestone under the MyoKardia Agreement and \$2.5 million of interest expense related to the beneficial conversion feature of the Perceptive Convertible Notes.

### *Other income (expense), net*

Other income (expense), net increased by \$0.1 million from \$0.0 million from July 17, 2019 to December 31, 2019 to \$0.1 million for the year ended December 31, 2020. The increase was primarily attributable to unrealized gains on foreign currencies held in our China subsidiary, offset by bank fees incurred on our cash balances.

### *Comparison of the Six Months Ended June 30, 2020 and 2021*

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

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2021
<b>Operating expenses (in thousands):</b>		
Research and development	\$ 1,258	\$ 146,383
General and administrative	5,363	13,607
Total operating expenses	6,621	159,990
Operating loss	(6,621)	(159,990)
Other income (expense):		
Interest income, net	13	139
Other expense, net	(18)	(192)
Net loss before income taxes	(6,626)	(160,043)
Income taxes	2	1,950
Net loss	\$ (6,628)	\$ (161,993)

### *Research and development expenses*

Research and development expenses increased by \$145.1 million from \$1.3 million for the six months ended June 30, 2020 to \$146.4 million for the six months ended June 30, 2021. For the six months ended June 30, 2021, research and development cost was primarily attributable to (i) \$55.0 million upfront and development milestone payments and \$9.4 million of expenses related to warrants issued in connection with the Tarsus Agreement, (ii) a \$20.0 million upfront payment pursuant to the Nanobiotix Agreement, (iii) a \$18.0 million upfront payment pursuant to the Landos Agreement, (iv) a \$14.0 million upfront payment pursuant to the ReViral Agreement, (v) a \$12.0 million upfront payment pursuant to the Lyra Agreement, and (vi) a \$8.5 million development milestone payment pursuant to the Navire Agreement. The remaining increase was attributable to higher personnel-related expenses, including share-based compensation expense, as a result of increased employee headcount, and development activities to support our clinical trials and professional fees.

For the six months ended June 30, 2020, research and development cost was primarily attributable to personnel-related expenses and development fees to support activities related to our clinical trials.

### *General and administrative expenses*

General and administrative expenses increased by \$8.2 million from \$5.4 million for the six months ended June 30, 2020 to \$13.6 million for the six months ended June 30, 2021. The increase was primarily attributable to (i) \$4.0 million increase in payroll and personnel-related expenses, including share-based compensation expense, and employee severance, as a result of changes to employee headcount, (ii) \$1.1 million increase in consulting costs, and (iii) \$1.0 million increase in legal service costs.

### *Interest income*

Interest income increased by \$0.1 million from \$0.0 million for the six months ended June 30, 2020 to \$0.1 million for the six months ended June 30, 2021. The increase was primarily attributable to interest income earned on our cash and cash equivalents.

### *Other income (expense), net*

Other income (expense), net decreased by (\$0.2) million from \$0.0 million for the six months ended June 30, 2020 to (\$0.2) million for the six months ended June 30, 2021. The decrease was primarily attributable to unrealized loss on foreign currencies held in our China subsidiary and by bank fees incurred on our cash balances.

### *Income taxes*

Our income tax expense was \$2.0 million, resulting in an effective income tax rate of 1.2% for the six months ended June 30, 2021 as compared to income tax expense of \$0.0 million, or an effective income tax rate of 0.0%, for the same period in 2020. Our income tax expense for the six months ended June 30, 2021 was primarily due to the effect of cash taxes associated with certain income that cannot be deferred for U.S. income tax purposes.

## **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 and the Series A financing, as well as the issuance of the Perceptive Convertible Notes. We expect to continue to incur significant expenses and operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter.

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. For an overview of our organizational structure, see “Prospectus Summary—Organizational structure.” 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 “Risk Factors—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 revenue. We do not expect to generate any product revenue 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, following the completion of this offering, we will incur material incremental costs in 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;
- 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

## [Table of Contents](#)

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 (in thousands):

	Period from July 17, 2019 (date of incorporation) to December 31, 2019	Year Ended December 31, 2020
Net cash (used in) provided by:		
Operating activities	\$ (11,700)	\$ (98,142)
Investing activities	—	(886)
Financing activities	55,000	309,753

### *Net cash used in operating activities*

During the period from July 17, 2019 to December 31, 2019, operating activities used approximately \$11.7 million, primarily due to our net loss of \$24.3 million, partially offset by non-cash items totaling \$9.5 million, including \$8.5 million associated with the Ordinary Shares issued to BridgeBio pursuant to the BridgeBio Exclusivity Agreement, \$1.0 million related to warrants granted to QED in consideration for the QED License, and a net increase in related party payable of \$2.8 million to QED for research and development costs incurred prior to the execution of the QED License.

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 Perceptive 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, 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 period from July 17, 2019 to December 31, 2019, financing activities provided approximately \$55.0 million in net proceeds due to our issuance of Series Seed Preferred shares.

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 Perceptive Convertible Notes.

## [Table of Contents](#)

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented (in thousands):

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2021
Net cash (used in) provided by:		
Operating activities	\$ (6,686)	\$ (94,776)
Investing activities	(322)	(67)
Financing activities	14,964	2,940

### *Net cash used in operating activities*

During the six months ended June 30, 2020, operating activities used approximately \$6.7 million, primarily due to our net loss of \$6.6 million.

During the six months ended June 30, 2021, operating activities used approximately \$94.8 million, primarily due to our net loss of \$162.0 million, partially offset by non-cash consideration of \$9.4 million related to the Tarsus Warrants, \$20.0 million of other receivables related to Pfizer in-licensing and co-development activities, a \$28.5 million increase in accounts payable related to Tarsus' and Navire's achievement of development milestones, and other changes related to operating assets and liabilities.

### *Net cash used in investing activities*

During the six months ended June 30, 2020, investing activities used approximately \$0.3 million, primarily resulting from the purchases of property and equipment.

During the six months ended June 30, 2021, investing activities used approximately \$0.1 million, primarily resulting from the purchases of property and equipment.

### *Net cash provided by financing activities*

During the six months ended June 30, 2020, financing activities provided approximately \$15.0 million in net proceeds, primarily resulting from the net proceeds from the Perceptive Convertible Notes.

During the six months ended June 30, 2021, financing activities provided approximately \$2.9 million in net proceeds, primarily resulting from the net proceeds from our issuance of Series A Preferred shares.

### *Contractual obligations*

The following table presents our contractual obligations at June 30, 2021 (in thousands):

	Payments Due by Period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
	(in thousands)				
Operating lease obligations(1)	\$ 688	\$1,149	\$ 90	\$ —	\$1,927

(1) The operating lease obligations are related to the facility lease for our China headquarters in Shanghai expiring in April 2024 and our Princeton, New Jersey lease expiring in May 2023.



We also have obligations to fund clinical trial commitments under the QED License over the remaining term of the QED License. \$2.8 million has been recorded as a related party payable as of December 31, 2019 with payment made in the first quarter of 2020.

### ***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 GAAP, which requires us to make judgments, estimates and assumptions. 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. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our 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 drug products 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.

## [Table of Contents](#)

The following table sets forth the components of our research and development expenses for the years indicated (in thousands):

	Period from July 17, 2019 (date of incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020	Six Months Ended June 30, 2021
<b>Research and development expenses:</b>				
Licensing fees	\$ 22,390	\$ 114,375	\$ —	\$ 136,915
Employee related expense	111	3,003	852	3,110
CRO costs	—	1,187	296	4,569
Other costs	123	2,320	110	1,789
<b>Total</b>	<b>\$ 22,624</b>	<b>\$ 120,885</b>	<b>\$ 1,258</b>	<b>\$ 146,383</b>

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

	Period from July 17, 2019 (date of incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020	Six Months Ended June 30, 2021
<b>Licensing fees:</b>				
BridgeBio Exclusivity Agreement	\$ 8,516	\$ —	\$ —	\$ —
Infigratinib	13,874	—	—	—
Mavacamten	—	106,375	—	—
BBP-398	—	8,000	—	8,500
Sisunatovir	—	—	—	14,000
TP-03	—	—	—	64,415
BT-11 and NX-13	—	—	—	18,000
NBTXR3	—	—	—	20,000
LYR-210	—	—	—	12,000
<b>Total</b>	<b>\$ 22,390</b>	<b>\$ 114,375</b>	<b>\$ —</b>	<b>\$ 136,915</b>

### *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 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 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 \$5.2 million and \$3.1 million for the year ended December 31, 2020 and the six months ended June 30, 2021, respectively. The fair values of the Ordinary Shares underlying our share-based awards are estimated on each grant date by our board of directors. Our board of directors considers, 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 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. 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.

Given the absence of a public trading market prior to this offering, our board of directors, with input from management, considered numerous objective and subjective factors to determine the fair value of our Ordinary Shares. The factors included, but were not limited to:

- third-party valuations of our Ordinary Shares;
- our stage of development;
- the status of research and development efforts;
- the rights, preferences and privileges of our redeemable convertible preferred shares relative to those of our Ordinary Shares;
- our operating results and financial condition, including our levels of available capital resources;
- equity market conditions affecting comparable public companies;
- general U.S. market conditions; and
- the lack of marketability of our Ordinary Shares.

For valuations after the completion of this offering, the fair value of each Ordinary Share will be based on the closing price of our ADSs as reported on the date of grant.

### Grants of stock-based awards

The following table summarizes by grant date and type of award, the number of equity awards granted since January 1, 2020, the per share exercise price, the fair value of Ordinary Shares on each grant date, and the per share estimated fair value of the awards:

GRANT DATE	TYPE OF AWARD	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	FAIR VALUE OF ORDINARY SHARE ON GRANT DATE <sup>(1)</sup>	ESTIMATED FAIR VALUE PER SHARE OF AWARDS <sup>(2)</sup>	ESTIMATED FAIR VALUE PER SHARE OF PERFORMANCE AWARDS <sup>(3)</sup>
January 1, 2020	Options	2,999,920	\$ 1.71	\$ 1.71	\$ 1.13	—
December 17, 2020	Options	5,374,114 <sup>(4)</sup>	\$ 6.49	\$ 6.49	\$ 3.54	—
March 31, 2021	Options	87,717	\$ 6.85	\$ 6.85	\$ 3.94	—
May 1, 2021	Options	1,115,502	\$ 6.90	\$ 6.90	\$ 3.93	—
May 17, 2021	Options	2,055,566	\$ 6.90	\$ 6.90	\$ 3.93	—
May 17, 2021	Options	969,307	\$ 6.90	\$ 6.90	—	\$ 4.72
May 17, 2021	Options	969,307	\$ 6.90	\$ 6.90	—	\$ 4.72

- (1) The fair value of our Ordinary Shares per Ordinary Share on grant date represents the fair value of Ordinary Shares per Ordinary Share on the date of the award grant.
- (2) The estimated fair value per share of the awards represents our measurement of the weighted-average fair value of option grants using the Black-Scholes model and does not reflect any subsequent modifications of the awards that may have occurred.
- (3) The estimated fair value per share of the performance awards represents our measurement of the weighted-average fair value of option grants using a Monte-Carlo simulation and does not reflect any subsequent modifications of the awards that may have occurred.
- (4) On February 28, 2021, 561,388 options were cancelled and the vesting for an additional 561,388 options were accelerated to February 28, 2021. These accelerated options were subsequently forfeited as of August 27, 2021.

The intrinsic value of all outstanding options as of June 30, 2021, was \$121.6 million based on an assumed initial public offering price of \$16.00 per ADS, the midpoint of the price range set forth on the cover of this prospectus.

### 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. and China 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.

At December 31, 2020, we had NOL carryforwards for federal income tax purposes of approximately \$22.7 million which do not expire. We had NOL carryforwards for state income tax purposes of approximately \$1.2 million, which will expire if unused in years 2039 through 2040. We had foreign NOL carryforwards of \$1.4 million which will expire if unused in 2025.

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.

We have not completed an analysis under Section 382 or 383 of the Code regarding the limitation of our NOL and research and development tax credit carryforwards. If a change in ownership were to have occurred, the annual limitation may result in the expiration of NOL and research and development tax credit carryforwards before utilization. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. We have not identified nor recorded any liabilities for unrecognized tax benefits as of June 30, 2021.

#### ***Emerging growth company and smaller reporting company status***

We are an emerging growth company, as defined in the JOBS Act, and we may remain an emerging growth company for up to five years following the completion of this offering. For so long as we remain an emerging growth company, we are permitted to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved and an exemption from compliance with the requirements regarding the communication of critical audit matters in the auditor's report on financial statements. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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. 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 will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least \$1.07 billion in annual revenue; (ii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Ordinary Shares held by non-affiliates exceeded \$700 million as of the last business day of the second fiscal quarter of such year; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of this offering.

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently

completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

#### ***Recently issued accounting standards***

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in the notes to which they relate within our financial statements also included in this registration statement.

#### ***Qualitative & quantitative 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 most of our 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 your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the renminbi because 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, 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 will receive from this offering 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 affected by, among other things, changes in China's political and economic conditions. To the extent that we need to convert U.S. dollars we receive from this offering 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.

## **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. In less than three years, 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 plan to initiate four registrational studies over the next 12 to 18 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.

### **Our pipeline**

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



## Table of Contents

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.

Global Development Status<sup>1</sup>

Therapeutic Area	Program	Indication	Phase 1	Phase 2	Phase 3/ Pivotal	Approved	Next step in China	Partner
Cardiovascular	Mavacamten	Obstructive Hypertrophic Cardiomyopathy (oHCM)					Initiate China bridging Phase 3 trial and PK study (conducted in parallel)	Bristol Myers Squibb
		Non-obstructive Hypertrophic Cardiomyopathy (nHCM)					Join BMS future global Phase 3 trial	
		Heart Failure with Preserved Ejection Fraction (HFpEF)					Join BMS future global Phase 3 trial	MYOKARDIA
Ophthalmology	TP-03	Demodex Blepharitis					Conduct China standalone Phase 3 trial	TARSUS
Oncology	NBTXR3 <sup>2</sup>	Head and Neck Squamous Cell Carcinoma (HNSCC)					Join NANORAY-312 global Phase 3 trial	NANOBIOTIX
		Solid Tumor IO Combinations					Join future global Phase 3 trial	
	Infigratinib <sup>3</sup>	Second-line Cholangiocarcinoma with FGFR2 Fusions					Explore development and patient access strategies	bridgebio
		First-line Cholangiocarcinoma with FGFR2 Fusions					Join ongoing PROOF-301 Phase 3 trial	
		Gastric Cancer with FGFR2 Amplification; Other Solid Tumors w FGFR Alterations <sup>4</sup>					Conduct China Phase 2a proof of concept trial	QED
	BBP-398	Solid Tumors Driven by Mutations in MAPK					Conduct China Phase 1 dose escalation trial	bridgebio navire
Inflammatory Disease	Omilancor	Ulcerative Colitis					Join future global Phase 3 trial	LANDOS
		Crohn's Disease					Join future global Phase 3 trial	
	NX-13	Ulcerative Colitis					Join future global Phase 3 trial	
	LYR-210	Chronic Rhinosinusitis (CRS)					Join future global Phase 3 trial	LYRA
Respiratory	Sisunatovir	Respiratory Syncytial Virus (RSV)					Join future global Phase 3 trial	REVIRAL

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 the Company. For more information regarding the risks related to our business operations and clinical and regulatory strategies, please see "Risk Factors—Risks related to our business and industry."
2. NBTXR3 has received European market approval (CE mark) in the European Union, which is not a part of our licensed territory, for the treatment of locally advanced soft tissue sarcoma. At present, we are not pursuing NBTXR3 in relation to this soft tissue sarcoma 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 gastric cancer and other FGFR-driven tumor standalone clinical trial in China. Separate investigator-sponsored Phase 2 clinical trial of infigratinib in FGFR-driven tumors is ongoing in the United States.

## Our strengths

Our goal is to become a leading global biopharmaceutical company focused on developing and commercializing innovative medicines to address critical unmet patient needs, initially in Greater China and other Asian markets. We leverage the following strengths to accomplish this goal.

### ***Diversified portfolio of clinically validated late-stage and highly innovative early- to mid-stage product candidates, providing multiple avenues of value creation for us and our partners***

Our pipeline currently consists of nine compelling product candidates across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications, a majority of which are late-stage and have been clinically validated. Our late-stage, clinically validated pipeline is comprised of five product candidates: mavacamten, TP-03, NBTXR3, infigratinib and LYR-210, all of which have

either obtained regulatory approval in certain jurisdictions and indications or have demonstrated achievement of statistically significant endpoints in controlled clinical trials. These product candidates are complemented by our earlier stage product candidates, BBP-398, omilancor, NX-13 and sisunatovir. 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 FGFR2 fusion or other rearrangement. NBTXR3 has received European market approval (CE mark) in the European Union, which is not a part of our licensed territory, for the treatment of locally advanced soft tissue sarcoma. We believe each of our assets has potential to address significant unmet medical needs in our target markets and several of our assets cover therapeutic areas that have been historically underserved and lacked innovation and investment, particularly those outside of oncology.

We intend to develop each of our lead product candidates, mavacamten, TP-03 and NBTXR3, in our licensed territories in Greater China and other Asian markets. Mavacamten is an oral therapy for the treatment of obstructive hypertrophic cardiomyopathy ("oHCM") that met all primary and secondary endpoints in its pivotal Phase 3 clinical trial conducted by MyoKardia, Inc. ("MyoKardia"), demonstrating statistically significant and clinically meaningful improvements in symptoms, functional status and key aspects of quality of life. Following the Phase 3 clinical trial, MyoKardia was acquired by Bristol-Myers Squibb Company ("BMS") for approximately \$13 billion. TP-03 (lotilaner ophthalmic solution) is an eye solution for the treatment of Demodex blepharitis ("DB"), a condition caused by an infestation of Demodex mites triggering inflammation and affecting approximately 43 million patients in China. There are currently no approved therapies for DB. 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, is ongoing.

Our third lead asset is NBTXR3, a nanoparticle-based radiosensitizer that enhances the localized effect of radiotherapy, one of the backbones of cancer treatment. When used in conjunction with radiotherapy, NBTXR3 enhances the activity of the radiotherapy and has been shown to enhance the localized effect of radiotherapy. In June 2021 Nanobiotix S.A. ("Nanobiotix") reported an 82.5% primary tumor objective response rate and 62.5% complete response rate from an ongoing Phase 1b extension clinical trial in head and neck ("H&N") cancer. NBTXR3 has potentially broad applicability across tumor types as a monotherapy and in combination with chemotherapy or immunotherapy, where recent data suggests NBTXR3 could expand the addressable population of patients that respond to immune checkpoint therapy. NBTXR3 has received European market approval (CE mark) in the European Union, which is not a part of our licensed territory, for the treatment of locally advanced soft tissue sarcoma.

Each of our lead assets represents a novel therapeutic candidate developed for patients who are in need of improved treatment options. These assets are complemented by additional product candidates in our portfolio with the potential to significantly improve the existing standard of care, including BBP-398, infigratinib, LYR-210, omilancor, NX-13 and sisunatovir. In totality, we have created a diverse, balanced portfolio of highly differentiated assets that reflect our broad program scope and represent significant potential market opportunity across various stages of development, providing multiple avenues for value creation for us and our partners.

### ***Strategic and selective asset sourcing***

We have leveraged our deep scientific understanding, combined with region-specific development, regulatory and commercial insights, to select and in-license promising assets for development in our target markets. We were founded by Perceptive, a leading life science-focused investment firm with deep experience investing in biopharmaceutical companies and access to a

global network within the biotechnology universe. Since our incorporation in July 2019, we have in-licensed nine assets across five therapeutic areas, establishing a foundation for our platform. We continue to build momentum, including through our strategic partnership with BridgeBio, which provides us with preferential access to more than 20 current and future product candidates in Greater China and other Asian markets. We have also broadened our network of key investors and partners and will continue to evaluate innovative, complementary product candidates with the potential to become new standards of care in Greater China and other Asian markets to deepen our pipeline.

#### ***Execution capabilities across development and regulatory functions and strong commercial leadership***

Our clinical development, regulatory affairs and market access teams have deep experience and proven track records of bringing medicines to patients in China. We drive regional initiatives that work synergistically with our partners' global development strategies. We carry out development plans designed to both maximize value to our stakeholders and prioritize the needs of local patients, in some cases by leading local indication expansion studies and pursuing new combination approaches.

Our team in aggregate has contributed to the development of more than 100 drugs that have been approved in China across multiple therapeutic areas, including Brilinta and Crestor in cardiovascular, renal and metabolic disease; Tagrisso, Tyvyt, Imfinzi, Nivolumab, Kadcyla and Tykerb in oncology; Benlysta, Dupixent, Otezla and Remicade in inflammatory, autoimmune and respiratory diseases; Keppra and Aricept in central nervous system diseases; and Volibris and Aubagio in orphan disease.

#### ***Asset-centric, cross-border partnership model***

We have built an asset-centric, cross-border platform to provide our partners with access to our regulatory and development expertise in our licensed territories. We seek to serve as an extension of our partners' global development strategies in order to maximize the value potential of our assets both in our licensed territories and globally. We have implemented both a partner and asset centric model that drives our execution, with project leadership at the asset level overlaying functional roles. Our model allows us to scale efficiently while delivering high quality execution. Our U.S.-based alliance management team drives partner interactions, starting with an institutionalized, robust onboarding process and then working hand-in-hand with our partners to navigate the Chinese development, regulatory and commercial landscapes to ensure optimal program integration and position each asset for success. We believe the accessibility of our U.S.-based colleagues improves the efficiency and quality of our partnerships and offers advantages to our partners who can more readily communicate in their own time zone. We believe this fundamental cross-border, partner and asset centric approach differentiates us from our competitors operating in these markets.

#### ***Highly experienced global management team***

We have built an executive management team with significant experience successfully executing cross-border transactions and clinical development strategies involving therapeutic products ranging from early-stage discovery through commercialization. Our management team consists of experienced industry leaders who have deep knowledge of the development, regulatory and commercial landscape in China and the United States, in addition to strong transactional and business development track records. We recognize that our ability to secure the best assets requires a trusted team with an established track record, and we have consistently focused on identifying and cultivating top-tier talent.

We are led by Yizhe Wang, Ph.D., our Chief Executive Officer, who has significant experience leading organizations and designing and executing clinical development and commercialization strategies in the United States, Europe and China, with past roles at Eli Lilly and Company,

GlaxoSmithKline plc and BMS. Debra Yu, M.D., our President and Chief Strategy Officer, is a recognized leader in cross-border U.S.-China life sciences transactions with 30 years of experience, including previous roles at Pfizer, WuXi AppTec Co., Ltd. and McKinsey & Company. Yi Larson, our Chief Financial Officer, has an extensive track record of successfully guiding biopharma corporate strategy across both operational and investment banking roles, with previous experience at Turning Point Therapeutics, Inc. and Goldman Sachs & Co. LLC.

***Broad network of institutional investors with deep sector knowledge***

We have raised over \$380 million in equity financing from a leading syndicate of investors based in the United States and China. We believe our relationships with these investors will contribute to our success in sourcing value-creating partnerships. Our investor base is comprised of leading firms in the United States, including our founder, Perceptive, and in Greater China

***Our Vision and Strategy***

Our vision is to bring novel therapies with the ability to address critical unmet medical needs to historically underserved patients in Greater China and other Asian markets. We plan to do so by continuing to pursue the following strategies:

***Advance our lead product candidates, mavacamten, TP-03 and NBTXR3, to seek regulatory approval and commercialization in our licensed territories***

In order to develop our lead assets, mavacamten, TP-03 and NBTXR3, in China, we have designed development and regulatory strategies that we believe will enable us to leverage data generated in our partners' global registrational trials as well as clinical development programs that account for considerations specific to our licensed territories, including local clinical practice, patient preferences and diagnostic equipment availability, with the goal of obtaining regulatory approval and maximizing patient reach for each asset. In addition, we believe we can capture additional value from our other territories in Asia through a fit-for-purpose development, registration and commercialization approach.

In China, we plan to simultaneously conduct a Phase 3 registrational trial of mavacamten in patients with oHCM, called EXPLORER-CN, and a pharmacokinetics ("PK") clinical trial. We expect to use the data from EXPLORER-CN and our PK study in combination with the data generated in MyoKardia's global Phase 3 EXPLORER-HCM clinical trial to obtain potential regulatory approval in Greater China and other Asian markets. We have received clearance from NMPA to initiate the Phase 3 and PK trials and we anticipate initiating these trials in the first quarter of 2022.

We are also pursuing the development of mavacamten for the treatment of non-obstructive HCM ("nHCM") and heart failure with preserved ejection fraction ("HFpEF").

For TP-03, we plan to conduct a local Phase 3 clinical trial in DB in China. We expect to use the data from this trial, together with data from two pivotal clinical trials conducted by Tarsus in the United States, to support regulatory approval in DB in Greater China. We anticipate initiating a Phase 3 clinical trial of TP-03 in China in the second half of 2022. We also plan to develop TP-03 for the treatment of Demodex-driven Meibomian Gland Disease ("MGD").

For NBTXR3, we plan to join the global development program by enrolling patients in China in Nanobiotix's planned Phase 3 clinical trial in H&N cancer, as well as future global pivotal clinical trials in other solid tumor indications.

### ***Advance our additional product candidates, infigratinib, BBP-398, LYR-210, omilancor, NX-13 and sisunatovir, toward regulatory approval via bespoke development strategies***

We are working closely with our partners to create bespoke development and regulatory strategies to maximize the global value of our assets and obtain potential regulatory approval in China and our other territories.

- ***Infigratinib (FGFR-selective TKI):*** We are pursuing a local development strategy for infigratinib for the treatment of gastric and other FGFR-driven cancers, and we expect to lead infigratinib's global development in gastric cancer indications. We initiated a Phase 2a proof of concept clinical trial in China for FGFR2-amplified gastric cancer and solid tumors with FGFR alterations in August 2021. Additionally, we plan to join QED Therapeutics, Inc.'s ("QED") ongoing global Phase 3 PROOF-301 clinical trial of infigratinib in first-line locally advanced or metastatic unresectable cholangiocarcinoma ("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 previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or other rearrangement (second-line CCA).
- ***BBP-398 (SHP2 inhibitor):*** We received clearance from the NMPA to enroll patients in China in a Phase 1 monotherapy clinical trial of BBP-398 in advanced solid tumors. We also plan to advance BBP-398 into combination trials with targeted therapies, including potentially epidermal growth factor receptor ("EGFR") tyrosine kinase inhibitors ("TKI") and programmed cell death protein 1 ("PD-1") inhibitors in the future.
- ***LYR-210 (implantable drug matrix):*** Based on its successful Phase 2 LANTERN clinical trial, Lyra Therapeutics, Inc. ("Lyra") has announced plans to advance LYR-210 into pivotal Phase 3 clinical trials, which we intend to join by enrolling patients in China.
- ***Omilancor (LANCL2 agonist):*** Based on supportive data from a Phase 2 clinical trial in ulcerative colitis ("UC"), Landos Biopharma, Inc. ("Landos") has announced plans to initiate two global Phase 3 clinical trials of omilancor in UC, PACIFY I and PACIFY II. We intend to participate in these trials by enrolling patients in China. Omilancor is also being studied by Landos for Crohn's disease ("CD"), currently in a Phase 2 clinical trial, and, should the program advance into Phase 3, we intend to participate in this future trial by enrolling patients in China.
- ***NX-13 (NLRX1 agonist):*** In April 2021, Landos initiated a Phase 1b clinical trial of NX-13 in patients with UC. Landos has also announced plans to study NX-13 in CD. If this program advances to Phase 3, we plan to participate in these future Phase 3 clinical trials of NX-13 in UC and CD by enrolling patients in China.
- ***Sisunatovir (RSV fusion inhibitor):*** ReViral Ltd. ("ReViral") is currently conducting Phase 2 clinical trials of sisunatovir in pediatric patients hospitalized due to respiratory syncytial virus ("RSV") infection and in immunocompromised patients. ReViral has also announced plans to study sisunatovir in elderly RSV patients. Should ReViral advance sisunatovir into pivotal Phase 3 clinical trials in pediatric and elderly patients, we plan to join these Phase 3 clinical trials by enrolling patients in China.

### ***Establish integrated launch capabilities and strategically build commercial infrastructure customized to each of our assets***

Our commercial strategy aims to efficiently maximize patient reach for each of our assets. For therapies we plan to commercialize on our own, we intend to build and utilize a focused salesforce in China in order to promote our products, if approved. We believe we will be able to leverage the commercial infrastructure we create for our lead programs to benefit our other assets. For example, in

China, prescription drugs across therapeutic areas are largely sold through hospitals. As a result, we believe the hospital relationships we establish will lay the groundwork for the future launch of programs across our portfolio. Our overall launch approach will focus on early integration of medical, regulatory and commercialization preparation.

For other therapies, we may pursue a co-commercialization strategy with strategic partners such as Pfizer. In November 2020, we entered a collaboration with Pfizer which provides for the co-development and potential co-commercialization of products covered by the collaboration in Greater China, which will enable us to access Pfizer's extensive sales network and established commercial organization in the region.

***Continue to deepen our pipeline in existing therapeutic areas with potentially transformative medicines that fit with our expertise, portfolio and strategy***

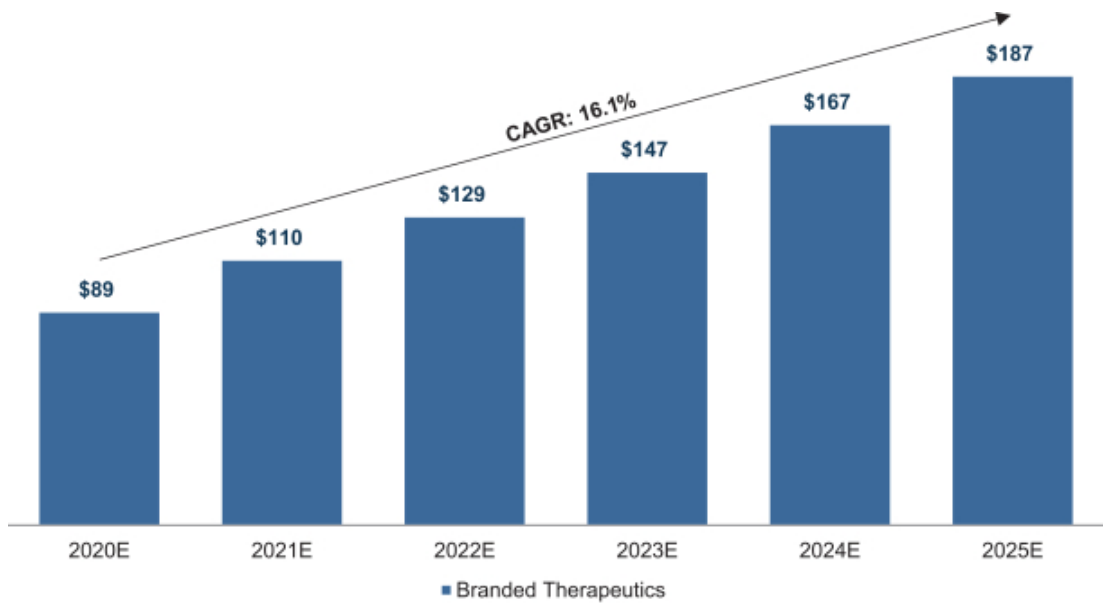
We seek to anchor each therapeutic focus area with a core asset and then build around these core areas. We intend to collaborate with world-class partners, selecting programs with a strong scientific basis and compelling clinical data to build out a broad and clinically validated pipeline. To enhance our sourcing capabilities, we intend to explore additional development synergies with other portfolio companies of our healthcare-specialist investors. Additionally, we intend to opportunistically seek out additional biotech and pharma partners based on our market assessments. Finally, we consider our existing portfolio of assets, as well as those of our strategic collaborations, to identify and pursue novel combination approaches. We intend to continue building our portfolio with innovative medicines that have the potential to become new standards of care in Greater China and other Asian markets.

**The China opportunity**

***The Chinese prescription pharmaceutical market***

China is the second-largest pharmaceutical market in the world, with estimated branded pharmaceutical market revenues of \$89 billion in 2020. The Chinese branded therapeutics market is forecasted to grow at a CAGR of 16.1% from 2020—2025, reaching \$187 billion by 2025.

Branded therapeutics China market sales projection (\$USD bn)



The Chinese pharmaceutical industry has traditionally been dominated by generics producers. Recent Chinese regulatory reforms have encouraged the development and use of more effective innovative drugs, as evidenced by the parallel increase in pharmaceutical research and development spending, which is projected to increase from an estimated \$25.3 billion in 2020 to an estimated \$47.6 billion in 2024.

These reforms have led to an increase in the pace of approval and patient access to innovative therapeutics in various disease groups. In 2018, the NMPA received only 264 applications for innovative drugs, but the number increased to 319 in 2019 and 597 in 2020. In addition, through healthcare reform, the Chinese government has been taking steps to improve the accessibility and affordability of innovative drugs. The Chinese government has also sought to bolster intellectual property protection for innovative new drugs, the lack of which has been a key concern for companies considering commercializing new drug products in China. Through the introduction of a new pricing negotiation mechanism for innovative drugs, the Chinese government has signaled its commitment to increasing patient access to new therapies, contributing to the addition of 58 innovative drugs to the version of the National Reimbursement Drug List (“NRDL”) released in 2020, compared to 35 innovative drugs on the 2019 list.

With a total population of 1.44 billion people in China, China’s 60-and-older population is estimated to reach 35% of the total population, or 486 million people, by 2050. As the population ages, the prevalence of certain conditions and diseases, including cardiovascular, metabolic and oncology-related disorders, is expected to increase, making China an attractive market for Western biopharmaceutical companies and certain therapeutic candidates where the top-line potential is limited in the United States.

**Regulatory reform**

Historically, Chinese patients have had considerably delayed access to innovative drugs relative to patients in the United States and other Western countries because it usually took several years to



gain marketing authorization approval in China for drugs already approved outside of China. These delays were often due to the additional burden of Chinese regulatory requirements, such as the need to secure marketing authorizations in the country where the drug product is manufactured or where the foreign legal manufacturer is domiciled, to conduct a Phase 3 clinical trial in Chinese patients to validate globally-generated safety and efficacy data, and the lack of coordination with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") requirements on dossier formality and technical review. However, recent improvements in the country's regulatory framework have changed the prior paradigm significantly, as China is now a member of the ICH and has instituted a number of policies that are conducive to innovation and improve the accessibility of new drugs, including allowing innovative new drugs to be approved in China ahead of the marketing authorizations issued in the country of origin, the creation of fast track priority review, breakthrough designation and conditional approval, the acceptance of foreign clinical trial data and the introductions of the Rare Disease List and the Urgently Needed Drug List, which may provide clinical trial waivers exempting products already approved outside China from requirements to conduct additional local trials prior to commercialization. These developments have led to increased interest by innovative Western companies to develop their product candidates in China.

### ***Recent government initiatives***

One of the main objectives of healthcare reform in China has been to establish a basic healthcare system to cover both urban and rural residents and provide Chinese citizens with safe, effective, convenient and affordable healthcare services. The Chinese government is pursuing these objectives through:

- ***Increased healthcare coverage:*** As of the end of 2020, Basic Medical Insurance coverage has reached more than 95% of China's population.
- ***Expanded reimbursement:*** The Chinese government has been expanding the number of innovative drugs qualified for listing on the NRDL through negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply and oncology drugs since 2016. The expansion of the NRDL has enabled an increasing number of innovative drugs to obtain reimbursement.
- ***Accelerated reimbursement eligibility:*** The NRDL is now updated on an annual basis, representing a clear improvement as compared to the eight-year gap between 2009 and 2017 where no updates were made.

In addition, the recently amended Patent Law of the People's Republic of China, which became effective in June 2021, provides enhanced intellectual property protection by extending patent terms to compensate for the regulatory review approval time, increasing damages for infringement and establishing early resolution mechanisms for patent disputes.

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 are built 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.

## Our pipeline

### Cardiovascular

#### **Mavacamten for the potential treatment of HCM**

We have partnered with MyoKardia (now 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, oHCM and 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 intend to evaluate mavacamten in Phase 3 and PK clinical trials in China and, if the data are consistent with the data demonstrated in global clinical trials, use the China data in combination with data generated in global trials by MyoKardia to seek regulatory approval in China. We also plan to develop mavacamten in nHCM and HFpEF.

#### *Hypertrophic cardiomyopathy disease overview*

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

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

HCM patients can be segmented into two groups:

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

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

#### *Current standard of care for HCM*

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

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

#### *HFpEF disease overview and current standard of care*

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

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

#### *Mavacamten development path*

Mavacamten was designed to correct or address the impaired cardiac muscle contractility and relaxation that characterizes HCM by acting on cardiac myosin, a key myocyte protein, to allow the heart muscle to relax, thereby expanding the volume of the heart and enabling it to pump more blood. In 2020, MyoKardia announced results from a global Phase 3 clinical trial called EXPLORER-HCM, in

which patients with symptomatic oHCM treated with mavacamten experienced statistically significant and clinically meaningful improvements in symptoms, functional status and key aspects of quality of life. 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 <sup>3</sup>1.5mL/kg/min improvement in peak oxygen consumption (“pVO<sub>2</sub>”) accompanied by an improvement of <sup>3</sup>1 NYHA functional class, or (2) the achievement of a <sup>3</sup>3.0mL/kg/min improvement of pVO<sub>2</sub> with no worsening in NYHA functional class. The 30-week treatment with mavacamten resulted in a highly statistically significant outcome relative to placebo (p=0.0005) for the primary endpoint.

Additionally, mavacamten demonstrated beneficial results (p£0.0006) for all secondary endpoints: post-exercise LVOT peak gradient, pVO<sub>2</sub>, 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 ( $p \leq 0.0006$  for all endpoints)

### Results from the EXPLORER-HCM trial published in 2020

	Mavacamten Group (n=123)	Placebo Group (n=128)	Difference <sup>1</sup> (95% CI), p Value
<b>Primary Endpoint<sup>2</sup></b>			
Either <sup>3</sup> 1.5 mL/kg per Min Increase in pVO <sub>2</sub> with <sup>3</sup> 1 NYHA Class Improvement or <sup>3</sup> 3.0 mL/kg per Min Increase in pVO <sub>2</sub> with No Worsening of NYHA Class	45 (37%)	22 (17%)	19.4 (8.7 to 30.1; p=0.0005)
<sup>3</sup> 1.5 mL/kg per Min Increase in pVO <sub>2</sub> with <sup>3</sup> 1 NYHA Class Improvement	41 (33%)	18 (14%)	19.3 (9.0 to 29.6)
<sup>3</sup> 3.0 mL/kg per Min Increase in pVO <sub>2</sub> with No Worsening of NYHA Class	29 (24%)	14 (11%)	12.6 (3.4 to 21.9)
Both <sup>3</sup> 3.0 mL/kg per Min Increase in pVO <sub>2</sub> and <sup>3</sup> 1 NYHA Class Improvement	25 (20%)	10 (8%)	12.5 (4.0 to 21.0)
<b>Secondary Endpoints<sup>3</sup></b>			
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 <sub>2</sub> 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)
<sup>3</sup> 1 NYHA Class Improvement from Baseline to Week 30 <sup>4</sup>	80 (65%)	40 (31%)	34% (22 to 45; p<0.0001)
Change from Baseline to Week 30 in KCCQ-CSS <sup>4</sup>	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 <sup>4</sup>	-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<sub>2</sub> = Peak Oxygen Consumption. NYHA = New York Heart Association.

<sup>1</sup> Model estimated least-square mean differences were reported for continuous variable.

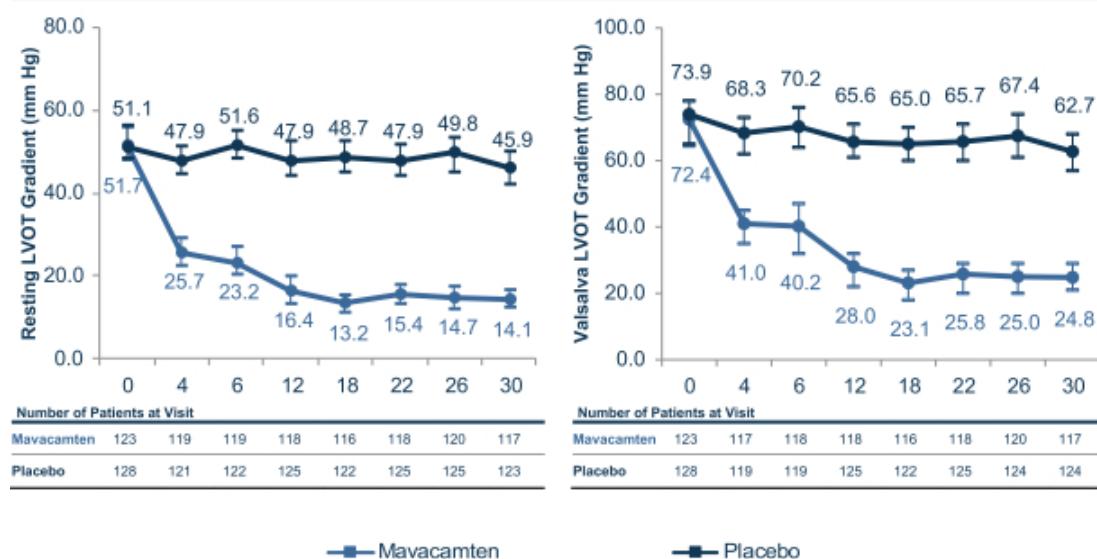
<sup>2</sup> Patients with a non-evaluable primary endpoint and NYHA secondary endpoint were considered as non-responders. The response rates were calculated with the N value as the denominator.

<sup>3</sup> N was the number analyzable for secondary endpoints based on availability of both baseline and week 30 values.

<sup>4</sup> 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.

#### 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 plan to concurrently conduct 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 received clearance from NMPA in August 2021 to initiate the Phase 3 and PK trials and we anticipate initiating these trials in the first quarter of 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 also plan to concurrently conduct 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 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 g-aminobutyric-gated chloride channels ("GABA-Cl") and which is initially being studied for the treatment of DB and has potential therapeutic applications for MGD. DB is caused by an infestation of Demodex mites triggering inflammation and is characterized by scaly scabs 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 DB 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, is ongoing. 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 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 there were 43 million DB 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 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 lasts two to three months, and 60% of patients relapse within six months. 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. 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 Demodex blepharitis signs was demonstrated in patients treated with TP-03.

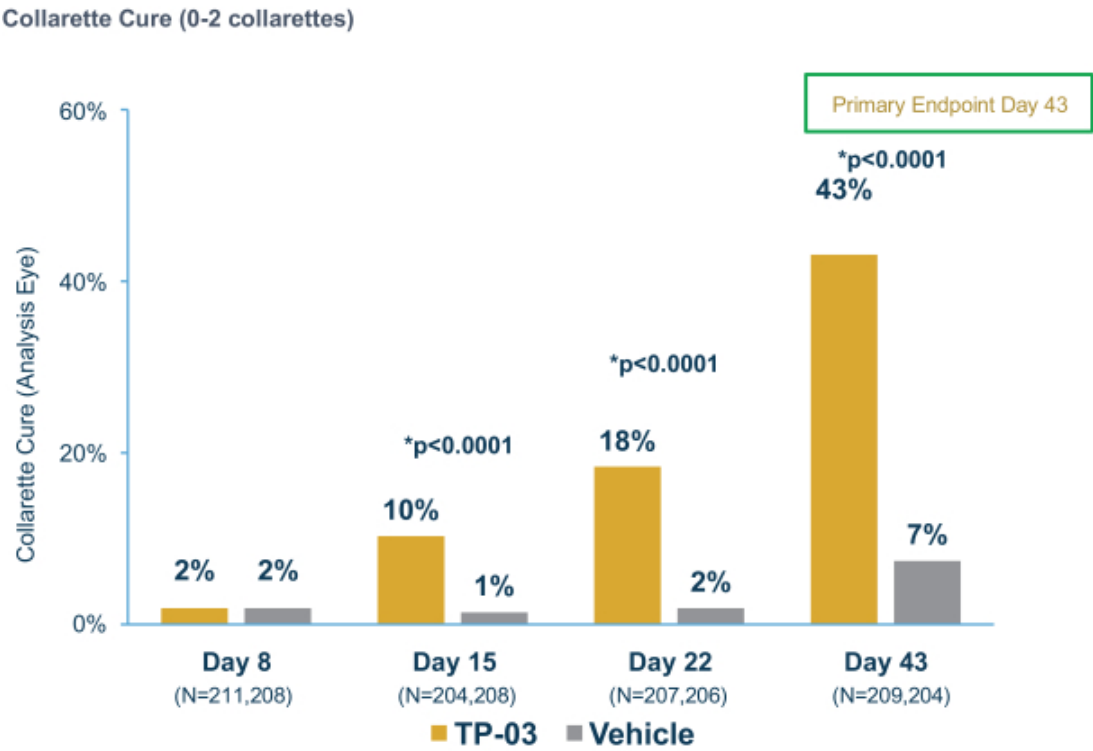
- 43% of patients on TP-03 achieved the primary endpoint of complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 7% on vehicle ( $p<0.0001$ ).
- 81% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared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

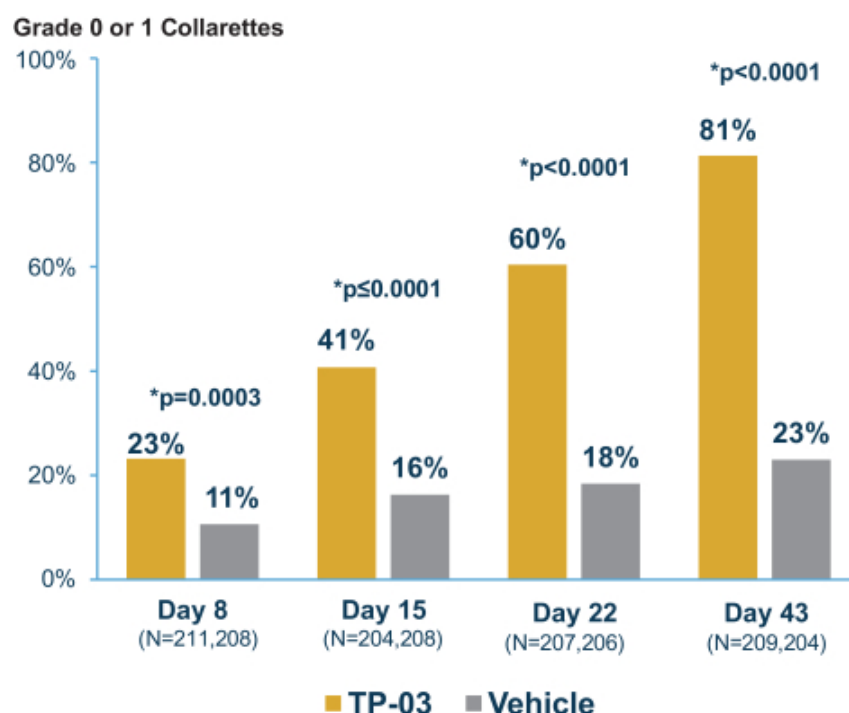
TP-03 was well tolerated with a safety profile similar to the vehicle group. Additionally, most TP-03 patients (92%) reported that the drop comfort was neutral to very comfortable. There were no

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 and potentially a PK trial in China 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 radiosensitizer for the potential treatment of head and neck cancer and other solid tumors***

We have partnered with Nanobiotix to develop and commercialize NBTXR3, a radiosensitizer 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. NBTXR3 is designed to enhance the effect of radiotherapy without resulting in additional side effects on 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, and 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 an 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 potential future global pivotal trials across indications and therapeutic combinations including immunotherapy, beginning with Nanobiotix's announced planned Phase 3 NANORAY-312 clinical trial in locally advanced head and neck 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.

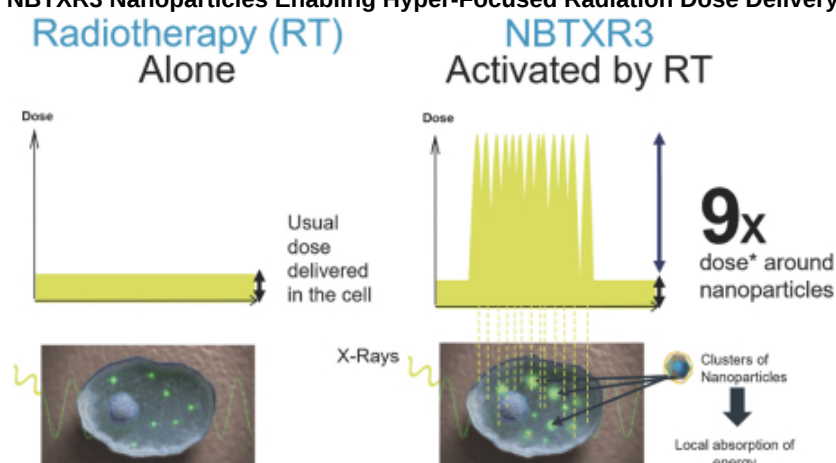
#### ***NBTXR3 overview***

NBTXR3 is a suspension of functionalized crystalline hafnium oxide nanoparticles designed for injection directly into a solid tumor prior to standard RT. NBTXR3's approach utilizes nanophysics to bring a physical 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 radiosensitizers. 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 serious adverse events (“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

Head and neck cancers include cancers of the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity and salivary glands. Tobacco use, heavy alcohol use, human papillomavirus (“HPV”) 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 there are approximately 90,000 non-nasopharyngeal cancer (“NPC”) H&N cancer patients 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

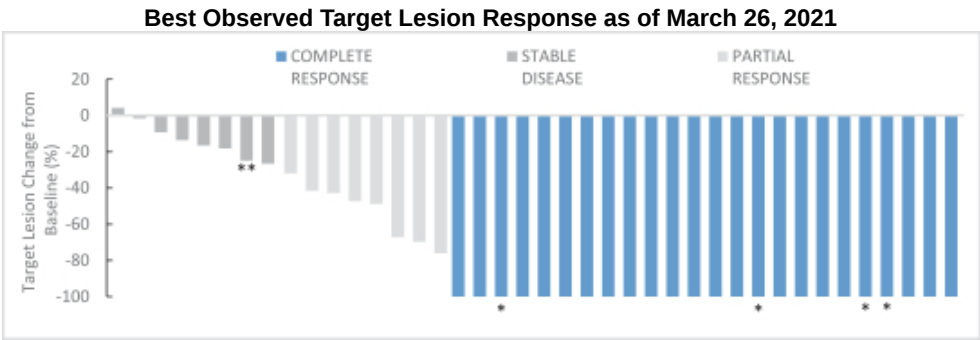
Chemotherapy in combination with concomitant radiation is the current standard of care for inoperable locally advanced H&N cancer. In China, KOL research indicates most patients with inoperable locally advanced H&N cancer are eligible to be treated by RT. This presents limitations in elderly patients, 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 PD-1 inhibitors and with chemotherapy.

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

In June 2021, Nanobiotix presented an interim analysis of safety and efficacy data from Study 102 at the 2021 ASCO Annual Meeting. At a median follow up of 8.1 months, out of the 40 evaluable patients in the Study 102 expansion cohort, 82.5% demonstrated a primary tumor objective response and 62.5% achieved complete response. These response rates include one patient recorded by the principal investigator of the study as an unconfirmed complete response.



\* Unconfirmed Response  
 \*\* Calculations include one patient marked recorded as unconfirmed Complete Response by principal investigator per eCR  
 NBTXR3 was observed to be feasible and well-tolerated. Six Grade 2-4 SAEs related to NBTXR3 were observed across five patients. Ten deaths related to adverse events were reported. Four deaths related to RT were observed, along with one death from sepsis that was investigator-assessed as possibly related to NBTXR3, RT, and cancer.

Phase 3 Registrational Trial (NANORAY-312)

Based on the preliminary Phase 1 data demonstrated in Study 102, Nanobiotix has designed a global pivotal Phase 3 clinical trial of NBTXR3 in elderly patients with locally advanced H&N squamous cell carcinoma (“HNSCC”) who are ineligible for platinum-based chemotherapy. Nanobiotix has announced plans to initiate this clinical trial in 2021.

NBTXR3 in Immuno-Oncology

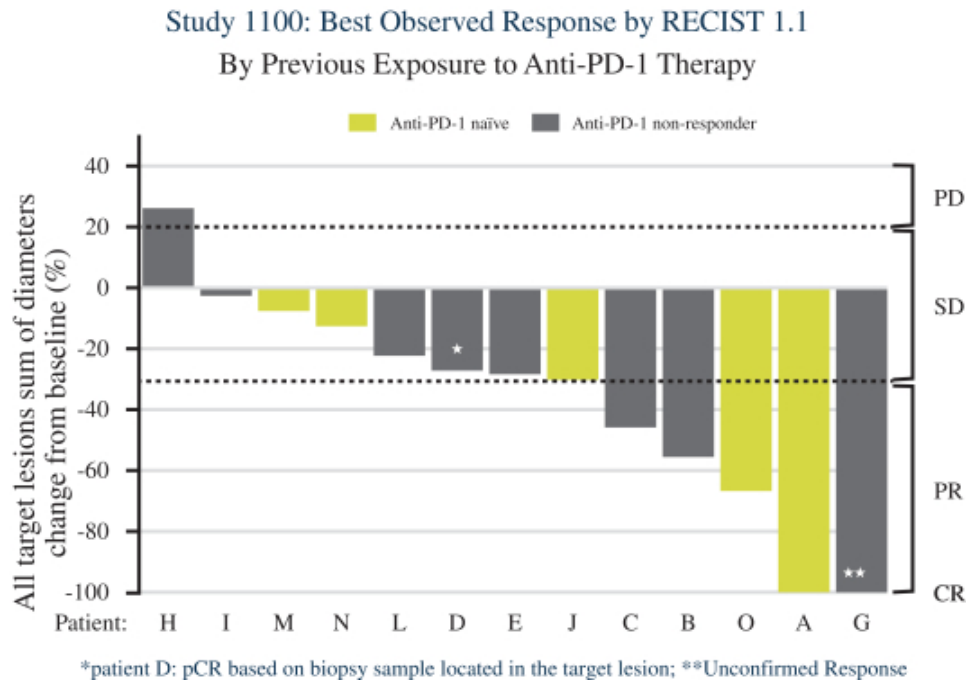
Nanobiotix has generated preclinical data demonstrating that RT-activated NBTXR3 resulted in greater tumor cell death than RT alone due to higher tumor recognition by the patient’s immune system.

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.

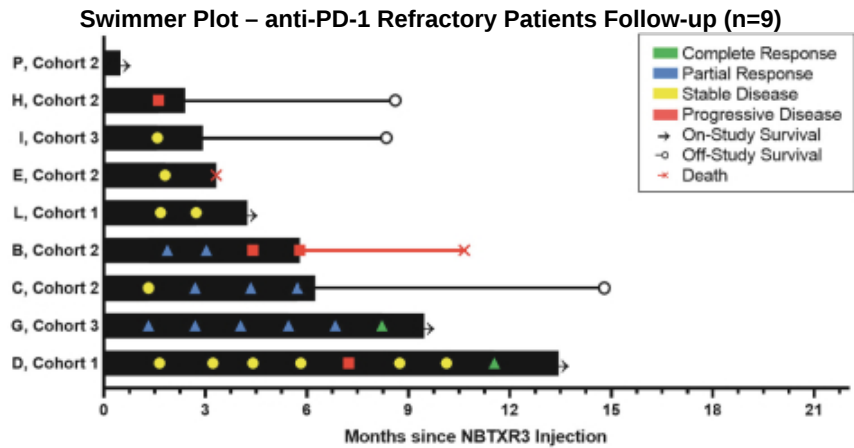
Phase 1 basket trial (Study 1100)

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 June 2021, Nanobiotix presented updated data from Study 1100 at ASCO. Tumor regression was observed in 10 out of 13 evaluable patients, including six of eight patients with prior primary or secondary resistance to anti-PD-1 and four of five anti- PD-1 naïve patients. In the subgroup of patients with prior primary or secondary resistance to anti-PD-1, 50% of the patients had investigator-assessed objective responses, including one complete response and two partial responses, along with one additional investigator-assessed pathological complete response. 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.







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 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 head and neck 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 CCA and gastric cancer*

We have partnered with BridgeBio Pharma, Inc. and its affiliate 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 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		FGFR Genomic Alterations
	Diagnosed Incidence	Estimated Occurrence of FGFR2 Genomic Alterations	Diagnosed Incidence	Estimated Occurrence of FGFR2 Genomic Alterations	
CCA	~11k	14-17%	~72k	14-17%	FGFR2 fusions
GC	~26k	4.0%	~480k	4.6%	FGFR2 amplification

### CCA disease overview

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 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 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 cholangiocarcinoma 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**

<b>Activity Endpoints in the Full Analysis Set</b>	<b>N=108</b>
<b>BICR-assessed objective response rate, % (95% CI)</b>	<b>23.1% (15.6-32.2)</b>
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%)
<b>BICR-assessed confirmed or unconfirmed response, % (95% CI)</b>	<b>34.3% (25.4-44.0)</b>
<b>BICR-assessed disease control rate, % (95% CI)</b>	<b>84.3% (76.0-90.6)</b>
<b>BICR-assessed median duration of response (IQR), months</b>	<b>5.0 (3.7-9.3)</b>
<b>BICR-assessed median progression-free survival (95% CI), months</b>	<b>7.3 (5.6-7.6)</b>
<b>Median overall survival (95% CI), months</b>	<b>12.2 (10.7-14.9)</b>

\* 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 or urothelial cancer. 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.

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

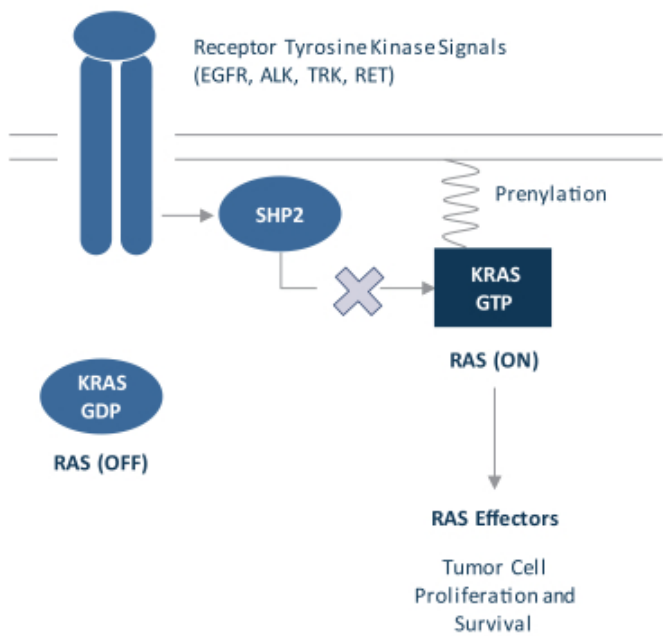
BBP-398 is an orally available allosteric inhibitor of SHP2, a tyrosine phosphatase that plays a key role in the RTK-mediated MAPK signal transduction pathway. We have partnered with BridgeBio Pharma, Inc. and its affiliate Navire Pharma, Inc. (“Navire”) to develop and commercialize BBP-398 in Greater China, Thailand, Singapore and South Korea. We plan to develop BBP-398 in combination with an 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 dose escalation study of BBP-398.

*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.

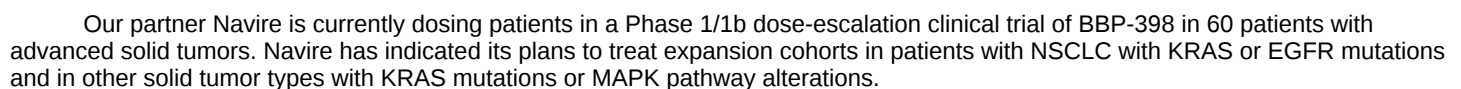
**Signaling Through Receptor Tyrosine Kinases and RAS Converge on SHP2**



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.

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 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 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 an EGFR-TKI 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 dose escalation study of BBP-398.

### ***LYR-210 for the potential treatment of chronic rhinosinusitis***

We have partnered with 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. Based on these data, Lyra has announced plans to advance LYR-210 into two Phase 3 pivotal trials. 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 and Xolair, have been approved in the United States for the treatment of CRS in adults with nasal polyps. These drugs have been approved in China for atopic dermatitis and for asthma, respectively, and, while not approved in China for CRS, they have been included in the treatment guidelines for CRSwNP. 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.

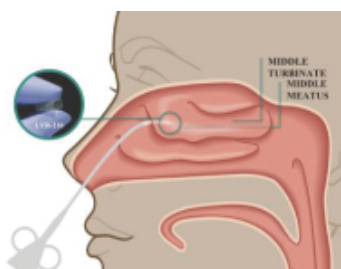
#### *LYR-210 overview*

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 miniaturized local drug delivery system based on Lyra's XTreo platform, which is a proprietary drug delivery technology designed to locally and continuously deliver small molecule 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, an air-containing space that plays a fundamental role in drainage of the paranasal sinuses. The active ingredient of 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. The composition and mass of the drug formulation matrix is specified to achieve the drug dose over time.

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. Moreover, the elastomeric matrix encapsulates the underlying mesh fibers to facilitate removal.

#### *LYR-210 development path*

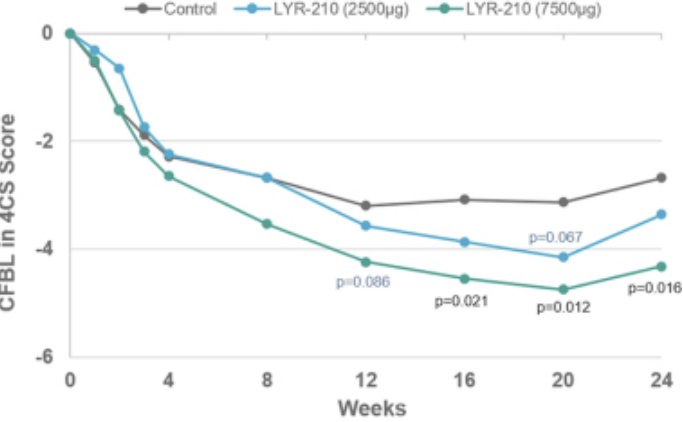
Lyra's Phase 2 LANTERN study was designed to inform a pivotal Phase 3 clinical trial for LYR-210. Based on the results of the LANTERN trial, Lyra has announced that it expects to initiate two global Phase 3 clinical trials of LYR-210 in CRS patients.

#### *Results from Phase 2 LANTERN Study*

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-

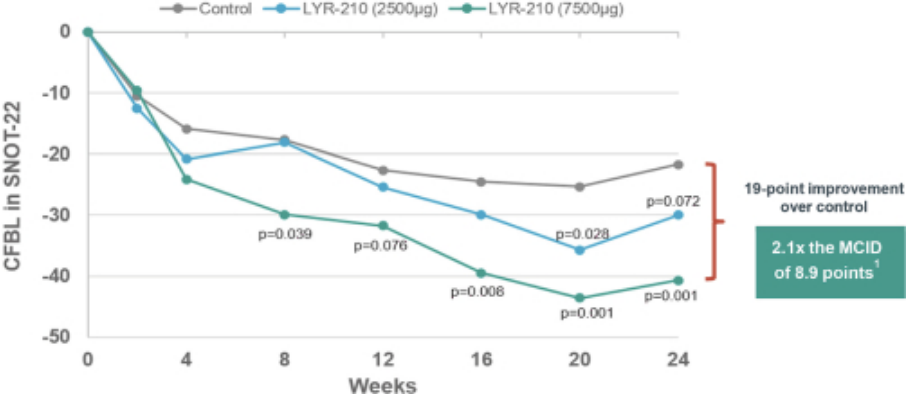
controlled, patient-blinded study that evaluated adult patients with CRS who had failed previous medical management and had not undergone FESS. The clinical trial enrolled 67 patients, with enrollment curtailed due to the COVID-19 pandemic, across Australia, Czech Republic, New Zealand and Poland. The 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 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. <sup>1</sup>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, with a retention rate of more than 80% at 24 weeks. There were no adverse events associated with the matrices that were dislodged.

#### *Our strategy to seek regulatory approval in China*

We plan to join Lyra's potential global pivotal trial of LYR-210 by opening sites and enrolling patients in China.

### **Inflammatory Disease**

#### ***Omilancor for the potential treatment of inflammatory bowel disease***

We have partnered with 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-restrictive small molecule activator of the lanthionine synthetase C-like 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 UC and CD. Landos has announced plans to initiate two Phase 3 clinical trials of omilancor in mild to moderate UC patients. In May 2021, Landos initiated a Phase 2 clinical trial in moderate to severe CD. 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, aminosalicilic 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 in this end-market.

#### *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 two global Phase 3 clinical trials of omilancor in mild to moderate UC patients, PACIFY I and PACIFY II.

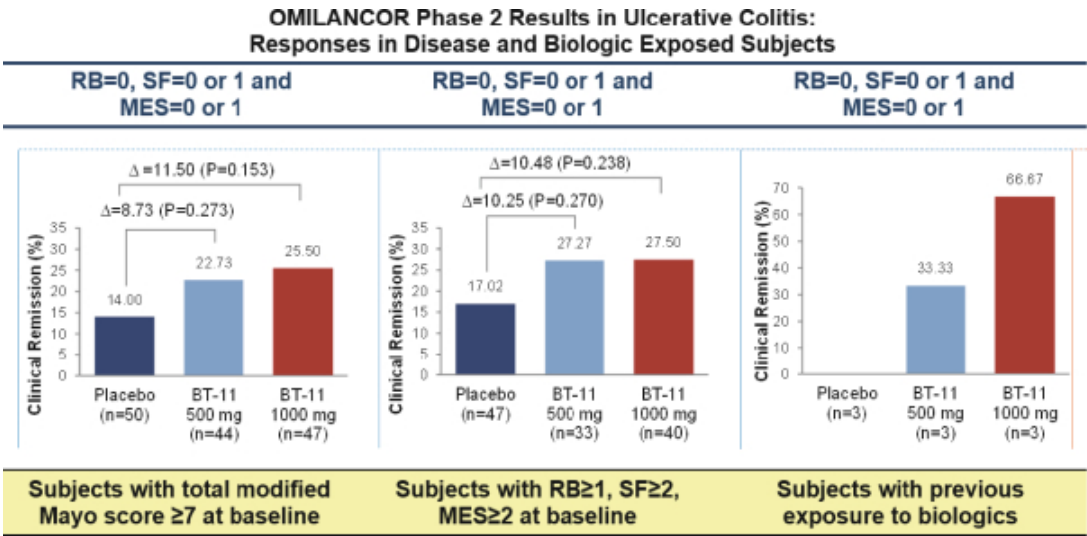
#### *Results from Phase 2 clinical trial in UC*

Landos released 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)	BT-11 500 mg (n = 66)	BT-11 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%)).



Our strategy to seek regulatory approval of omilancor in China

We plan to join Landos's potential future global pivotal trials of omilancor in UC and CD by opening sites and enrolling patients in China. The well-tolerated profile to date of omilancor provides us the opportunity to treat both mild to moderate UC patients and potentially more severe UC patients. We believe that enrolling patients in China in the global Phase 3 clinical trial may expedite the global development program as well as support regulatory approval 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 mild to moderate 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*

We plan to join Landos's potential future global pivotal trials of NX-13 in UC and CD. We believe that enrolling patients in China in global pivotal trials may expedite the global development program as well as support regulatory approval in China.

### **Respiratory**

#### ***Sisunatovir for the potential treatment of RSV***

We have partnered with 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-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 elderly patients with RSV infections. Should these clinical trials be successful, ReViral intends to initiate global pivotal Phase 3 clinical trials, and we intend to join 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 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*

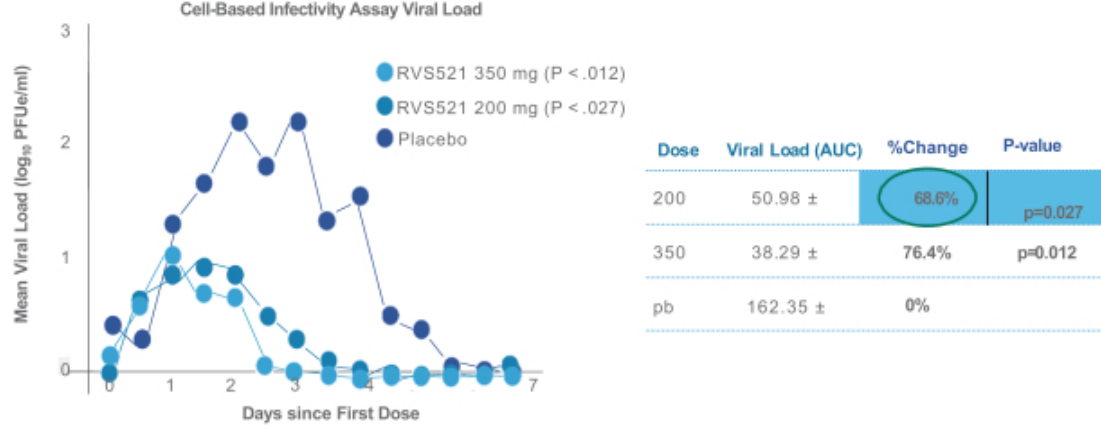
Sisunatovir is a small-molecule antiviral fusion inhibitor designed to inhibit RSV replication by suppressing F-mediated fusion with the host cell. We believe fusion inhibitors represent a promising treatment approach for RSV because the RSV-F protein plays a key role in infectivity and pathogenesis. 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 (n=53). The mean AUC of RT-qPCR-assessed RSV viral load (log<sub>10</sub> 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).

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



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**



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)<sup>a</sup>

TEAE <sup>b</sup>	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 is also currently conducting a global Phase 2 clinical trial of sisunatovir in immunocompromised patients and has announced plans to initiate a Phase 2 clinical trial of sisunatovir in elderly patients.

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 elderly populations. Should ReViral advance sisunatovir into pivotal Phase 3 trials in pediatric and elderly patients, we plan to join 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 “Risk Factors” included in this prospectus.

## **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 (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, issued warrants to MyoKardia exercisable for 17% of the ordinary shares of Lian Cardiovascular, our wholly owned subsidiary, upon issuance and paid an additional \$35.0 million upon a specified financing event, which occurred on October 29, 2020. 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 prospectus, 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 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 agreed to enter into separate supply agreements, pursuant to which we will purchase mavacamten exclusively from MyoKardia. 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 this license 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.

#### ***QED License Agreement***

In October 2019, we entered into a license agreement with QED (as amended September 2020, 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.

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 and issued warrants to QED representing 10% of the then-fully diluted equity of Lian Oncology, our wholly owned subsidiary, at the time of issuance. On top of those, we will be required to pay QED development milestone payments of up to \$45.0 million if we achieve specified development milestones, and sales milestone payments of up to \$87.5 million if we achieve specified commercialization milestones. In addition, 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 low- to mid-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 prospectus, 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 agree to enter into a separate supply agreement pursuant to which we will purchase licensed products from QED. 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 this license 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. In addition, 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 (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

## [Table of Contents](#)

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 prospectus, 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 also agree 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 supply agreements.

### ***Pfizer Strategic Collaboration Agreement***

In November 2020, we entered into a strategic collaboration agreement (the “Pfizer Agreement”) with Pfizer Inc., 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 us 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.

### ***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 agree 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 III registrational study in head and neck 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 agree to execute, within a certain number of days 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 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 \$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 prospectus, the last-to-expire patent under the agreement is an European application and will be extended to each of the licensed territories according to Nanobiotix. The European application will have a twenty-year statutory expiration date in 2041 in each of the licensed territories, provided such European application would be extended to each 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. 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 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 an 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 agree 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 \$20.0 million upon the occurrence of a specified milestone event which occurred on June 22, 2021. We also issued warrants to Tarsus exercisable for ordinary shares in Lian Ophthalmology representing 12.5% of the fully diluted equity of Lian Ophthalmology at fair market value as of the date of the transaction. If we achieve specified development and commercialization milestones, we may be required to pay milestone payments of up to \$75.0 million (including the \$20.0 million milestone payment 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 prospectus, 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 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 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, BT-11 and NX-13, in the licensed territory 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 agree 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 III 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 agree 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 prospectus, the last-to-expire patent under the agreement is a provisional United States application and will have a twenty-year statutory expiration date in 2041 in each licensed territory, provided such provisional U.S. application will be converted into a non-provisional application, extended to each 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. 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 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 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 agree 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 agree 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 III clinical trial for a licensed product, then we are obligated to use commercially reasonable efforts to engage clinical trial sites and enroll a certain percentage of study patients in the territory.

We agreed to purchase all licensed product 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 product 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. 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 prospectus, 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 agree 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 prospectus, 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 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 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 September 30, 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 September 30, 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 September 30, 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 cholangiocarcinoma, respectively, with infigratinib. This patent family includes two pending PCT applications. 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. 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.

### ***BBP-398***

As of September 30, 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 September 30, 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 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. 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 September 30, 2021, we licensed from Nanobiotix eight 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 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. An European application has been filed for this family and Nanobiotix will extend this patent application via PCT to China per its general intellectual property strategy. Any patents that may issue from this family of patent applications will have a twenty-year statutory expiration date no later than 2041 if a PCT application is timely filed, 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 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 September 30, 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.

#### ***BT-11***

As of September 30, 2021, we licensed from Landos four families of patent applications. The first patent family is directed to composition of matter for BT-11. The family includes issued patents 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 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 BT-11 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 polymorphs of BT-11. A U.S. provisional application has been filed for this family and will extend via PCT 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 no later than 2041 if a non-provisional application is timely filed, 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 BT-11. A U.S. provisional application has been filed for this family and will extend via PCT 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 no later than 2041 if a non-provisional application is timely filed, 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 September 30, 2021, we licensed from Landos one family of patent applications. The patent family is directed to 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. We will only have a license to patent applications in this families to the extent that patent applications are filed in countries within the territory of our license prior to applicable deadlines.

#### **LYR-210**

As of September 30, 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 has come in 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 “Risk Factors—Risks related to our intellectual property.”

#### **Employees and human capital resources**

As of September 30, 2021, we had 87 full-time employees in the United States, China and Singapore. Of these full-time employees, 43 employees are engaged in research and development activities and 44 are engaged in general and administrative activities. As of September 30, 2021, 21 employees were employed in the United States, 65 employees were employed in China and 1 employee was employed in Singapore. 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.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

## **Facilities**

Our principal executive office 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, subject to the completion of construction on the newly leased premises, we anticipate relocating to a new floor within our current building, where we will occupy 7,152 square feet of office space. The term of our amended lease agreement is expected to run for three years from the date on which we occupy the new premises. Until the new premises are completed, we have entered into a temporary agreement to rent an additional 1,825 square feet of office space elsewhere within our current building. The lease under this building expires on April 6, 2022, and we have an option to extend for one additional period of 24 months. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

## **Manufacturing**

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

We currently do not have any clinical or commercial supply contracts for our product candidates. However, we plan to enter into 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.

## **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.

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

To implement the regulatory reform introduced by the Innovation Opinion, the SCNPC and the NMPA have recently 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 appliances and equipment, as well as cosmetics in China;
- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical device, and cosmetics industry;
- evaluating, registering and approving chemical drugs, biological products and traditional Chinese medicine ("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 CFDA's Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs, 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 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 prospectus, 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 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 HGRAO 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 HGRAO 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 are still subject to the advance approval of the HGRAO.

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 its commencement.

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

#### ***Qualification of clinical trial institutions and compliance with GCP***

According to the Innovation Opinion, certification of clinical trial institutions by the former CFDA and the former NHFPC was no longer required. Instead, a clinical trial institution can be engaged by a drug marketing authorization applicant (i.e., a sponsor) to conduct a drug clinical study after it has been duly registered with the online platform designated by the NMPA. On November 29, 2019, pursuant to the 2019 Amendment, the NMPA and the NHC jointly released the Rules for Administration of the Drug Clinical Trial Institutions, which became effective on December 1, 2019. The rules specify requirements for clinical trial institutions and recordal procedures. Pursuant to the rules, a clinical trial institution

should comply with the requirements of the GCP and be capable of undertaking pharmaceutical 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 ICH-CTD (International Conference on Harmonization-Common Technical Document) 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.

#### ***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 2019 Amendment 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 the contract manufacturers have 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 drugs, 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 items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), 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 September 2020, the NMPA and the China National Intellectual Property Administration (“CNIPA”), jointly published the draft Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (“Draft Measures on Patent Linkage”) for public comments. The Draft 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, but lacks operational details. The Draft Measures on Patent Linkage are intended to answer these operational questions.

The Draft Measures on Patent Linkage describe a framework for a patentee to defend their patent exclusivity. Upon discovery of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the CDE’s publication and must submit a copy of the case acceptance notification to the CDE within 10 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 Draft 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 receiving marketing authorization approval. As of the date of this prospectus, the final version of the Draft Measures on Patent Linkage has not been published by the NMPA.

***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 April 2020, the Cyberspace Administration of China, NDRC and several other administrations jointly promulgated the Cybersecurity Review Measures, which became effective in June 2020. The Cybersecurity Review Measures establish the basic framework for national security reviews of network products and services, and provide the principle provisions for undertaking cybersecurity reviews. The Cybersecurity Review Measures, together with the Cyber Security Law, provides that a critical information infrastructure operator (the “CIIO”) must pass a cybersecurity review when purchasing network products and services which do or may affect national security. According to the Cybersecurity Review Measures, CIIOs shall be identified by the relevant department responsible for protecting critical information infrastructures. In July 2021, the Cyberspace Administration of China published the draft amendment to the Cybersecurity Review Measures for public comment. The draft amendment proposes the following key changes: (i) in addition to CIIO, companies who are engaged in data processing are also subject to the cybersecurity review; (ii) the China Securities Regulatory

Commission is included as one of the regulatory authorities on the panel for the state cybersecurity review; (iii) the operators (including both CIIOs and relevant parties who are engaged in data processing) holding personal information of more than one million users and seeking a listing outside China shall file for cybersecurity review with the Cybersecurity Review Office; and (iv) the risks of core data, material data or large amounts of personal information being stolen, leaked, destroyed, damaged, illegally used or transmitted to overseas parties and the risks of critical information infrastructure, core data, material data or large amounts of personal information being influenced, controlled or used maliciously by foreign governments shall be collectively taken into consideration during the cybersecurity review process. Since the Cyberspace Administration of China is currently still soliciting comments for the draft amendment, uncertainties remain in relation to the final version of the draft amendment to the Cybersecurity Review Measures as well as its implementation and interpretation.

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.

Additional regulations, guidelines, and measures relating to data privacy and data protection are expected to be adopted, including the Measures for Security Assessment for Cross-border Transfer of Personal Information and Important Data (Draft for Comment), published in 2017, the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, and the Personal Information Protection Law promulgated in August 2021 which will become effective on November 1, 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.

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

#### ***Good Laboratories Practice certification for nonclinical research***

To improve the quality of animal research, the former SFDA promulgated the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory in 2003 (“GLP 2003”), and began to conduct the certification program of the GLP. The GLP 2003 was then abolished and replaced by the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of



Good Laboratory Practice of Pre-clinical Laboratory, providing that the former SFDA (now the NMPA) is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, the former SFDA (now the NMPA) decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution's organizational administration, personnel, laboratory equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all requirements are met, a GLP Certification will be issued by the former SFDA (now the NMPA) and published on the government website.

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

Conditions for the application of drug production technology transfer

Applications for drug production technology transfer may be submitted if:

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

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

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

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

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

Conditions for the application for marketing authorization transfer

As previously discussed under “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 letters and other types of enforcement-related letters,

product recalls, product seizures, 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 manually;
- approval by an 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 product for its proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 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 ("NCEs"), 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

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 I, Phase II and Phase III clinical trials.

- **Phase I:** The drug is initially introduced into a small number of healthy volunteers 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 II:** The drug is administered to a limited patient population 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 III:** 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 III clinical trials may include comparisons with placebo and/or other comparator treatments. Post-approval trials, sometimes referred to as Phase IV 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 IV 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. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. 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. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

#### *NDA submission and FDA review process*

The results of non-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 IV 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. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. 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 2019, approximately 1.3 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 2020, 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 ("2020 NRDL"), and 119 new drugs were admitted to the 2020 NRDL. Previous updates to the NRDL occurred in 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 amounts 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 Central Committee of the Communist Party of China 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, and 2020. In 2020, the average price reduction of the 119 new drugs added to the 2020 NRDL is 50.64%.

### 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 public medical institution. The 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 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 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 nationwide 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 and fourth round of the national centralized volume-based procurement and tender program published on August 24, 2020 and February 8, 2021, respectively, show similar levels of reduction in average price reduction of more than 50%, with the highest reduction reaching 93% and 96%, respectively.

### Two-invoice system

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

### Medical insurance reimbursement standards

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

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

To further standardize payment in the Basic Medical Insurance schemes, in October 2019, the NHSA issued two key technical documents for a pilot project that introduces DRGs, the Technical Guideline of the Classification and Payment for China Healthcare Security Diagnosis Related Groups (CHS-DRG) and the CHS-DRG Classification Plan. According to the classification plan, patients will be sorted into 26 major diagnostic categories and 376 adjacent diagnosis-related groups. DRG-based settlement is currently only applicable to expenses of inpatient care incurred by the insureds at designated hospitals participating in the DRG payment pilot programs and payable by regional medical insurance fund under the Basic Medical Insurance schemes. DRG-based payments are made directly

to the participating medical institutions, while the covered benefits enjoyed by the insureds, under the current public insurance schemes, are not affected by such settlement. In June 2020, the NHSA issued a more detailed CHS-DRG Classification Plan, further dividing the 376 diagnosis-related groups into 618 basic reimbursement units. The 30 municipalities participating in the DRG pilot project were required to submit technical assessment reports 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 launch in 2021.

### **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 Central Committee of the Communist Party of China 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 and 2019. 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. As of the end of 2020, Basic Medical Insurance coverage has reached 95% of the country's population.

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 healthcare 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 Central Committee of the Communist Party of China 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 medical 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.

### ***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 will be covered 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 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. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates 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 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 unless additional Congressional action is taken. However, relief legislation related to the COVID-19 pandemic suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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 product 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 payer, 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.

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 Special Administrative Measures (Negative List) for Foreign Investment Access (2020) (the “Negative List”), which was promulgated by the Ministry of Commerce of the People's Republic of China (“MOFCOM”) and NDRC on June 23, 2020 and took effect on July 23, 2020. 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, and utility models and designs are effective for ten and fifteen years, respectively, from the date of application. The PRC Patent Law adopts the principle of “first-to-file” system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity 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. 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, uses or imports patented drugs or patented medical equipment for the abovementioned 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 abovementioned 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 September 30, 2021, we had eleven trademark applications pending in Mainland China, four trademarks registered in Hong Kong, two trademarks registered in Singapore, two trademark applications pending in the United States, four trademark applications pending in Taiwan, four trademark applications pending 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 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](http://www.lianbiopharma.com) and [www.lianbio.com](http://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 and August 31, 2014, 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 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 amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees, which become effective on December 14, 1994, 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 stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee stock 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. 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.

## MANAGEMENT

### Our Executive Officers and Directors

The following table sets forth the name, position, a brief account of the business experience, and age as of September 30, 2021 of each of our executive officers and directors:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Executive Officers</b>		
Yizhe Wang, Ph.D.	52	Chief Executive Officer and Director
Yi Larson	41	Chief Financial Officer
Debra Yu, M.D.	57	President and Chief Strategy Officer
Brianne Jahn	35	Chief Business Officer
Pascal Qian	53	China General Manager
<b>Non-Employee Directors</b>		
Konstantin Poukalov	38	Executive Chairman, Board of Directors
Adam Stone	42	Director
Neil Kumar, Ph.D.	42	Director
Tassos Gianakakos	48	Director
Susan Silbermann	59	Director
Jesse Wu	64	Director
<b>Other Key Employees</b>		
Nathan Chen	53	Vice President of Regulatory Affairs
Levy Lv, D. Eng	39	Vice President of Translational Development & Clinical Operations
Michael Humphries, FRCP	67	Chief Scientific Advisor

#### **Executive officers**

**Yizhe Wang, Ph.D.**, has served as our Chief Executive Officer since May 2021. Dr. Wang previously served as Global Brand Development Leader, Lilly Oncology, at Eli Lilly and Company ("Eli Lilly"), from April 2018 to May 2021. From June 2020 to November 2020, Dr. Wang served as Global Platform Lead for anti-COVID Therapy, Lilly Research Lab, where he led a new operating model integrating discovery, development and launch resulting in the EUA of bamlanivimab. From April 2018 to May 2020, Dr. Wang was Senior Vice President, Head of BioMedicines and Oncology Businesses, Lilly China, where he was a member of the Global Oncology and Biomedicines Business Unit lead teams, and China Executive Committee. Prior to Eli Lilly, Dr. Wang was at GlaxoSmithKline plc for 15 years where he held product and commercial strategy roles of increasing responsibility in the United States (2003-2012), United Kingdom (2012-2014) and China (2014-2018), ultimately serving as Head of GlaxoSmithKline plc China Pharmaceuticals' Respiratory Business Unit. Earlier in his career, he was a researcher at BMS. Dr. Wang received a doctorate in organic chemistry from Yale University. He also earned a master's degree in business administration from the Wharton School at the University of Pennsylvania and a bachelor's degree in chemistry from Ramapo College of New Jersey. We believe Dr. Wang's significant experience within the United States and China life sciences markets qualify him to serve as a member of our board of directors.

**Yi Larson** has served as our Chief Financial Officer since May 2021. Ms. Larson previously served as Executive Vice President and Chief Financial Officer at Turning Point Therapeutics, Inc., a clinical stage precision oncology company, from August 2019 to March 2021. Prior to that, Ms. Larson worked at Goldman Sachs & Co. LLC, where she held various roles since 2008, most recently as a Managing Director of Healthcare Investment Banking. During her tenure at Goldman Sachs & Co. LLC, Ms. Larson

advised a variety of biopharmaceutical company boards of directors and management teams on a range of strategic financial matters and executed equity offerings, debt offerings and M&A transactions. She also has served as a member of the board of directors of Olema Pharmaceuticals, Inc., a clinical stage biopharmaceutical company, since April 2021. Ms. Larson graduated from The Wharton School at the University of Pennsylvania with a master's degree in business administration concentrated in finance. She also earned a master's degree in electrical engineering and computer science and a bachelor's degree in electrical engineering, both from the Massachusetts Institute of Technology.

**Debra Yu, M.D.**, has served as our President and Chief Strategy Officer since September 2021, and previously served as our President and Chief Business Officer from October 2019 until September 2021. Dr. Yu previously served as Managing Director and Head of Cross Border Healthcare Investment Banking at China Renaissance Securities (U.S.), a brokerage firm, from August 2016 to September 2019. Prior to that, she was Managing Director of Labrador Advisors, LLC, where she advised numerous cross-border partnerships and licensing transactions from May 2009 to June 2016. Earlier, she was Vice President, Strategy at WuXi Apptec between 2008 and 2009, and helped to architect and co-lead Pfizer's venture capital team and was a member of Pfizer's Worldwide Business Development organization between 2005 and 2008. Dr. Yu was a Bay Area venture investor for several years, serving as General Partner of Delphi Ventures from 1995 to 1998 and Managing Director of Bay City Capital from 1998 to 2001. She also held positions at McKinsey & Co. in New York and London between 1992 and 1995. She began her career as an analyst at Morgan Stanley in 1987 to 1988. Dr. Yu has also served as a member of the board of directors of ARYA Sciences Acquisition Corp V since July 2021. Dr. Yu received a bachelor's degree with high honors in molecular biology from Princeton University in 1986 and earned a medical degree from Harvard Medical School in 1992.

**Brianne Jahn** has served as our Chief Business Officer since September 2021, and previously served as our Head of Operations and Finance, U.S., from February 2020 to September 2021. Before joining LianBio, Ms. Jahn served in roles of increasing responsibility at Kadmon Holdings, Inc. ("Kadmon"), a biopharmaceutical company, from April 2012 to January 2020, ultimately serving as Senior Vice President, Finance and Strategic Operations. While at Kadmon, she oversaw financial operations, including involvement in equity raises, debt restructuring and cash flow management. Ms. Jahn received her bachelor's degree in business administration from the University of Massachusetts, Amherst, and a master's degree in business administration from New York University.

**Pascal Qian** has served as our China General Manager since July 2021. Mr. Qian previously served as the Vice President, Head of Oncology Business Unit, Lilly China, at Eli Lilly and Company from June 2018 to July 2021, where he oversaw the China Oncology BU team and was responsible for the group's P&L and organizational development. From December 2012 to May 2018, Mr. Qian held various roles of increasing responsibility at Novartis AG, ultimately serving as Executive Director, BU Head of Solid Tumor at Novartis Oncology. Prior to Novartis AG, Mr. Qian served in several key roles at Pfizer Inc., including Business Liaison Head, Global Clinical Development and Medical Affairs, and China Oncology Business Unit Head. Mr. Qian graduated from Shanghai Jiaotong University Medical Institute (Shanghai 2nd Medical University) with a bachelor's degree in clinical medicine.

#### Non-Employee Directors

**Konstantin Poukalov** has served as the Executive Chairman of our board of directors since October 2019. Mr. Poukalov has served as a Managing Director at Perceptive Advisors, a life sciences-focused investment firm and affiliate of the Company, since March 2019. From July 2012 to October 2018, Mr. Poukalov served in roles of increasing responsibility at Kadmon, most recently



serving as Executive Vice President and Chief Financial Officer from July 2014 to October 2018. Prior to joining Kadmon, Mr. Poukalov was a member of the healthcare investment banking group at Jefferies LLC from 2009 to 2012, focusing on companies across the life sciences and biotechnology sectors. Prior to Jefferies LLC, Mr. Poukalov was a member of UBS Investment Bank, focusing on the healthcare industry from 2006 to 2009. Mr. Poukalov has also served as a member of the boards of directors of Lyra Therapeutics since January 2020. Mr. Poukalov earned a bachelor's degree in electrical engineering from Stony Brook University. We believe Mr. Poukalov's extensive financial and industry experience qualifies him to serve on our board of directors.

**Adam Stone** has served as a member of our board of directors since October 2019. Since July 2021 and February 2021, respectively, Mr. Stone has served as the Chief Executive Officer of ARYA Sciences Acquisition Corp V and ARYA Sciences Acquisition Corp IV, respectively, and as a member of their board of directors. Mr. Stone previously served as the chief executive officer and a member of the board of directors of ARYA Sciences Acquisitions Corps I, II, and III. Mr. Stone joined Perceptive Advisors, a life sciences focused investing firm and affiliate of the Company, in 2006 and has served as Chief Investment Officer since 2012 and is a member of the internal investment committees of Perceptive Advisors' credit opportunities and venture funds. Mr. Stone previously served as a Senior Analyst at Ursus Capital from 2001 to 2006, where he focused on biotechnology and specialty pharmaceuticals. Mr. Stone has also served as a member of the boards of directors of Solid Biosciences since November 2015 and Immatics since July 2020. Mr. Stone earned a bachelor's degree in molecular biology from Princeton University. We believe Mr. Stone's extensive experience developing early-stage biotech and healthcare companies qualifies him to serve on our board of directors.

**Neil Kumar, Ph.D.**, has served as a member of our board of directors since October 2019. Dr. Kumar has served as the Chief Executive Officer of BridgeBio Pharma, Inc., a commercial-stage biopharmaceutical company, and has been a member of BridgeBio Pharma, Inc.'s board of directors since April 2015. Dr. Kumar has also served as the Chief Executive Officer of Eidos Therapeutics, a clinical-stage biopharmaceutical company, and a member of Eidos Therapeutics' board of directors since March 2016. Prior to that, he served as the interim vice president of business development at MyoKardia, Inc., a clinical-stage biopharmaceutical company, from 2012 to 2014. Prior to that, Dr. Kumar was a principal at Third Rock Ventures, a healthcare venture capital firm, from 2011 to 2014, and an associate principal at McKinsey & Company, a management consulting firm, from 2007 to 2011. Dr. Kumar received his bachelor's and master's degrees in chemical engineering from Stanford University and received his doctorate in chemical engineering from the Massachusetts Institute of Technology. We believe Dr. Kumar's extensive experience in leading roles as an executive officer at various biotechnology companies qualifies him to serve on our board of directors.

**Tassos Gianakakos** has served as a member of our board of directors since August 2020. Mr. Gianakakos served as Chief Executive Officer and President and as a member of the board of directors of MyoKardia from October 2013 through November 2020 when it was acquired by Bristol-Myers Squibb. Mr. Gianakakos previously served as senior vice president and chief business officer at MAP Pharmaceuticals, Inc. from September 2006 to March 2013 when it was acquired by Allergan PLC. Prior to MAP Pharmaceuticals, Mr. Gianakakos led the formation of Codexis, Inc. in 2001. At Codexis, Mr. Gianakakos served as president and senior vice president, business development, and global head of Codexis' Pharmaceuticals Business Unit. Before forming Codexis, Mr. Gianakakos was director of business development at Maxygen, a directed evolution company, where he led the company's business development efforts for its vaccine and bio-industrial platforms, as well as financing activities including the company's initial public offering. Prior to Maxygen, Mr. Gianakakos was a process engineer in Merck & Co., Inc.'s vaccine division. Mr. Gianakakos holds bachelor's degrees in chemical engineering and economics from the Massachusetts Institute of Technology, a master's degree in biotechnology from Northwestern University and an a master's degree in business

administration from Harvard Business School. We believe Mr. Gianakakos' extensive management experience in the pharmaceutical industry qualifies him to serve on our board of directors.

**Susan Silberman** has served as a member of our board of directors since October 2021. Currently retired, Ms. Silberman worked for Pfizer for over 30 years, most recently serving as the chair of Pfizer's Global COVID-19 Task Force from January 2020 to March 2021. From December 2018 to December 2020, Ms. Silberman served as the Global President of Emerging Markets and from June 2012 to December 2018, she served as president and general manager of Pfizer Vaccines. Ms. Silberman earned both a master's degree in business administration and a master's degree in Administration in French Social and Political Sciences from New York University. She also earned a bachelor's degree in Biology and French from Tufts University. We believe Ms. Silberman's extensive experience in the international biotechnology and pharmaceutical industries qualifies her to serve on our board of directors.

**Jesse Wu** has served as a member of our board of directors since October 2021. Before retiring in 2016, Mr. Wu worked for Johnson & Johnson for over 26 years in roles of increasing responsibility, most recently serving as Chairman of Johnson & Johnson China and a member of the Johnson & Johnson Management Committee. Mr. Wu has served as a director of AptarGroup, Inc., a dispensing solution company, since February 2018. Mr. Wu earned his bachelor's degree in economics from National Chengchi University in Taiwan. He also earned a master's degree in business administration from Duke's University Fuqua School of Business. We believe Mr. Wu's extensive experience in the global healthcare and pharmaceutical industries qualifies him to serve on our board of directors.

### Other Key Employees

**Nathan Chen** has served as our Vice President of Regulatory Affairs since February 2020. Mr. Chen previously served as Therapeutic Area Head of Immunology and Inflammation for GlaxoSmithKline plc from November 2018 to February 2020. From November 2015 to August 2018, Mr. Chen served as Director of APAC Clinical Development and Medical Affairs at UCB Trading (Shanghai) Co. Ltd. ("UCB"). Prior to UCB, Mr. Chen served at Boehringer Ingelheim for nearly eight years as Director of Regional Clinical Development and Medical Affairs and as an Associate Director of Drug Regulatory Affairs, where he was in charge of integrating China and other Asian countries into global development and launching Pradaxa in Asia. Mr. Chen also previously held positions in regulatory affairs and drug discovery at BMS, Achillion Pharmaceuticals, Inc., and Neurogen Corporation in the United States. Mr. Chen received a master's degree in medicinal chemistry from Purdue University, a master's degree in computer and information sciences from Rensselaer Polytechnic Institute and a master's degree in organic chemistry from SUNY Albany.

**Levy Lv, D. Eng** has served as our Vice President of Translational Development & Clinical Operations since April 2020. Dr. Lv previously served as Head of Translational Medicine for CSPC Pharmaceutical Group Limited from April 2019 to April 2020. From June 2017 to April 2019, Dr. Lv was Senior Director, Scientific Engagement & Development at Covance R&D (Shanghai) Co., Ltd ("Covance"). Prior to Covance, Dr. Lv was with Roche R&D Center China and GlaxoSmithKline R&D China/China Investment Co., Ltd. for 10 years, where he lead multiple Phase I—Phase III clinical programs in multiple regions and therapeutic areas. Dr. Lv received his doctor of engineering degree in biology and medicine from Huashan Hospital, Fudan University.

**Michael Humphries, FRCP** has served as our Chief Scientific Advisor since October 2021. Dr. Humphries previously served as the Chief Medical Officer and Head of Development Strategy at CellularBioMedicine Group, Shanghai from December 2018 to October 2021. From 2004 to November 2018, Dr. Humphries held various senior leadership roles at Novartis including Chief Scientific Officer at Novartis Development China. He previously held the role of Country Medical Director at

GlaxoWellcome/GSK China from 1998 to 2004, and from 1990 until 1998, Dr. Humphries was Regional Medical Director, Roche China/Hong Kong/Asia-Pacific. Dr. Humphries received his Master of Arts, Medical Sciences at Cambridge University and his Bachelor of Medicine/Surgery from London University. He is a Fellow of the Royal College of Physicians and also holds Fellowships at the Hong Kong College of Physicians and Hong Kong Academy of Medicine.

### **Board Composition**

Following the completion of this offering, our board of directors will be composed of seven members, each of whom will be members pursuant to the board composition provisions of our fifth amended and restated memorandum and articles of association, which will become effective immediately upon the completion of this offering, and agreements with our shareholders, including the Director Nomination Agreement. See “Certain Relationships and Related Party Transactions—Director Nomination Agreement” for additional information. In selecting candidates for nomination to our board of directors, our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee’s and our board of directors’ priority in selecting board members is the identification of persons who will further the interests of our shareholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. Although we take diversity seriously, we currently have no formal policy regarding board diversity. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our board of directors has determined that Tassos Gianakakos, Susan Silberman and Jesse Wu are independent directors, as determined in accordance with the rules of Nasdaq. In making such independence determination, our board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence. Upon the effectiveness of the registration statement of which this prospectus forms a part, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC.

### **Staggered Board**

In accordance with the terms of our fifth amended and restated memorandum and articles of association, which will become effective and replace the current fourth amended and restated memorandum and articles of association in its entirety immediately upon the completion of this offering, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the shareholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The initial terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of shareholders to be held during the years 2022 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- Our Class I directors will be Tassos Gianakakos and Neil Kumar;
- Our Class II directors will be Susan Silberman and Adam Stone; and
- Our Class III directors will be Konstantin Poukalov, Yizhe Wang and Jesse Wu.

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

### **Duties of Directors**

Under Cayman Islands law, all of our directors owe us fiduciary duties, including a duty of loyalty, a duty to act honestly and a duty to act in good faith and in a manner they believe to be in our best interests. Our directors also have a duty to exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended and restated memorandum and articles of association, as amended and restated from time to time. We have the right to seek damages if a duty owed by any of our directors is breached.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each committee following this offering are described below. Members serve on these committees until their resignation or until otherwise determined by our board.

For each committee below, the rules of the SEC and the Nasdaq Global Market require us to have one independent committee member upon the listing of our ADSs, a majority of independent committee members within 90 days of the effective date of the registration statement of which this prospectus forms a part and all independent committee members within one year of the effective date of the registration statement of which this prospectus forms a part. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. If we qualify as a controlled company after this offering 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.

### **Audit Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of Tassos Gianakakos, Adam Stone and Konstantin Poukalov, with Tassos Gianakakos serving as chair of the committee. Our board of directors has determined that Tassos Gianakakos qualifies as a financial expert as set forth under the applicable rules of the SEC and that Tassos Gianakakos satisfies the independence requirements under the rules of the Nasdaq Global Market and under Rule 10A-3 of the Exchange Act. Within 90 days following the effective date of the registration statement of which this prospectus forms a part, we anticipate that the audit committee will

consist of a majority of independent directors, and within one year following the effective date of the registration statement of which this prospectus forms a part, we expect the audit committee will consist exclusively of independent directors.

The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance and independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm, and pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting periodically in separate executive sessions with management, the internal auditors (or other personnel responsible for the internal audit function) and the independent auditor;
- reviewing and approving any related person transactions;
- reviewing and discussing our guidelines and policies governing risk assessment and risk management;
- overseeing the integrity of our information technology systems, process and data, and assessing with management and the internal auditor the adequacy of security for our information technology systems;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

### **Compensation Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, our compensation committee will consist of Jesse Wu, Tassos Gianakakos, and Konstantin Poukalov, with Jesse Wu serving as chair of the committee. Our board of directors has determined that Jesse Wu and

Tassos Gianakakos satisfy the independence standards of the applicable rules of the Nasdaq Global Market.

The compensation committee's responsibilities upon completion of this offering will include, among other things:

- assisting our board of directors in developing and reviewing potential candidates for executive positions;
- reviewing our overall compensation strategy, including base salary, incentive compensation and equity-based grants, to provide for appropriate rewards and incentives for our management and employees;
- reviewing and recommending to the board of directors for approval corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- recommending to our board of directors the compensation of our chief executive officer and our other executive officers;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- overseeing and administering our equity-based plans, cash incentive plans, deferred compensation plans and management incentive compensation plans and making recommendations to the board of directors to grant awards under such plans;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and directors;
- reviewing and approving all employment contract and other compensation, severance and change-in- control arrangements for our executive officers;
- recommending to our board of directors any share ownership guidelines for our executive officers and non-employee directors;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other adviser, and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual proxy statement in accordance with the proxy rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- overseeing our compliance with applicable SEC rules regarding shareholder approval of certain executive compensation matters;
- reviewing the risks associated with our compensation policies and practices;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

Prior to establishing a compensation committee, our board of directors made decisions relating to the compensation of our executive officers.

### ***Nominating and Corporate Governance Committee***

Upon the effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee will consist of Susan Silbermann, Neil Kumar and Jesse Wu, with Susan Silbermann serving as chair of the committee. Our board of directors has determined that Susan Silbermann and Jesse Wu satisfy the independence standards of the applicable rules of the Nasdaq Global Market.

The nominating and corporate governance committee's responsibilities upon completion of this offering will include, among other things:

- identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- subject to the rights of Perceptive under the Director Nomination Agreement, recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- reviewing and assessing the policy under which our shareholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- subject to the rights of Perceptive under the Director Nomination Agreement, recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principals applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility;
- making recommendations to our board of directors processes for annual evaluations of the performance of our board of directors, our chief executive officer and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors, chief executive officer and committees of our board of directors and certifying that performance of our chief executive officer and other members of executive management is being properly evaluated;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.



## **Role of the Board in Risk Oversight**

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

## **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

## **Code of Ethics and Corporate Governance Guidelines**

Prior to the completion of this offering, we have adopted, effective upon completion of this offering, a Code of Ethics, which will be applicable to all of our directors, executive officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. Following the completion of this offering we will make our Code of Ethics publicly available on our website. Our Code of Ethics is a "code of ethics," as defined in Item 406(b) of Regulation S-K. The information contained on, or accessible from, our website is not part of this prospectus by reference or otherwise. We will make any legally required disclosures regarding amendments to, or waivers of, provisions of our Code of Ethics on our website.

In addition, prior to the completion of this offering, we have adopted, effective upon completion of this offering, a set of corporate governance guidelines covering a variety of matters, including approval of related party transactions. The guidelines will reflect certain guiding principles with respect to our board's structure, procedures and committees. The guidelines are not intended to change or interpret any applicable law, rule or regulation or our amended and restated memorandum and articles of association.

## EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion and analysis of compensation arrangements should be read with the compensation tables and related disclosures set forth below. This discussion contains forward looking statements that are based on our current plans and expectations regarding future compensation programs. The actual compensation programs that we adopt may differ materially from the programs summarized in this discussion.

This section describes the material elements of the compensation awarded to, earned by, or paid to our former Chief Executive Officer, Bing Li, and our two most highly compensated executive officers (other than our former Chief Executive Officer), Debra Yu, our President and Chief Strategy Officer (formerly our President and Chief Business Officer), and Brianne Jahn, our Chief Business Officer (formerly our Head of Operations and Finance, U.S.), for our fiscal year ended December 31, 2020. These executives are collectively referred to as our named executive officers. Dr. Li's employment with the Company was terminated effective March 26, 2021, and Yizhe Wang, Ph.D. was hired as the Company's new Chief Executive Officer effective May 17, 2021.

The following table shows information regarding the compensation of our named executive officers for the fiscal year ended December 31, 2020.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Non-Equity Incentive Plan Compensation (\$)</b>	<b>Option Awards \$(1)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Bing Li, Ph.D. <i>Former Chief Executive Officer</i>	2020	550,000	605,000	4,495,960	92,308(2)	5,743,268
Debra Yu, M.D. <i>President and Chief Strategy Officer</i>	2020	500,000	500,000	2,257,759	125,000(3)	3,382,759
Brianne Jahn <i>Chief Business Officer</i>	2020	397,467(4)	200,000	1,996,669	100,000(5)	2,694,136

- (1) Amounts reflect the aggregate grant date fair value of stock options awarded to our named executive officers under the 2019 Equity Incentive Plan during fiscal year 2020, computed in accordance with ASC Topic 718, disregarding the effects of estimated forfeitures. See Note 8 to our audited financial statements for the fiscal year ended December 31, 2020, included elsewhere in this prospectus, for information regarding assumptions underlying the valuation of equity awards. For Dr. Li, the amount reflects the aggregate grant date fair value of the stock option grants made to him on January 1, 2020 (\$1,128,880) and December 17, 2020 (\$3,367,080).
- (2) Under his employment agreement, Dr. Li was entitled to housing assistance payments while working in China in an amount equal to CNY 50,000 per month. The amount reported above has been converted to USD using the spot rate of 1 U.S. dollar to 6.50 Chinese Yuan as of December 31, 2020.
- (3) Amount reflects Dr. Yu's annual cost-of-living allowance, as provided for under her employment agreement with the Company in effect during 2020.
- (4) Ms. Jahn commenced employment with the Company on February 4, 2020 with an annual base salary of \$400,000. The reported amount reflects her prorated base salary for 2020 of \$366,667 plus \$30,800 in consulting fees that she received from the Company prior to her commencement of employment.
- (5) Ms. Jahn received tuition reimbursement for her MBA program of \$100,000 in accordance with the terms of her employment agreement with the Company in effect during 2020.

## **Narrative Disclosure to Summary Compensation Table**

### ***Base Salaries and Annual Incentive Opportunities***

The initial base salaries of our named executive officers were set forth in their respective employment agreements and are reviewed from time to time and adjusted when our board of directors or compensation committee determines that an adjustment is appropriate. For our 2020 fiscal year, Dr. Li's annual base salary was \$550,000 and Dr. Yu and Ms. Jahn's annualized base salaries were \$500,000 and \$400,000, respectively.

Beginning in 2020, each of our named executive officers is eligible to earn a performance-based bonus, the amount of which shall be determined by our board of directors. In 2020, we met or exceeded the vast majority of the Company's performance goals. As a result of our performance during 2020, the bonus payouts as a percentage of target were in line with payout amounts, as described in further detail above.

### ***Equity Compensation***

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Stock options are granted with an exercise price equal to the fair market value of a share of our Ordinary Shares on the date of grant. On January 1, 2020, Dr. Li and Dr. Yu received stock option grants that vested immediately upon grant as to one-third of the shares subject to the award and as to an additional one-third of the shares subject to the award on October 1, 2020, with the final one-third of the shares subject to the award vesting on October 1, 2021, subject to the named executive officer's continued employment on the vesting date. Dr. Li also received an additional stock option grant on December 17, 2020 that was vested immediately upon grant as to two-thirds of the shares subject to the award, with the remaining portion of the award vesting on October 1, 2021, subject to his continued employment. The unvested portions of Dr. Li's 2020 stock option grants as well as certain vested portions were forfeited in connection with his termination of employment, as described below. Ms. Jahn received a stock option grant on December 17, 2020 that vested as to one-third of the shares subject to the award on February 4, 2021, with the remaining portion of the award vesting as to one-third of the shares subject to the award on February 4, 2022 and the final one-third of the shares subject to the award on February 4, 2023, in each case subject to her continued employment on the applicable vesting date. See "—Outstanding Equity Awards at 2020 Fiscal Year-End" for more information on such grants.

### ***Employee Benefits and Perquisites***

Our named executive officers are eligible to participate in our health and welfare and retirement plans to the same extent as our full-time employees generally. Dr. Li was entitled under his employment agreement to housing assistance payments while working in China in an amount equal to CNY 50,000 per month. He was also entitled to reimbursement for business class air transportation and accommodation expenses with respect to one visit to China per year for each of his immediate family members. In addition, under her employment agreement in effect during 2020, Dr. Yu was entitled to receive an annual cost-of-living adjustment of \$125,000, less any required tax withholding. Finally, under her employment agreement in effect during 2020, Ms. Jahn was entitled to receive up to \$100,000 in tuition reimbursement for her MBA program.

## **Employment Arrangements with Named Executive Officers**

### ***Agreements with our Named Executive Officers***

Each of our currently employed named executive officers is party to an employment agreement with us that sets forth the terms and conditions of the executive's employment, including an annual

## [Table of Contents](#)

base salary and the general terms and conditions of her initial stock option grants, as described above. In addition, our named executive officers are bound by certain restrictive covenant obligations pursuant to a Compliance Agreement, including covenants relating to non-disclosure and use of confidential information and assignment of inventions, as well as a covenant not to compete or solicit our employees, customers or prospective customers, and suppliers during employment and for a period of two-years (one-year, in the case of Dr. Yu, and one-year in the case of Ms. Jahn with respect to her non-compete obligation) immediately following termination of employment for any reason.

Each of Dr. Yu and Ms. Jahn entered into amended and restated employment agreements in September 2021. For Ms. Jahn, the amended and restated employment agreement reflected her new role as our Chief Business Officer and included an updated annual base salary of \$450,000 and a performance-based annual bonus target equal to 50% of her base salary. In addition, her right to tuition reimbursement provided for under her prior agreement was removed and the amended agreement updated certain other terms and conditions of her employment, including providing her with the right to receive Severance Benefits (as defined below) in the event that we elect not to renew the term of her contract ("Contract Non-renewal") and the right to receive the CiC Termination Benefits (as defined below). For Dr. Yu, the amended and restated employment agreement reflected her new role as our Chief Strategy Officer, removed the annual cost of living allowance provided for under her prior agreement, and updated certain other terms and conditions of her employment, including providing her with the right to receive Severance Benefits (as defined below) in the event of a Contract Non-renewal.

### Outstanding Equity Awards at 2020 Fiscal Year-End

The following table sets forth information regarding the outstanding stock option awards held by our named executive officers as of December 31, 2020:

	Grant Date	Option Awards			
		Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Bing Li, Ph.D.	1/1/2020	666,649(1)	333,324	1.71	12/31/2029
	12/17/2020	666,649(2)	333,324	6.49	12/16/2030
Debra Yu, MD.	1/1/2020	1,333,298(1)	666,649	1.71	12/31/2029
Brianne Jahn	12/17/2020	—	584,780(3)	6.49	12/16/2030

- (1) The stock option grants vested immediately upon grant as to one-third of the shares subject to the award and as to an additional one-third of the shares subject to the award on October 1, 2020, with the final one-third of the shares subject to the award vesting on October 1, 2021, subject to the named executive officer's continued employment on the vesting date.
- (2) The stock option grant vested immediately upon grant as to two-thirds of the shares subject to the award, with the remaining portion of the award vesting on October 1, 2021, subject to Dr. Li's continued employment. The unvested portions of Dr. Li's 2020 stock option grants as well as certain vested portions were forfeited in connection with his termination of employment, as described below.
- (3) The stock option grant vested as to one-third of the shares subject to the award on February 4, 2021, with the remaining portion of the award vesting as to one-third of the shares subject to the award on February 4, 2022 and the final one-third of the shares subject to the award vesting on February 4, 2023, in each case subject to Ms. Jahn's continued employment on the applicable vesting date.

## **Severance and Change in Control Benefits**

Pursuant to their employment agreements, Dr. Yu and Ms. Jahn are eligible for the following severance benefits, generally subject to their execution of a release of claims in a form reasonably satisfactory to the Company, in the event of a termination of employment by the Company without “cause” (as defined in the agreement), by the executive with “good reason” (as defined in the agreement), or as a result of the executive’s death or disability (collectively, a “qualifying termination”): unpaid base salary as of the termination date; reimbursement of unreimbursed business expenses; base salary and fringe benefits for the 12-month period following the date the executive’s employment terminates; and any other benefits required by applicable law (collectively, the “Severance Benefits”). In addition, pursuant to their amended and restated employment agreements as described above, Dr. Yu and Ms. Jahn are entitled to receive Severance Benefits in the event of a Contract Non-renewal (as defined above). The severance benefits that Dr. Li received in connection with his termination of employment are described below.

In addition, if Dr. Yu’s employment is terminated by the Company without “cause” or by her with “good reason,” in each case within 12 months following a change in control (as defined in her agreement), then in addition to the Severance Benefits, she is also eligible to receive full acceleration of any then unvested stock options or other equity-based incentives she holds (collectively, the “CiC Termination Benefits”). Pursuant to the terms of her amended employment agreement, Ms. Jahn is also entitled to the CiC Termination Benefits.

In the event of a change in control (as defined in the 2019 Equity Incentive Plan), the stock options granted to our named executive officers in 2020, to the extent outstanding and unvested, will automatically vest in full immediately prior to the consummation of the change in control to the extent that no provision is made under the 2019 Equity Incentive Plan to assume or substitute the stock options, or cancel the stock options in exchange for cash or property.

## **Executive Transitions**

### ***Separation of Former CEO***

Effective March 26, 2021, Dr. Li’s employment with the Company terminated. As part of his severance agreement, he is receiving 12 months of severance pay in the form of base salary continuation (in the amount of \$550,000). In addition, we agreed to extend the exercise period for a portion of the vested options held by Dr. Li as of his termination date until the earlier of the second anniversary of the effective date of the Company’s initial public offering or the tenth anniversary of the grant date applicable to the options. The unvested portions of Dr. Li’s 2020 stock option grants, together with the portion of the vested options held by Dr. Li that did not have their exercise periods extended, were forfeited in connection with his termination of employment. Dr. Li remains subject to the post-employment restrictive covenant obligations set for in his Compliance Agreement, as described above.

### ***Appointment of New CEO***

Effective May 17, 2021, Yizhe Wang, Ph.D., was appointed as the Company’s new Chief Executive Officer. Under the terms of his employment agreement, Dr. Wang’s annual base salary is \$500,000, he received a one-time sign-on bonus of \$175,000 (which was subsequently increased by an additional \$65,000) and he will be entitled to receive an annual bonus in his first year of 100% of his base salary, calculated on a prorated basis for 2021 based on his hire date. In subsequent years, Dr. Wang may be entitled to receive performance-based annual bonuses at the discretion of our board of directors. In addition, Dr. Wang received a stock option award in respect of 3,877,225 shares of the

Company (the “CEO Grant”). 50% of the options under the CEO Grant are subject solely to the following time-based vesting condition (the “Time-Vesting Options”): 25% of the Time-Vesting Options will vest on each of the first four anniversaries of Dr. Wang’s hire date, subject to his continued employment on each such vesting date (such vesting condition, the “Time-Vesting Condition”). The remaining 50% of the options under the CEO Grant are subject to both a time- and performance-based vesting condition (the “Performance Options”). 50% of the Performance Options will become earned upon the Company achieving an enterprise value of not less than \$2 billion at any time after Dr. Wang’s hire date and the remaining 50% of the Performance Options will become earned upon the Company achieving an enterprise value of not less than \$4 billion at any time after Dr. Wang’s hire date. To the extent earned based on the satisfaction of the foregoing performance conditions, the Performance Options will vest in accordance with the Time-Vesting Condition.

### ***Appointment of New CFO***

Effective May 1, 2021, Yi Larson was appointed as the Company’s new Chief Financial Officer. Under the terms of her employment agreement, Ms. Larson’s base salary is \$500,000 and she will be entitled to receive an annual bonus of 50% of her base salary, calculated on a prorated basis for 2021 based on her hire date. In addition, Ms. Larson received a stock option award in respect of 969,307 Ordinary Shares, which options will vest as to 25% of the shares subject to the award on each of the first four anniversaries of her hire date, subject to her continued employment on each such vesting date (such options, the “Initial Options”). In connection with our initial public offering, Ms. Larson will be eligible to receive an additional stock option grant to purchase that number of our Ordinary Shares (the “Subsequent Options”), at the offering price set forth on the cover page of this registration statement, such that the aggregate number of shares granted under the Initial Options and the Subsequent Options shall be one percent of our fully diluted share capital immediately following the closing of our initial public offering. The Subsequent Options shall be subject to the terms and conditions of the 2021 Equity Incentive Plan and shall vest as to 25% of the shares subject to the award on each of the first four anniversaries of the grant date, subject to her continued employment on each such vesting date.

## **Equity Plans**

### ***2019 Equity Incentive Plan***

Our board of directors adopted our 2019 Equity Incentive Plan in December 2019. The 2019 Equity Incentive Plan provides for the grant of incentive stock options, nonqualified stock options, restricted shares, restricted share units and other share-based awards to our employees, directors, and consultants.

*Share Reserve.* Subject to adjustment as described below, the maximum number of shares that may be granted under the 2019 Equity Incentive Plan is 11,986,188. As of December 31, 2020, we had 915,402 shares of Ordinary Shares that remained available for issuance under the 2019 Equity Incentive Plan.

*Administration.* Our board of directors has administered our 2019 Equity Incentive Plan since its adoption; however, following this offering, the compensation committee of our board of directors will generally administer our 2019 Equity Incentive Plan and the term “administrator” as used in this summary should be construed accordingly. The administrator has complete discretion to make all decisions relating to our 2019 Equity Incentive Plan and outstanding awards, subject to the terms of the 2019 Equity Incentive Plan.

*Eligibility.* Employees, non-employee members of our board of directors and consultants are eligible to participate in our 2019 Equity Incentive Plan. However, only employees are eligible to receive incentive stock options.

*Types of Awards.* Our 2019 Equity Incentive Plan provides for the following types of awards to be granted with respect to shares of our Ordinary Shares:

- incentive stock options and nonqualified stock options to purchase Ordinary Shares;
- restricted shares and restricted share units; and
- other share-based awards, including awards entitling participants to receive Ordinary Shares to be delivered in the future.

*Options.* The exercise price for options granted under our 2019 Equity Incentive Plan is determined by our board of directors but may not be less than 100% of the fair market value of our Ordinary Shares on the grant date. Options vest as determined by the administrator. Options expire at the time determined by the administrator, but in no event more than ten years after they are granted, and generally expire earlier if the optionee's employment or service terminates.

*Restricted Shares and Restricted Share Units.* Restricted shares may be awarded or sold under our 2019 Equity Incentive Plan subject to our right to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) in the event that the vesting conditions specified by the administrator are not satisfied prior to the end of the applicable restricted period for such award. In addition, the administrator may grant restricted share units, which may be subject to vesting and forfeiture conditions established by the administrator.

*Corporate Transactions.* In the event that we are a party to any transaction or event, including a reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of assets, or any unusual or nonrecurring transaction or event affecting us or our financial statements including, without limitation any change in control (as such term is defined in the 2019 Equity Incentive Plan), the administrator may in its discretion take any one or more of the following actions with respect to outstanding awards granted under the 2019 Equity Incentive Plan:

- cancellation of the award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such award;
- providing that such award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the 2019 Equity Incentive Plan or an applicable award agreement;
- continuation, assumption or substitution of an award by the surviving entity or its parent;
- adjustments to the number and type of shares (or other securities or property) subject to outstanding awards, and/or to the terms and conditions of (including, without limitation, the grant or exercise price), and the criteria included in, outstanding awards;
- replacement of such award with other rights or property selected by the administrator; and/or
- termination of the award.

*Changes in Capitalization.* In the event of an equity restructuring, which generally includes any non-reciprocal transaction between us and our shareholders, such as a share dividend, share split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the shares of our Ordinary Shares or their share price and causes a change in the per share value of the shares underlying outstanding awards, the administrator will equitably adjust each outstanding award. Adjustments may include adjustments to the number and type of securities subject to each outstanding award and/or the exercise price or grant price and/or the making of a cash payment to participants.



*Amendments or Termination.* The administrator may at any time amend, suspend or terminate the 2019 Equity Incentive Plan, provided that no amendment shall materially and adversely affect any awards outstanding at the time of such amendment without the consent of the affected participant. No awards shall be granted under the 2019 Equity Incentive Plan after the completion of ten years from the earlier of the date on which the 2019 Equity Incentive Plan was adopted by our board of directors or the date the 2019 Equity Incentive Plan was approved by our shareholders but awards previously granted may extend beyond that date in accordance with the terms of the 2019 Equity Incentive Plan.

### **Post-IPO Compensation Plans**

In connection with this offering, our board has adopted the LianBio 2021 Equity Incentive Plan, or the 2021 Equity Plan, and the LianBio 2021 Cash Incentive Plan, or the 2021 Cash Plan. We refer to these plans collectively as the “2021 Plans”. The following summaries describe the material terms of the 2021 Plans. These summaries are not complete descriptions of all of the terms of the 2021 Plans and are qualified in their entirety by reference to the 2021 Plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

### **2021 Equity Plan**

*In General.* The 2021 Equity Plan provides for the grant of shares, share options and other share-based awards. Following its adoption by our board, all equity-based awards to our employees, directors, and consultants will be granted under the 2021 Equity Plan.

*Administration.* The 2021 Equity Plan will generally be administered by our board or our compensation committee. As used in this summary, the term “administrator” refers to our board, our compensation committee or any authorized delegates, as applicable. The administrator will have the discretionary authority to administer and interpret the plan and any awards; determine eligibility for and grant awards; determine the exercise price, base value or purchase price, if any, applicable to any award; determine, modify, accelerate or waive the terms and conditions of any award; determine the form of settlement of awards; designate whether an award will be over or with respect to ordinary shares or ADSs; prescribe forms, rules and procedures relating to the plan and awards; and otherwise do all things necessary or desirable to carry out the purposes of the plan or any award. Our board or our compensation committee, as applicable, may delegate to one or more of its members such of its duties, powers, and responsibilities as it may determine and, to the extent permitted by law, may delegate certain of its duties, powers, and responsibilities to officers, employees and other persons.

*Eligibility.* Employees and directors of, and consultants to, us and our affiliates will be eligible to participate in the 2021 Equity Plan. Eligibility for share options intended to be incentive share options, or ISOs, will be limited to our employees or employees of certain of our affiliates. Eligibility for share options, other than ISOs, and share appreciation rights, or SARs, is limited to individuals who are providing direct services to us or certain of our affiliates on the date of grant of the award.

*Authorized Shares.* Subject to adjustment as described below, the maximum number of shares that may be delivered in satisfaction of awards under the 2021 Equity Plan will be 14,174,972 shares, plus that number of shares that remain available for issuance under the 2019 Equity Incentive Plan and that may again become available for issuance under such plan, not to exceed 10,676,210 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. The number of shares available for delivery in satisfaction of awards under the 2021 Equity Plan is referred to in this summary as the “Share Pool”. A maximum of 5,000,000 shares from the Share Pool

may be delivered in satisfaction of ISOs. For purposes of the Share Pool, shares will not be treated as delivered under the 2021 Equity Plan, and will not reduce the Share Pool, unless and until, and to the extent, they are actually delivered to a participant. The Share Pool will not be reduced by any shares withheld by us in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements or any shares underlying any portion of an award that is settled in cash or that expires, becomes unexercisable, terminates or is forfeited to or repurchased by us without the delivery (or retention, in the case of restricted or unrestricted shares) of shares. The Share Pool will not be increased by any shares delivered under the 2021 Equity Plan that are subsequently repurchased using the proceeds directly attributable to share option exercises. Shares delivered in substitution for equity awards of an acquired company that are converted, replaced or adjusted in connection with the acquisition will not reduce the Share Pool.

For purposes of the 2021 Equity Plan, “share” means an ordinary share of the Company (an “ordinary share”), unless there are ADSs representing ordinary shares available, in which case “share” will also mean the number of ADSs equal to an ordinary share. If the ratio of ADSs to ordinary shares is not 1:1, then (a) the maximum number of shares that may be delivered under the 2021 Equity Plan, (b) all award adjustments made pursuant to the 2021 Equity Plan, and (c) all awards designated as awards over ordinary shares will automatically be adjusted to reflect the ratio of the ADSs to ordinary shares, as reasonably determined by the administrator.

Shares that may be delivered under the 2021 Equity Plan may be authorized but unissued ordinary shares, treasury ordinary shares or previously issued ordinary shares that are acquired by us, or ADSs, as determined in the discretion of the administrator. No fractional ordinary shares or ADSs will be delivered under the 2021 Equity Plan.

*Types of Awards.* The 2021 Equity Plan provides for the grant of share options, SARs, restricted and unrestricted shares and share units, performance awards, and other awards that are convertible into or otherwise based on shares. Dividend equivalents may also be provided in connection with awards under the 2021 Equity Plan.

- *Share Options and SARs.* The administrator may grant share options, including ISOs, and SARs. A share option is a right entitling the holder to acquire shares upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the closing price of the shares subject to the right over the base value from which appreciation is measured. The per share exercise price of each share option, and the per share base value of each SAR, granted under the 2021 Equity Plan may not be less than 100% of the closing price of a share on the date of grant (or, if no closing price is reported on that date, the closing price on the immediately preceding date on which a closing price was reported) (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, share options and SARs granted under the 2021 Equity Plan may not be repriced, amended or substituted for with new share options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any share options or SARs that have a per share exercise price or base value greater than the closing price of a share on the date of such cancellation (or, if no closing price is reported on that date, the closing price on the immediately preceding date on which a closing price was reported), in each case, without shareholder approval. Each share option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).
- *Restricted and Unrestricted Shares and Share Units.* The administrator may grant awards of shares, share units, restricted shares and restricted share units. A share unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted share unit is a share unit that is subject to the

satisfaction of specified performance or other vesting conditions. A restricted share is a share subject to restrictions requiring that it be forfeited, redelivered or offered for sale to us if specified performance or other vesting conditions are not satisfied.

- *Performance Awards.* The administrator may grant performance awards, which are awards that vest subject to the achievement of performance criteria.
- *Other Share-Based Awards.* The administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as are determined by the administrator.
- *Substitute Awards.* The administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of the 2021 Equity Plan.

*Director Limits.* The aggregate value of all compensation granted or paid to any director with respect to any calendar year, including the grant date fair value of awards granted under the 2021 Equity Plan and cash fees or other compensation paid by us and our affiliates to such director outside of the 2021 Equity Plan for services as a director during such calendar year (which, for the avoidance of doubt, will not include compensation granted or paid to a director for services other than as a director, including without limitation, for services as a consultant or advisor to us), may not exceed \$750,000 in the aggregate (\$1,000,000 in the aggregate with respect to a director's first calendar year of service on our board).

*Vesting; Terms and Conditions of Awards.* The administrator will determine the terms and conditions of all awards granted under the 2021 Equity Plan, including the time or times an award vests or becomes exercisable, the terms and conditions on which an option or SAR remains exercisable, and the effect of termination of a participant's employment or service on awards. The administrator may at any time accelerate the vesting or exercisability of an award or limit the exercisability of an award.

*Transfer Restrictions.* Except as the administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

*Effect of Certain Transactions.* Except as otherwise expressly provided in an award or other agreement or by the administrator, in the event of certain covered transactions (including a consolidation, merger or similar transaction, a sale of substantially all of our assets or shares, our dissolution or liquidation or other corporate transaction determined by the administrator), the administrator may, with respect to outstanding awards, provide for (in each case, on such terms and conditions as it determines):

- the assumption, continuation or substitution of some or all awards (or any portion thereof) by the acquirer or surviving entity;
- the acceleration of exercisability or issuance of shares in respect of any award (or any portion thereof), in full or in part; and/or
- a payment, which may be made in cash, property, rights or a combination of the foregoing, in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the administrator may otherwise determine, each award will automatically terminate or be forfeited immediately upon the consummation of the covered transaction, other than awards that are substituted for, assumed or continued or awards that by their terms continue following the covered transaction.

*Adjustment Provisions.* In the event of a share dividend, share split or combination of shares (including a reverse share split), recapitalization or other change in our capital structure, the

administrator will make appropriate adjustments to the maximum number of shares that may be delivered under the 2021 Equity Plan, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of, outstanding awards, and any other provisions affected by such event. The administrator may also make such adjustments to take into account other distributions to shareholders, or any other event, if it determines that adjustments are appropriate to avoid distortion in the operation of the 2021 Equity Plan or any award.

*Clawback.* The administrator may provide that any outstanding award or the proceeds from, or other amounts received in respect of, any award or share acquired under any award will be subject to forfeiture and disgorgement to us (or our designated affiliate), with interest and other related earnings, if the participant to whom the award was granted breaches, violates or otherwise fails to comply with the plan or the applicable award or any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant. Each award will be subject to any policy maintained by us or any of our affiliates that relates to trading on non-public information and permitted transactions with respect to shares, including limitations on hedging and pledging, and any policy that provides for the forfeiture, disgorgement or clawback with respect to incentive compensation that includes awards under the 2021 Equity Plan and will be subject to forfeiture and disgorgement to the extent required by law or applicable stock exchange listing standards.

*Amendment and Termination.* The administrator may at any time amend the 2021 Equity Plan or any outstanding award and may at any time terminate the 2021 Equity Plan as to future grants. However, except as expressly provided in the 2021 Equity Plan or the applicable award, the administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent, unless the administrator expressly reserved the right to do so at the time the award was granted. Any amendments to the 2021 Equity Plan will be conditioned on shareholder approval to the extent required by applicable law or stock exchange requirements.

## **2021 Cash Plan**

*In General.* The 2021 Cash Plan provides for the grant of cash-based incentive awards. For years beginning following its adoption by our board, the 2021 Cash Plan is intended to be the only plan under which we grant cash-based incentive awards to our executive officers.

*Administration.* The 2021 Cash Plan will generally be administered by our board or our compensation committee. As used in this summary, the term "administrator" refers to our board, our compensation committee or any authorized delegates, as applicable. The administrator will have the discretionary authority to interpret the 2021 Cash Plan and any award granted under it; determine eligibility for and grant awards; adjust the performance criteria applicable to awards; determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures relating to the 2021 Cash Plan and awards; and otherwise do all things necessary or desirable to carry out the purposes of the 2021 Cash Plan or any award. Our board or our compensation committee, as applicable, may delegate to one or more of its members such of its duties, powers, and responsibilities as it may determine and, to the extent permitted by law, may delegate certain of its duties, powers and responsibilities to officers, employees and other persons.

*Eligibility and Participation.* Executive officers and other key employees of us and our subsidiaries will be eligible to participate in the 2021 Cash Plan.

*Awards.* The Administrator will select the participants who receive awards for each performance period under the plan and, for each award, will establish (i) the performance criteria applicable to the award; (ii) the amount payable if the performance criteria are achieved in whole or in part; and (iii) such other terms and conditions as it determines.

**Determination of Performance; Amounts Payable under Awards.** As soon as practicable following the end of a performance period, the Administrator will determine whether and to what extent the performance criteria applicable to each award have been satisfied and the amount payable under each award. The Administrator may adjust the actual payment to be made with respect to any award in its discretion.

**Clawback.** The Administrator may provide that any outstanding award and any amounts received in respect of any award will be subject to forfeiture and disgorgement to us, with interest and other related earnings, if the participant to whom the award was granted breaches, violates or otherwise fails to comply with the 2021 Cash Plan or any applicable award or any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant. Each award will be subject to any policy maintained by us or any of our affiliates that provides for the forfeiture, disgorgement or clawback with respect to incentive compensation that includes awards under the 2021 Cash Plan and will be subject to forfeiture and disgorgement to the extent required by law or applicable stock exchange listing standards.

**Amendment and Termination.** The Administrator may amend the 2021 Cash Plan or any outstanding award at any time, and may terminate the 2021 Cash Plan as to future grants of awards at any time.

### Compensation of Directors

The following table sets forth information regarding the compensation that we paid or awarded during the year ended December 31, 2020 to each of our non-employee directors who served on our board of directors during 2020:

Name	Fees earned or paid in cash (\$)	Option awards (\$) (2)	Total (\$)
Konstantin Poukalov(1)	—	525,125	525,125
Adam Stone(1)	—	525,125	525,125
Neil Kumar, Ph.D.	35,000(3)	525,125	560,125
Tassos Gianakakos	14,000(4)	525,125	539,125

- (1) Directors who are affiliated with Perceptive, our largest shareholder, do not receive annual retainers for their service on our board of directors.
- (2) Amounts reported reflect the aggregate grant date fair value of stock options awarded during 2020 computed in accordance with the provisions of FASB ASC Topic 718, disregarding the effects of estimated forfeitures. See Note 8 to our audited financial statements for the fiscal year ended December 31, 2020, included elsewhere in this prospectus for information regarding assumptions underlying the valuation of equity awards.
- (3) Beginning in 2021, Mr. Kumar no longer receives an annual retainer for his service on our board of directors.
- (4) Mr. Gianakakos was appointed as a director of the Company in August 2020 with an annual base fee of \$35,000. The reported amount reflects his prorated base fee for 2020 of \$14,000.

As of December 31, 2020, each of our non-employee directors held outstanding stock options with respect to 146,195 Ordinary Shares, none of which had vested at that time. The 146,195 stock options held by Mr. Kumar have subsequently been canceled. Our non-employee directors are entitled to reimbursement for their reasonable out-of-pocket expenses incurred in attending meetings of the board of directors and in connection with other services provided to us. Dr. Li, our former Chief Executive Officer, was also a director as of December 31, 2020, but did not receive any additional compensation for his director service. See elsewhere in this section for more information regarding the compensation earned by Dr. Li.

During 2020, our non-employee directors were compensated for their service as directors, including as members of the various committees of our board of directors, as follows:

- an annual retainer for board service of \$35,000 (other than directors who are affiliated with Perceptive, our largest shareholder); and
- an option grant to purchase 146,195 Ordinary Shares, which vests over four years in equal installments, commencing on December 17, 2020, subject to continued service as a director.

Each of the option grants described above was granted under our 2019 Equity Incentive Plan, the terms of which are described in more detail above under the section titled “—Equity Plans—2019 Equity Incentive Plan.”

### ***Director compensation policy***

In connection with this offering, our board of directors adopted a non-employee director compensation policy. The following summary describes the material terms of the non-employee director compensation policy.

Under the non-employee director compensation policy, our directors, other than our employee directors, are anticipated to be compensated as follows following this offering:

- each non-employee director will receive an annual cash fee of \$40,000 (\$65,000 for our lead independent director, if applicable);
- each non-employee director who is a member of the audit committee will receive an additional annual cash fee of \$10,000 (\$20,000 for the audit committee chair);
- each non-employee director who is a member of our compensation committee will receive an additional annual cash fee of \$6,000 (\$12,000 for our compensation committee chair);
- each non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash fee of \$5,000 (\$10,000 for the nominating and corporate governance committee chair);
- each non-employee director who is first elected or appointed to our board of directors after the completion of this offering will be granted an option to purchase 72,600 Ordinary Shares; and
- beginning in fiscal 2022, each non-employee director will annually be granted an option to purchase 36,300 Ordinary Shares.

The share options granted to our non-employee directors will have a per share exercise price equal to the closing price of a share on the date of grant (or if no closing price is reported on that date, the closing price on the immediately preceding date on which a closing price was reported) and will expire not later than ten years after the date of grant. The share option granted to a non-employee director in connection with this offering, or upon his or her initial election to our board of directors following this offering, will vest in equal monthly installments over a period of three years commencing from the date of grant, subject to such director's continued service on our board of directors. The annual share options granted to our non-employee directors will vest as to 100% of the shares underlying the option on the one-year anniversary of the date of grant, subject to the director's continued service on our board of directors. Upon a change in control (as defined in the 2021 Equity Plan), each initial share option and each annual share option that is then outstanding will vest in full, subject to the director's continued service on our board of directors through such change in control.

Each director is entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee on which he or she serves.

### ***New Equity Awards***

In connection with this offering, we intend to grant options to purchase approximately 3,124,731 Ordinary Shares under the 2021 Equity Plan to certain of our employees, including the current named executive officers. It is anticipated that Dr. Yu and Ms. Jahn will receive an option to purchase 747,227 and 330,942 Ordinary Shares, respectively. Such awards to our named executive officers will vest over four years with one-fourth of the shares subject to the option vesting on the first anniversary of the grant date and the remaining three-fourths of the shares subject to the option vesting monthly over three years beginning from the first anniversary of the grant date, in each case generally subject to the executive remaining in continuous employment on the applicable vesting date.

In connection with the appointments of Susan Silbermann and Jesse Wu to our board of directors in October 2021, in connection with this offering, each such director will be granted an option to purchase 72,600 Ordinary Shares, with such options vesting in 36 equal monthly installments beginning on the date of grant, subject to the individual's continued service on our board of directors through the applicable vesting date.

All options will have an exercise price equal to the initial public offering price of an ADS.



## SECURITY OWNERSHIP OF BENEFICIAL OWNERS AND MANAGEMENT

The following table and accompanying footnotes set forth information relating to the beneficial ownership of our Ordinary Shares as of September 30, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding Ordinary Shares;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each shareholder is determined in accordance with the rules issued by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all Ordinary Shares beneficially owned by them, subject to any community property laws.

Percentage ownership of our Ordinary Shares prior to this offering is based on 86,254,421 Ordinary Shares deemed to be outstanding as of September 30, 2021 after giving effect to the Conversions. Beneficial ownership after this offering is based on 106,566,921 Ordinary Shares outstanding as of September 30, 2021 after giving effect to (i) the Conversions and (ii) the issuance of 20,312,500 Ordinary Shares represented by ADSs in this offering, which does not contemplate exercise of the underwriters' option to purchase additional ADSs.

In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, Ordinary Shares subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of July 31, 2021 are considered outstanding for the purpose of computing percentage ownership of that person, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Except as otherwise indicated in the footnotes below, the address of each director, executive officer and named beneficial owner is c/o LianBio, 103 Carnegie Center Drive, Suite 215, Princeton, New Jersey 08540.

Entities affiliated with Perceptive have indicated an interest in purchasing an aggregate of up to \$35.0 million of our ADSs in this offering at the initial public offering price. Assuming an initial public offering price of \$16.00 per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, these entities would purchase an aggregate of up to approximately 2,187,500 of the 20,312,500 ADSs in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no ADSs to any of these entities and any of these entities could determine to purchase more, less or no ADSs in this offering. The following table does not reflect any such potential purchases by Perceptive or its affiliated entities. However, if any ADSs are purchased by these entities, the number of Ordinary Shares beneficially owned after this offering and the percentage of Ordinary Shares beneficially owned after this offering will differ from that set forth in the table below.

Name of Beneficial Owner	Ordinary Shares Beneficially Owned Prior to Offering		Ordinary Shares Beneficially Owned After this Offering	
	Number	Percent	Number	Percent
<b>5% Shareholders:</b>				
Entities affiliated with Perceptive Advisors(1)	53,829,960	62.4%	53,829,960	50.5%
Entities affiliated with RA Capital(2)	6,192,515	7.2%	6,192,515	5.8%
BridgeBio Pharma LLC(3)	5,002,792	5.8%	5,002,792	4.7%
<b>Named Executive Officers and Directors</b>				
Bing Li, Ph.D.(4)	1,309,907	1.5%	1,309,907	1.2%
Debra Yu(5)	1,999,947	2.3%	1,999,947	1.8%
Brianne Jahn(6)	194,927	*	194,927	*
Konstantin Poukalov(1)	—	—	—	—
Adam Stone(1)	—	—	—	—
Neil Kumar(3)	5,002,792	5.8%	5,002,792	4.7%
Tassos Gianakakos(7)	309,623	*	309,623	*
Susan Silbermann	—	—	—	—
Jesse Wu	—	—	—	—
<b>All Executive Officers and Directors as a Group (11 persons)</b>	<b>7,507,289</b>	<b>8.5%</b>	<b>7,507,289</b>	<b>6.9%</b>

\* Represents beneficial ownership of less than one percent.

- (1) Consists of (i) 7,033,885 Ordinary Shares held by Perceptive Life Sciences Master Fund, Ltd. ("Perceptive Life"), (ii) 7,033,885 Ordinary Shares held by LEV LB Holdings, LP ("LEV LB"), (iii) 1,406,775 Ordinary Shares held by Perceptive Xontogeny Venture Fund, LP ("Perceptive Xontogeny"), (iv) 14,619,500 Ordinary Shares issued upon the conversion of Series Seed Preferred Shares held by Perceptive Life, (v) 14,619,500 Ordinary Shares issued upon the conversion of Series Seed Preferred Shares held by LEV LB, (vi) 2,923,900 Ordinary Shares issued upon the conversion of Series Seed Preferred Shares held by Perceptive Xontogeny, (vii) 3,715,510 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by Perceptive Life and (viii) 2,477,005 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by C2 Life Sciences LLC ("C2 Life"). Perceptive Advisors, LLC serves as the investment advisor to Perceptive Life and C2 Life. Perceptive Venture Advisors, LLC serves as the investment advisor to Perceptive Xontogeny and is an affiliate of Perceptive Advisors, LLC. LEV LB Holdings GP, LLC is the manager of LEV LB. Joseph Edelman is the managing member of Perceptive Advisors, LLC and the sole member of LEV LB Holdings GP, LLC. Konstantin Poukalov, the Executive Chairman of our board of directors, is a Managing Director at Perceptive Advisors, and Adam Stone, a member of our board of directors, is the Chief Investment Officer at Perceptive Advisors. The address of Perceptive Life and Perceptive LS is c/o Perceptive Advisors, LLC, 51 Astor Place, 10th Floor, New York, New York 10003.
- (2) Consists of (i) 4,792,038 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by RA Capital Healthcare Fund, L.P. ("RA Healthcare"), (ii) 928,876 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by RA Capital Nexus Fund II, L.P. ("Nexus II Fund") and (iii) 471,601 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by Blackwell Partners LLC – Series A ("Blackwell"). RA Capital Management, L.P. ("RA Capital") is the investment manager for RA Healthcare, Nexus II Fund and Blackwell. The general partner of RA Healthcare is RA Healthcare Fund GP, LLC ("RA Healthcare GP"). The general partner of Nexus II Fund is RA Capital Nexus Fund II GP, LLC ("Nexus II Fund GP"). The general partner of RA Capital is RA Capital Management GP, LLC ("RA Capital GP"). Peter Kolchinsky and Rajeev Shah are the managing members of RA Healthcare GP, Nexus II Fund GP and RA Capital GP and have voting and investment power over the shares held of record by RA Healthcare, Nexus II Fund, and Blackwell. The address of RA Capital, Peter Kolchinsky and Rajeev Shah is 200 Berkeley Street, 18th Floor, Boston, MA 02116.

- (3) Consists of 5,002,792 Ordinary Shares held by BridgeBio Pharma LLC, a wholly-owned subsidiary of BridgeBio Pharma, Inc. Dr. Kumar is the President and Chief Executive Officer and a director of BridgeBio Pharma, Inc. Dr. Kumar, Eric Aguiar, Jennifer Cook, Ronald Daniels, Charles Homcy, Andrew Lo, James Momtazee, Ali Satvat, Brenton Saunders, Richard Scheller and Randal Scott, the members of the board of directors of BridgeBio Pharma, Inc., may be deemed to have shared voting and investment power over the Ordinary Shares beneficially owned by BridgeBio Pharma, Inc. The address of BridgeBio Pharma, Inc. is 421 Kipling St., Palo Alto, California 94301.
- (4) Represents 1,309,907 Ordinary Shares issued in September 2021 upon the exercise of Mr. Li's vested options.
- (5) Represents 1,999,947 Ordinary Shares underlying options exercisable within 60 days of September 30, 2021.
- (6) Represents 194,927 Ordinary Shares underlying options exercisable within 60 days of September 30, 2021.
- (7) Represents 309,623 Ordinary Shares issued upon the conversion of Series A Preferred Shares held by AEG 2021 Trust, of which Mr. Gianakakos is the sole trustee and current lifetime beneficiary. The address of AEG 2021 Trust is 405 El Camino Real, Suite 104, Menlo Park, CA 94025.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions or series of transactions since our incorporation on July 17, 2019, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed \$120,000; and
- in which any of our executive officers, directors or holders of 5% or more of any class of our share capital, or the immediate family members of, or any person sharing the household with, the foregoing persons, or any affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under the sections titled “Executive and Director Compensation.”

### Series Seed Preferred Share Financing

In October 2019, we issued and sold an aggregate of 5,500,000 Series Seed Preferred Shares at a purchase price of \$10.00 per share, for an aggregate amount of approximately \$55.0 million (the “Series Seed Financing”). All of our outstanding Series Seed Preferred Shares will be converted into 32,162,900 Ordinary Shares immediately prior to the completion of this offering. See “The Conversions.”

The following table summarizes the Series Seed Preferred Shares purchased by related persons in connection with the Series Seed Financing:

Investor	Shares of Series Seed Preferred Shares	Purchase Price (\$)
Entities affiliated with Perceptive(1)	5,500,000	\$ 55,000,000

- (1) Consists of (i) 2,500,000 Series Seed Preferred Shares held by Perceptive Life Sciences Master Fund, Ltd., (ii) 2,500,000 Series Seed Preferred Shares held by LEV LB Holdings, LP and (iii) 500,000 Series Seed Preferred Shares held by Perceptive Xontogeny Venture Fund, LP. Konstantin Poukalov, the Executive Chairman of our board of directors, is a Managing Director at Perceptive, and Adam Stone, a member of our board of directors, is the Chief Investment Officer at Perceptive. Entities affiliated with Perceptive collectively hold more than 5% of our Series Seed Preferred Shares.

### Series A Preferred Shares Financing

Pursuant to closings in October 2020 and December 2020, we issued and sold an aggregate of 5,471,231 Series A Preferred Shares at a purchase price of \$56.66 per share, for an aggregate amount of approximately \$310.0 million (the “Series A Financing”). In March 2021, we issued and sold an additional 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 Gianakokos, a member of our board of directors. All of our outstanding Series A Preferred Shares will be converted into 32,304,277 Ordinary Shares immediately prior to the completion of this offering. See “The Conversions.”

Certain purchasers of our Series A Preferred Shares are entitled to certain contractual management rights pursuant to management rights letters (collectively, the “Management Rights

## [Table of Contents](#)

Letters”) we entered into which such purchasers in connection with the Series A Financing, including, but not limited to, the right to (i) consult with and advise our management on significant business issues, (ii) inspect our books and records and its facilities upon reasonable advance written request, and (iii) receive all information and materials provided to our board of directors, other than any information or materials that are highly confidential or proprietary information. The Management Rights Letters and the rights thereunder will terminate upon the closing of this offering.

The following table summarizes the Series A Preferred Shares purchased by related persons in connection with the Series A Financing:

Investor	Shares of	
	Series A Preferred Shares	Purchase Price (\$)
Entities affiliated with Perceptive(1)	1,058,948	\$59,999,993.68
Entities affiliated with RA Capital(2)	1,058,948	\$59,999,993.68

- (1) Consists of (i) 635,369 Series A Preferred Shares held by Perceptive Life Sciences Master Fund, Ltd. and (ii) 423,579 Series A Preferred Shares held by C2 Life Sciences LLC. Konstantin Poukalov, the Executive Chairman of our board of directors, is a Managing Director at Perceptive, and Adam Stone, a member of our board of directors, is the Chief Investment Officer at Perceptive. Entities affiliated with Perceptive collectively hold more than 5% of our Series A Preferred Shares.
- (2) Consists of (i) 819,460 Series A Preferred Shares held by RA Capital Healthcare Fund, L.P., (ii) 158,842 Series A Preferred Shares held by RA Capital NEXUS Fund II, L.P. and (iii) 80,646 Series A Preferred Shares held by Blackwell Partners LLC – Series A. Entities affiliated with RA Capital collectively hold more than 5% of our Series A Preferred Shares.

### **Certain Transactions with BridgeBio**

In October 2019, we issued 584,780 Ordinary Shares to BridgeBio in exchange for the grant of certain preemptive rights to the Company pursuant to the BridgeBio Exclusivity Agreement. In addition, we issued an additional 4,418,012 Ordinary Shares to BridgeBio following the closing of the Series Seed Financing for no additional consideration. In connection with these issuances, we entered into an information rights agreement with BridgeBio, pursuant to which we agreed to provide, upon BridgeBio’s reasonable request, certain financial statements within specified time periods at the end of each fiscal year and fiscal quarter, for so long as BridgeBio continues to hold 5% or more of the fully-diluted equity of the Company. We also agreed, upon reasonable request by BridgeBio, to provide BridgeBio a statement with sufficient details as to permit BridgeBio to calculate its percentage equity ownership in the Company, for so long as BridgeBio continues to hold equity in the Company.

### **Certain Transactions with QED**

In October 2019, we granted three warrants (collectively, the “QED Warrants”) to QED as partial consideration for the grant of certain licenses and rights to us pursuant to the QED Agreement, exercisable for an aggregate of 100,000 ordinary shares of Lian Oncology 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 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”), 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 their option to convert. 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.

### **Certain Transactions with MyoKardia**

In August 2020, we 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 at any time and from time to time at the option of the holder. In accordance with the terms of the Option Agreement, MyoKardia had an option to (i) convert the 170,000 ordinary shares of Lian Cardiovascular into 2,924,011 of our Ordinary Shares or (ii) convert the MyoKardia Warrant into a warrant to purchase 103,805 of our Ordinary Shares, with an exercise price of \$47.03 per share, in connection with the completion of this offering. As of October 12, 2021, MyoKardia elected not to exercise this option and, therefore, will continue to hold the MyoKardia Warrant following the completion of this offering. The Option Agreement, and MyoKardia’s option to convert the MyoKardia Warrant under the Option Agreement, will terminate as of the completion of this offering.

Pursuant to an equity holders’ agreement, so long as MyoKardia holds securities representing at least 5% or more of the equity securities of LianBio Cardiovascular on an as-converted fully-diluted basis, MyoKardia has the right to designate one director to the board of directors of the Company. Such designated director shall be subject to the prior approval of Perceptive. Similarly, MyoKardia can also designate one director to the board of directors of Lian Cardiovascular (if a board is formed) so long as it holds securities representing at least 5% or more of the equity of Lian Cardiovascular on an as-converted fully-diluted basis.

### **Certain Transactions with Tarsus**

In March 2021, we granted three warrants (collectively, the “Tarsus Warrants”) to Tarsus as partial consideration for the grant of certain licenses and rights to us pursuant to the Tarsus Agreement. 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. Accordingly, on October 18, 2021, we 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.

### **Shareholders Agreement**

In October 2020, we entered into a second amended and restated shareholders agreement (the “Shareholders Agreement”) with certain of our shareholders relating to rights and obligations with respect to ownership of our share capital, including the designation of certain director nominees, certain corporate governance rights, drag along rights, tag along rights, preemptive rights, information rights, demand and piggyback registration rights and related lockup obligations. All rights under the Shareholders Agreement, other than the registration rights, will terminate upon the closing of this offering.

## Director Nomination Agreement

In connection with this offering, we have entered into a 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 owns as of the completion of this offering.

The Director Nomination Agreement provides Perceptive the right to designate: (i) a number of directors equal to 66% of the total directors (rounded up to the nearest whole number) for so long as Perceptive beneficially owns 75% or more of the Original Perceptive Shares, defined as the number of Ordinary Shares held by Perceptive as of the closing of this offering; (ii) a number of directors equal to 55% of the total directors (rounded up to the nearest whole number) for so long as Perceptive beneficially owns at least 50% and less than 75% of the Original Perceptive Shares; (iii) a number of directors equal to 40% of the total directors (rounded up to the nearest whole number) for so long as Perceptive beneficially owns at least 25% and less than 50% of the Original Perceptive Shares; (iv) a number of directors equal to 25% of the total directors (rounded up to the nearest whole number) for so long as Perceptive beneficially owns at least 10% and less than 25% of the Original Perceptive Shares, and (v) one director for so long as Perceptive beneficially owns at least 5% of the Original Perceptive Shares. In each case, the nominees designated by Perceptive must comply with applicable law and Nasdaq listing rules. In addition, Perceptive shall be entitled to nominate the Chairman of the board of directors so long as Perceptive owns more than 5% of the Original Perceptive Shares. The Director Nomination Agreement will terminate at such time as Perceptive owns less than 5% of the Original Perceptive Shares.

## Director Affiliations

Some of our directors are affiliated with and serve on our board of directors as representatives of entities which beneficially own or owned 5% or more of our issued shares, as indicated below:

<u>Director</u>	<u>Principal Shareholder</u>
Konstantin Poukalov	Entities affiliated with Perceptive
Adam Stone	Entities affiliated with Perceptive
Neil Kumar	Entities affiliated with BridgeBio

Mr. Poukalov also serves as a director on the boards of directors of Landos Biopharma, Inc. and Lyra Therapeutics, Inc., with which we have entered into license and collaboration agreements. See “Business—License and collaboration agreements—Lyra License and Collaboration Agreement” and “Business—License and collaboration agreements—Landos License and Collaboration Agreement” for descriptions of our licensing arrangements with these entities.

## Arrangements with our Directors and Executive Officers

In addition, we have certain agreements with our directors and officers which are described in the section entitled “Executive and Director Compensation.”

Prior to this offering, we entered into an indemnification agreement with Perceptive, certain of Perceptive's affiliates, and Konstantin Poukalov, in his role as Executive Chairman of our board of directors and as a Managing Director at Perceptive. The indemnification agreement provides that, among other things, Mr. Poukalov, Perceptive and its affiliates party to the agreement will be entitled to indemnification by us for claims related to actions taken on behalf of the Company in their capacities as agents. We have entered into indemnification agreements with our officers and directors. We also



maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capacities as directors or officers.

### **Related Persons Transaction Policy**

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the completion of this offering, to set forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. No related person transaction subject to this policy entered into following this offering will be executed without the approval or ratification of our board of directors or a duly authorized committee of our board of directors. The board of directors or applicable committee will not approve or ratify a related person transaction unless it determines in good faith that, upon consideration of all relevant information, the related person transaction is in, or is not inconsistent with, the best interests of the Company. It is our policy that directors interested in a related person transaction will recuse themselves from any vote on a related person transaction in which they have an interest.

## DESCRIPTION OF SHARE CAPITAL

*The following describes our issued share capital, summarizes the material provisions of our memorandum and articles of association and highlights certain differences in corporate law in the Cayman Islands and the United States. Please note that this summary is not intended to be exhaustive. For further information, please refer to the full version of our memorandum and articles of association, which are included as an exhibit to the registration statement of which this prospectus is a part.*

We are a Cayman Islands company and our affairs are governed by our amended and restated memorandum and articles of association and the Companies Act.

Our authorized share capital is \$50,000 divided into (i) 2,859,432,812 Ordinary Shares, par value \$0.000017100448 per share, (ii) 5,500,000 Series Seed Preferred Shares, par value \$0.0001 per share, and (iii) 5,524,178 Series A Preferred Shares, par value \$0.0001 per share. In respect of all of our share capital, we have power insofar as is permitted by law, to redeem or purchase any of our shares and to increase or reduce the said capital subject to the provisions of the Companies Act and the articles of association and to issue any part of our capital, whether original, redeemed or increased with or without any preference, priority or special privilege or subject to any postponement of rights or to any conditions or restrictions and so that unless the conditions of issue shall otherwise expressly declare every issue of shares whether declared to be preference or otherwise shall be subject to the powers under our amended and restated memorandum and articles of association.

Prior to the completion of this offering, we will (i) convert all of our outstanding Series Seed Preferred Shares into an aggregate of 32,162,900 Ordinary Shares and (ii) convert all of our outstanding Series A Preferred Shares into an aggregate of 32,304,277 Ordinary Shares. See “The Conversions.”

As of September 30, 2021, there were 21,787,244 Ordinary Shares, 5,500,000 Series Seed Preferred Shares, and 5,524,178 Series A Preferred Shares issued and outstanding. Upon completion of this offering, our authorized share capital will be \$50,000 divided into 2,923,900,005 Ordinary Shares, par value \$0.000017100448 per share.

Our shareholders have adopted a fifth amended and restated memorandum and articles of association, which will become effective and replace the current fourth amended and restated memorandum and articles of association in its entirety immediately upon the completion of this offering. We will issue Ordinary Shares represented by our ADSs in this offering. All options, regardless of grant dates, will entitle holders to an equivalent number of Ordinary Shares once the vesting and exercising conditions are met. The following are summaries of material provisions of our post-offering amended and restated memorandum and articles of association and the Companies Act insofar as they relate to the material terms of our Ordinary Shares that we expect will become effective upon the closing of this offering.

### Ordinary Shares

#### **General**

Upon completion of this offering, our authorized share capital will be \$50,000 divided into 2,923,900,005 Ordinary Shares, par value \$0.000017100448 per share. All of our outstanding Ordinary Shares are fully paid and non-assessable. Certificates representing the Ordinary Shares are issued in registered form. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their Ordinary Shares.

### ***Dividend rights***

The holders of our Ordinary Shares are entitled to such dividends as may be declared by our board of directors. Our post-offering amended and restated memorandum and articles of association provides that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose in accordance with the Companies Act. Holders of Ordinary Shares will be entitled to the same amount of dividends, if declared.

### ***Voting rights***

In respect of all matters subject to a shareholders' vote, each Ordinary Share is entitled to one vote. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one or more shareholders present in person or by proxy and who together hold not less than 10% of the nominal value of the total issued voting shares of our company. Each holder of our Ordinary Shares is entitled to have one vote for each Ordinary Share registered in his or her name on our register of members.

A quorum required for a meeting of shareholders consists of one or more shareholders who hold at least one-third of all voting power of our share capital in issue at the date of the meeting present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. Shareholders' meetings may be held annually. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Extraordinary general meetings may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-third of the aggregate voting power of our company. Advance notice of at least seven days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our articles of association.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to all issued and outstanding shares cast at a meeting, while a special resolution also requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our post-offering amended and restated memorandum and articles of association.

### ***Transfer of Ordinary Shares***

Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her Ordinary Shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any Ordinary Share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any Ordinary Share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the Ordinary Shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;

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## [Table of Contents](#)

- in the case of a transfer to joint holders, the number of joint holders to whom the Ordinary Share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Nasdaq Global Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 14 days' notice being given by advertisement in one or more newspapers or by electronic means, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

### ***Liquidation***

On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of Ordinary Shares), assets available for distribution among the holders of Ordinary Shares shall be distributed by a liquidator who may divide our assets for distribution among our shareholders in his discretion. The liquidator also may vest all or part of our assets in trust. None of our shareholders may be compelled to accept any shares subject to liability.

### ***Calls on Ordinary Shares and forfeiture of Ordinary Shares***

Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their Ordinary Shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The Ordinary Shares that have been called upon and remain unpaid are subject to forfeiture.

### ***Redemption of Ordinary Shares***

The Companies Act and our post-offering amended and restated memorandum and articles of association permit us to purchase our own shares. In accordance with our post-offering amended and restated memorandum and articles of association and provided the necessary shareholders or board approval have been obtained, we may issue shares on terms that are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner, including out of capital, as may be determined by our board of directors.

### ***Variations of rights of shares***

All or any of the special rights attached to any class of shares may, subject to the provisions of the Companies Act and our post-offering amended and restated memorandum and articles of association, be varied with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed by the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

### ***Inspection of books and records***

Holders of our Ordinary Shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will file annual audited financial statements with the SEC. See “Where You Can Find More Information.”

### ***Issuance of additional shares***

Our post-offering amended and restated memorandum and articles of association authorizes our board of directors to issue additional Ordinary Shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our post-offering amended and restated memorandum and articles of association also authorizes our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of Ordinary Shares.

### ***Anti-takeover provisions***

Some provisions of our post-offering amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

### ***Exempted company***

We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;

- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

## **Warrants**

As of October 19, 2021, we had the following warrants outstanding:

- In accordance with and following QED’s election to convert the QED Warrants, QED holds a warrant to purchase 347,569 of our Ordinary Shares at an exercise price equal to \$0.000017100448 per share. This warrant expires on October 17, 2031.
- The MyoKardia Warrant is exercisable for 170,000 ordinary shares of Lian Cardiovascular, our wholly-owned subsidiary, with an exercise price of \$275 per share. The MyoKardia Warrant was issued in partial consideration for the MyoKardia Agreement by and between Lian Cardiovascular and MyoKardia and may be exercised, in whole or in part, at any time. In accordance with the terms of the Option Agreement, MyoKardia had an option to (i) convert the 170,000 ordinary shares of Lian Cardiovascular into 2,924,011 of our Ordinary Shares or (ii) convert the MyoKardia Warrant into a warrant to purchase 103,805 of our Ordinary Shares, with an exercise price of \$47.03 per share, in connection with the completion of this offering. MyoKardia has elected not to exercise this option and therefore, will continue to hold the MyoKardia Warrant following the completion of this offering. The Option Agreement, and MyoKardia’s option to convert the MyoKardia Warrant under the Option Agreement, will terminate upon the completion of this offering.
- In accordance with and following Tarsus’ election to convert the Tarsus Warrants, Tarsus holds two warrants, each exercisable upon the achievement of certain specified milestone events for 78,373 of our Ordinary Shares at an exercise price equal to \$0.000017100448. Both warrants expire on October 17, 2031.

The MyoKardia Warrant has a net exercise provision under which MyoKardia may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of ordinary shares of Lian Cardiovascular based on the fair market value of such shares at the time of exercise of the warrants after deduction of the aggregate exercise price. The MyoKardia Warrant and the warrants for the purchase of our Ordinary Shares held by QED and Tarsus described above contain provisions for the adjustment of the exercise price and number of ordinary shares of Lian Cardiovascular (in the case of the MyoKardia Warrant) or LianBio (in the case of the warrants for the purchase of our Ordinary Shares held by QED and Tarsus) issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

## **Registration Rights**

The Shareholders Agreement grants the parties thereto certain registration rights in respect of the “registrable securities” held by them, which securities include (a) the Ordinary Shares issued or issuable by holders of shares of our convertible preferred shares; (b) any Ordinary Shares issued or issuable upon conversion or exercise of any other of our securities; (c) any Ordinary Shares issued or issuable as a dividend or other distribution with respect to, in exchange for or in replacement of the securities referenced in (a); and (d) with respect solely to the “piggyback” registration rights described below, the issued Ordinary Shares. The registration of Ordinary Shares pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Shareholders Agreement, we will pay all expenses relating to such registrations, including the fees of

one special counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Shareholders Agreement also includes customary indemnification and procedural terms.

Holders of 86,332,794 of our Ordinary Shares (including shares issuable upon the conversion of our convertible preferred shares) are entitled to such registration rights pursuant to the Shareholders Agreement. These registration rights will expire, with respect to any holder of registrable securities, at such time at which such shareholder can sell all of the Ordinary Shares held by it pursuant to Rule 144 of the Securities Act in any ninety-day period.

#### ***Demand registration rights***

At any time beginning six months after the closing of this offering, the holders under the Shareholders Agreement of not less than 40% of the voting power of the registrable securities then outstanding may request that we prepare, file and maintain a registration statement on Form S-1 to register all or part of their registrable securities (subject to a limitation of the company only being obligated to consummate no more than two registrations pursuant to this right). Once we are eligible to use a registration statement on Form S-3, the holders under the Shareholders Agreement of at least 30% of the registrable securities then outstanding may request that we prepare, file and maintain a registration statement on Form S-3 in any jurisdiction in which we have had an underwriting public offering, but only if the aggregate offering amount of the registrable securities requested to be registered would exceed \$5 million.

#### ***Piggyback registration rights***

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the shareholders party to the Shareholders Agreement will be entitled to certain “piggyback” registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

#### **Differences in corporate law**

The Companies Act is modeled after that of English law but does not follow many recent English law statutory enactments. In addition, the Companies Act differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of the significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the State of Delaware. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and the laws of the Cayman Islands.

#### ***Mergers and similar arrangements***

A merger of two or more constituent companies under Cayman Islands law requires a plan of merger or consolidation to be approved by the directors of each constituent company and authorization by (i) a special resolution of the shareholders and (ii) such other authorization, if any, as may be specified in such constituent company's articles of association.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member



agrees otherwise. For this purpose, a subsidiary is a company of which at least 90% of the issued shares entitled to vote are owned by the parent company.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain circumstances, a dissentient shareholder of a Cayman constituent company is entitled to payment of the fair value of his shares upon dissenting to a merger or consolidation. The exercise of appraisal rights will preclude the exercise of any other rights save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

In addition, there are statutory provisions that facilitate the reconstruction and amalgamation of companies, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act.

When a takeover offer is made and accepted by holders of 90% of the shares within four months, the offeror may, within a two-month period commencing on the expiration of such four month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction is thus approved, the dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

### ***Shareholders' suits***

In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, there are exceptions to the foregoing principle, including when:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and

- those who control the company are perpetrating a “fraud on the minority.”

### ***Indemnification of directors and executive officers and limitation of liability***

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our post-offering amended and restated memorandum and articles of association permit indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from the willful neglect or default of such directors or officers. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. We have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our post-offering amended and restated memorandum and articles of association. In addition, we have entered into an indemnification agreement with Perceptive, certain of Perceptive's affiliates, and Konstantin Poukalov, in his role as Executive Chairman of our board of directors and as a Managing Director at Perceptive. The indemnification agreement provides that, among other things, Mr. Poukalov, Perceptive and its affiliates party to the agreement will be entitled to indemnification by us for claims related to actions taken on behalf of the Company in their capacities as agents.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### ***Directors' fiduciary duties***

Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he or she owes the following duties to the company— a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his or her position as director (unless the company permits him or her to do so) and a duty not to put himself or herself in a position where the interests of the company conflict with his or her personal interest or his or her duty to a third party. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be

expected from a person of his or her knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

#### ***Shareholder action by written consent***

Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Cayman Islands law and our post-offering amended and restated memorandum and articles of association provide that shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

#### ***Shareholder proposals***

Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

Cayman Islands law does not provide shareholders any right to put proposal before a meeting or requisition a general meeting. However, these rights may be provided in the articles of association. Our post-offering amended and restated memorandum and articles of association allows our shareholders holding not less than one-third of all voting power of our share capital in issue to requisition a shareholders' meeting. Other than this right to requisition a shareholders' meeting, our post-offering amended and restated memorandum and articles of association do not provide our shareholders other right to put proposal before a meeting. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings, but we anticipate that we will hold general meetings annually.

#### ***Cumulative voting***

Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholders' voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands but our post-offering amended and restated memorandum and articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

#### ***Removal of directors***

Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our post-offering amended and restated memorandum and articles of association, directors may be removed with or without cause, by an ordinary resolution of our shareholders.

### ***Transactions with interested shareholders***

The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an “interested shareholder” for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

### ***Dissolution; winding up***

Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board. Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Act, our company may be dissolved, liquidated or wound up by a special resolution of our shareholders.

### ***Variation of rights of shares***

Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our post-offering amended and restated memorandum and articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

### ***Amendment of governing documents***

Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. As permitted by Cayman Islands law, our post-offering amended and restated memorandum and articles of association may only be amended with a special resolution of our shareholders.

***Rights of non-resident or foreign shareholders***

There are no limitations imposed by our post-offering amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Citibank, N.A. has agreed to act as the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, NY 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 typically appoints 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.

We will appoint Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement will be on file with the SEC under cover of a Registration Statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website ([www.sec.gov](http://www.sec.gov)). Please refer to Registration Number 333-260162 when retrieving such copy.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, Ordinary Shares that are 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-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.

If you become an owner of ADSs, you 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 your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary bank. As an ADS holder you appoint the depositary bank to act on your 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 you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You 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 your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

*As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary bank will hold on your behalf the shareholder rights attached to the Ordinary Shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholder rights for the Ordinary Shares represented by your 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 you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.*

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to you. As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary bank in your 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 you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your 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 your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you 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 you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

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**

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your 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.

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 you 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). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your 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 you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; 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 you. 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 you 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 you 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 you, you 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 you. 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 you 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 the 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 you and will sell the property if:

- We do not request that the property be distributed to you or if we request that the property not be distributed to you; 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 you is not reasonably practicable. 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 the 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. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your 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 your 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, your 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 you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your 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 you, the depositary bank may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

### **Issuance of ADSs Upon Deposit of Ordinary Shares**

Upon completion of this offering, the Ordinary Shares being offered pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADSs to the underwriters named in this prospectus.

After the closing of this offer, the depositary bank may create ADSs on your behalf if you or your broker deposit Ordinary Shares with the custodian. The depositary bank will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the Ordinary Shares to the custodian. Your 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 you make a deposit of Ordinary Shares, you will be responsible for transferring good and valid title to the depositary bank. As such, you 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.
- You are 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 your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

### **Transfer, Combination and Split Up of ADRs**

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you 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 your ADRs either combined or split up, you must surrender the ADRs in question to the depositary bank with your request to have them combined or split up, and you 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**

As a holder, you will be entitled to present your ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying Ordinary Shares at the custodian's offices. Your 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 your ADSs, you 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.

You 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 you hold ADSs registered in your name, the depositary bank may ask you 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 your ADSs. The withdrawal of the Ordinary Shares represented by your 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.

You will have the right to withdraw the securities represented by your 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 your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

### **Voting Rights**

As a holder, you generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the Ordinary Shares represented by your ADSs. The voting rights of holders of Ordinary Shares are described in "Description of share capital."

At our request, the depositary bank will distribute to you 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 of ADSs, the depositary bank will vote (or instruct the Custodian to vote) the Ordinary Shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Holders of ADSs 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 of ADSs 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 you that you will receive voting materials in time to enable you to return voting instructions to the depositary bank in a timely manner.

## Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

<u>Service</u>	<u>Fees</u>
• 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

As an ADS holder you 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;

## [Table of Contents](#)

- 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 of 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 the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You 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 your 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 your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the Ordinary Shares represented by your 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 the holders at least 30 days before termination. Until termination, your 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 you request the cancellation of your 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. You 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 you. 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 you 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 of Association, 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 of Association 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 of ADSs 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 you.
- 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 you as ADS holder.
- 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**

You 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. You 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 your behalf. However, you 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. You 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 you.

### **Foreign Currency Conversion**

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You 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 practical 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 practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- 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, you 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 you 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, YOU IRREVOCABLY WAIVE YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY BANK.

## ORDINARY SHARES AND AMERICAN DEPOSITARY SHARES ELIGIBLE FOR FUTURE SALE

Based on the number of shares outstanding as of September 30, 2021, upon completion of this offering, we will have 20,312,500 ADSs outstanding, representing approximately 19.1% of our outstanding Ordinary Shares (or 23,359,375 ADSs outstanding, representing approximately 21.3% of our outstanding Ordinary Shares, if the underwriters exercise in full their option to purchase additional ADSs). All of the ADSs sold in this offering and the Ordinary Shares they represent will be freely transferable by persons other than our “affiliates” without restriction or further registration under the Securities Act. Rule 144 under the Securities Act defines an “affiliate” of a company as a person that, directly or indirectly, through one or more intermediaries, controls or is controlled by, or is under common control with, our company. All outstanding Ordinary Shares prior to this offering are “restricted securities” as that term is defined in Rule 144 because they were issued in a transaction or series of transactions not involving a public offering. Restricted securities, in the form of ADSs or otherwise, may be sold only if they are the subject of an effective registration statement under the Securities Act or if they are sold pursuant to an exemption from the registration requirement of the Securities Act such as those provided for in Rule 144 or 701 promulgated under the Securities Act, which rules are summarized below. Restricted Ordinary Shares may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S under the Securities Act. This prospectus may not be used in connection with any resale of the ADSs acquired in this offering by our affiliates.

Sales of substantial amounts of our ADSs in the public market could materially and adversely affect prevailing market prices of the ADSs. Prior to this offering, there has been no public market for our Ordinary Shares or ADSs, and while we have applied to list the ADSs on the Nasdaq Global Market, we cannot assure you that a regular trading market will develop for the ADSs. We do not expect that a trading market will develop for our Ordinary Shares not represented by the ADSs.

### Lock-up Agreements

Our directors and executive officers, and substantially all of our shareholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of Goldman Sachs & Co LLC, Jefferies LLC and BofA Securities, Inc.:

- offer, sell, contract to sell, pledge, grant any option to purchase, lend or otherwise dispose of, directly or indirectly, any Ordinary Shares or ADSs, or any options or warrants to purchase any Ordinary Shares or ADSs, or any securities convertible into, exchangeable for or that represent the right to receive Ordinary Shares or ADSs; or
- engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of any Ordinary Shares or ADSs or derivative instruments.

whether any such transaction described above is to be settled by delivery of Ordinary Shares or ADSs or other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and BofA Securities, Inc. on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any Ordinary Shares or ADSs or any security convertible into or exercisable or exchangeable for Ordinary Shares or ADSs.

The restrictions described in the immediately preceding paragraph do not apply to, among other items:

- as a bona fide gift or gifts, provided that the donee or donees thereof agree to be bound in writing by the restrictions set forth in the lock-up agreement and provided further that no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- to any trust for the direct or indirect benefit of the holder or the immediate family of the holder, provided that (i) the trustee of the trust agrees to be bound in writing by the restrictions set forth in the lock-up agreement, (ii) any such transfer shall not involve a disposition for value and (iii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- in connection with the sale of the holder's or its affiliate's Ordinary Shares, ADSs or any security convertible into or exercisable or exchangeable for Ordinary Shares or ADSs acquired in the offering or in open market transactions after the completion of the offering, provided that no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- to us in connection with the exercise of options, warrants or other rights to acquire Ordinary Shares or ADSs or any security convertible into or exercisable for Ordinary Shares or ADSs pursuant to our equity incentive plans or other rights described in this prospectus for the offering, provided that (i) any such Ordinary Shares or ADSs issued upon exercise of such option, warrant or other right shall be subject to the restrictions on transfer set forth in the lock-up agreement and (ii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- by will or intestacy, provided that (i) the legatee, heir or other transferee, as the case may be, agrees to be bound in writing by the restrictions set forth in the lock-up agreement and (ii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Form 4 (which must indicate in the footnotes thereto the nature and conditions of such transfer), Schedule 13G, Schedule 13G/A or Form 13F);
- pursuant to a court order or a settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union, provided that (i) such transferee agrees to be bound in writing by the restrictions set forth in the lock-up agreement and (ii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Form 4 (which must indicate in the footnotes thereto the nature and conditions of such transfer), Schedule 13G, Schedule 13G/A or Form 13F);
- to us pursuant to agreements in effect as of the date of this prospectus for the offering under which we have the option to repurchase such securities or a right of first refusal with respect to transfers of such securities upon termination of service of the holder, provided that no filing

under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Form 4 (which must indicate in the footnotes thereto the nature and conditions of such transfer), Schedule 13G, Schedule 13G/A or Form 13F);

- pursuant to the conversion of our outstanding preferred shares into Ordinary Shares or ADSs, provided that (i) any such any such Ordinary Shares or ADSs issued upon conversion shall be subject to the restrictions on transfer set forth in the lock-up agreement and (ii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- if the holder is a corporation, partnership, limited liability company, trust or other business entity, as part of a distribution, transfer or disposition without consideration by the holder to its limited or general partners, members, stockholders or affiliates, provided, however, that (i) in the case of any such transfer or disposition, it shall be a condition to the transfer or disposition that the transferee agrees to be bound in writing by the restrictions set forth in the lock-up agreement and (ii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period (other than a required filing on Form 5 made after the restricted period and other than a required filing on Schedule 13G, Schedule 13G/A or Form 13F);
- pursuant to a merger, consolidation, tender offer or other similar transaction involving a "Change of Control" (as defined in such lock-up agreements) and approved by the our board of directors, provided that, in the event that such Change of Control is not completed, the holder's Ordinary Shares or ADSs remain subject to the restrictions set forth in the lock-up agreement and title to holder's Ordinary Shares or ADSs remain with the holder;
- if the holder is a corporation, partnership, limited liability company, trust or other business entity, to another corporation, partnership, limited liability company, trust or other business entity that directly or indirectly, controls, is controlled by, or is under common control with, the holder, provided that it shall be a condition to the transfer or disposition that the transferee agrees to be bound in writing by the restrictions set forth in the lock-up agreement, (ii) any such transfer shall not involve a disposition for value and (iii) no filing under the Exchange Act or public announcement shall be required or shall be voluntarily made during the restricted period; or
- establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of the holder's Ordinary Shares or ADSs, provided that (i) no public report or filing under Section 16 of the Exchange Act shall be required during the restricted period, (ii) the holder does not otherwise voluntarily effect any public filing or report regarding the establishment of such plan during the restricted period and (iii) no sales are made during the restricted period pursuant to such plan.

Other than this offering, we are not aware of any plans by any significant shareholders to dispose of significant numbers of our ADSs or Ordinary Shares. However, one or more existing shareholders or owners of securities convertible or exchangeable into or exercisable for our ADSs or Ordinary Shares may dispose of significant numbers of our ADSs or Ordinary Shares in the future. We cannot predict what effect, if any, future sales of our ADSs or Ordinary Shares, or the availability of ADSs or Ordinary Shares for future sale, will have on the trading price of our ADSs from time to time. Sales of substantial amounts of our ADSs or Ordinary Shares in the public market, or the perception that these sales could occur, could adversely affect the trading price of our ADSs.

## **Rule 144**

All of our Ordinary Shares that will be outstanding upon the completion of this offering, other than those Ordinary Shares represented by ADSs sold in this offering, are “restricted securities” as that term is defined in Rule 144 under the Securities Act and may be sold publicly in the United States only if they are subject to an effective registration statement under the Securities Act or pursuant to an exemption from the registration requirement such as those provided by Rule 144 and Rule 701 promulgated under the Securities Act. In general, beginning 90 days after the date of this prospectus, a person (or persons whose shares are aggregated) who at the time of a sale is not, and has not been during the three months preceding the sale, an affiliate of ours and has beneficially owned our restricted securities for at least six months will be entitled to sell the restricted securities without registration under the Securities Act, subject only to the availability of current public information about us, and will be entitled to sell restricted securities beneficially owned for at least one year without restriction. Persons who are our affiliates and have beneficially owned our restricted securities for at least six months may sell a number of restricted securities within any three-month period that does not exceed the greater of the following:

- 1% of the then outstanding Ordinary Shares of the same class, in the form of ADSs or otherwise, which immediately after this offering will equal approximately 1.1 million Ordinary Shares, assuming the underwriters do not exercise their option to purchase additional ADSs; or
- the average weekly trading volume of our Ordinary Shares of the same class, represented by ADSs or otherwise, during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by our affiliates under Rule 144 are also subject to certain requirements relating to manner of sale, notice and the availability of current public information about us.

## **Rule 701**

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, consultants or advisors who purchases our Ordinary Shares from us in connection with a compensatory stock plan or other written agreement executed prior to the completion of this offering is eligible to resell those Ordinary Shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144. However, the Rule 701 shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

## **Registration Statement on Form S-8**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all of the Ordinary Shares subject to outstanding stock options and the Ordinary Shares subject to issuance under the 2019 Equity Incentive Plan and the 2021 Equity Incentive Plan to be adopted in connection with this offering. We expect to file these registration statements as promptly as possible after the completion of this offering. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, ADRs registered under such registration statements will be available for sale in the open market. We expect that the initial registration statement on Form S-8 relating to our 2019 Equity Incentive Plan and the 2021 Equity Incentive Plan will cover approximately 24.9 million Ordinary Shares.

## **Registration Rights**

Beginning 180 days after the date of this prospectus, subject to certain exceptions, holders of 86,332,794 Ordinary Shares will be entitled to the registration rights described under “Description of

Share Capital—Registration Rights.” Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration.



## TAXATION

### 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 our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

### China taxation

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of China with a “de facto management body” within China is considered a “resident enterprise,” and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, 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 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 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 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 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 China. For the same reasons, we believe our other subsidiaries outside of China are also not Chinese resident enterprises. 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 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 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 China in the event that we are treated as a Chinese resident enterprise.

See “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 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 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, 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 Chinese incorporated subsidiaries 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. Please see “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. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire our ADSs. This discussion is limited to U.S. Holders who hold our ADSs as capital assets (generally, property held for investment) and who are initial purchasers of our ADSs pursuant to this offering. 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 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 through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;

## [Table of Contents](#)

- 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 ADS pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding our ADSs 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. 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. 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.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs, 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.

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 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 for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depository 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**

As described in "Dividend Policy" above, we do not currently anticipate paying any distributions on our ADSs 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, the gross amount of any distribution on the ADSs (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 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 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, 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.

We have applied to list our ADSs on the Nasdaq Global Market, which is an established securities market in the United States. Provided that such listing is approved, 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. 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 “–China taxation” above), U.S. Holders might be subject to Chinese withholding taxes on dividends paid with respect to our ADSs. 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 will be treated as income from sources outside the United States and will generally constitute passive category income. 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, 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. The initial tax basis of ADSs to a U.S. Holder will generally be the U.S. Holder’s U.S. dollar purchase price for the ADS.

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 “ –China 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, 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 shares or ADS, 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 “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, which is likely to fluctuate significantly after the offering. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from the offering in our business.

We do not believe we were a PFIC for our most recently completed taxable year, and we do not expect to become a PFIC in the current taxable year though there can be no assurances, including because the determination of whether a corporation will be a PFIC for any taxable year generally can only be made after the close of such taxable year. Because we hold, and will continue to hold after this offering, 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, 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 the current or any future taxable year. 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, 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 the “deemed sale election” described below in “U.S. federal income tax treatment of a shareholder of a PFIC.” 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 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 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, 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 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) and (2) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs.

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 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. 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 can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs, provided that the ADSs are "marketable." ADSs 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 will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs 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 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 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 in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs, 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 for any taxable year significantly in excess of any cash distributions received on the ADSs for such taxable year. U.S. Holders should consult their tax advisors regarding the advisability of, and procedure for, making QEF elections in their particular circumstances.

#### *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, 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.

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 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 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,

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. 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.

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.

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the ADSs being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of ADSs indicated in the following table. Goldman Sachs & Co. LLC, Jefferies LLC and BofA Securities, Inc. are the representatives of the underwriters.

Underwriters	Number of ADSs
Goldman Sachs & Co. LLC	
Jefferies LLC	
BofA Securities, Inc.	
Raymond James & Associates, Inc.	
Total	20,312,500

The underwriters are committed to take and pay for all of the ADSs being offered, if any are taken, other than the ADSs covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 3,046,875 ADSs from us to cover sales by the underwriters of a greater number of ADSs than the total number set forth in the table above. They may exercise that option for 30 days. If any ADSs are purchased pursuant to this option, the underwriters will severally purchase ADSs in approximately the same proportion as set forth in the table above.

The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to 3,046,875 additional ADSs from us.

Paid by us	No Exercise	Full Exercise
Per ADS	\$	\$
Total	\$	\$

ADSs sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any ADSs sold by the underwriters to securities dealers may be sold at a discount of up to \$ per ADS from the initial public offering price. After the initial offering of the ADSs, the representatives may change the offering price and the other selling terms. The offering of the ADSs by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of ADSs made outside of the United States may be made by affiliates of the underwriters.

We and our executive officers, directors, and holders of substantially all of our equity securities and securities convertible into or exchangeable for our equity securities have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their equity securities or securities convertible into or exchangeable for equity securities during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives.

Prior to the offering, there has been no public market for the ADSs. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the ADSs, in addition to prevailing market conditions, will

be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list the ADSs on the Nasdaq Global Market under the symbol "LIAN."

In connection with the offering, the underwriters may purchase and sell ADSs in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of ADSs than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional ADSs for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional ADSs or purchasing ADSs in the open market. In determining the source of ADSs to cover the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase additional ADSs pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional ADSs for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ADSs made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased ADSs sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our ADSs, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding estimated underwriting discounts and commissions, will be approximately \$5.5 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$30,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### ***European Economic Area***

In relation to each Member State of the European Economic Area (each a “Relevant State”), no securities (the “Securities”) have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the Securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of Securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(C) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Securities shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any Securities in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Securities to be offered so as to enable an investor to decide to purchase or subscribe for any Securities, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

### **United Kingdom**

No securities have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities which has been approved by the Financial Conduct Authority, except that the securities may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the securities shall require us or any of the representatives to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the securities in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

### **Canada**

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### **Hong Kong**

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (“Companies (Winding Up and Miscellaneous Provisions) Ordinance”) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the

Laws of Hong Kong) (“Securities and Futures Ordinance”), or (ii) to “professional investors” as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

### **Japan**

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended) (the “FIEA”). The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

### **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the securities under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (“Regulation 32”)

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be

transferable for 6 months after that trust has acquired the securities under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

### **Switzerland**

This prospectus is not intended to constitute an offer or solicitation to purchase or invest in the ADSs. The ADSs may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act ("FinSA") and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading venue (exchange or multilateral trading facility) in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to, the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading venue (exchange or multilateral trading facility) in Switzerland.

Neither this document nor any other offering or marketing material relating to the ADSs constitutes a prospectus pursuant to the FinSA, and neither this document nor any other offering or marketing material relating to the ADSs or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, the Company, or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

### **United Arab Emirates**

The ADSs have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.



## LEGAL MATTERS

We are being represented by Ropes & Gray LLP with respect to certain legal matters as to United States federal securities and New York state law. The underwriters are being represented by Cooley LLP with respect to certain legal matters as to United States federal securities and New York state law. The validity of the Ordinary Shares represented by the ADSs offered in this offering will be passed upon for us by Travers Thorp Alberga. Certain legal matters as to Chinese law will be passed upon for us by Zhong Lun Law Firm and for the underwriters by Commerce & Finance Law Offices. Ropes & Gray LLP may rely upon Travers Thorp Alberga with respect to matters governed by Cayman Islands law and Zhong Lun Law Firm with respect to matters governed by Chinese law. Cooley LLP may rely upon Commerce & Finance Law Offices with respect to matters governed by Chinese law.

## EXPERTS

The consolidated financial statements of LianBio as of December 31, 2019 and 2020, and for the period from July 17, 2019 (date of incorporation) to December 31, 2019 and the year ended December 31, 2020, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

## ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated in the Cayman Islands to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

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

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

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

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

A majority of our operations are conducted in China, and certain of our assets are located in China. Certain of our directors and executive officers are nationals or residents of jurisdictions other than the United States may have assets located outside the United States. As a result, it may be difficult for a shareholder to effect service of process within the United States upon these persons, or to

enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

Travers Thorp Alberga, our legal counsel as to Cayman Islands law, and Zhong Lun Law Firm, our legal counsel as to Chinese law, have advised us, respectively, that there is uncertainty as to whether the courts of the Cayman Islands and China, respectively, would:

- recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States; or
- entertain original actions brought in each respective jurisdiction against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

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

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

Zhong Lun Law Firm has further advised us that the recognition and enforcement of foreign judgments are provided for under 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 form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in China will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of Chinese law or national sovereignty, security or social 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 or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign shareholders may originate actions based on Chinese law against a company in China for disputes if they can establish sufficient nexus to China for a Chinese court to have jurisdiction, and meet other procedural requirements, including, among others, the plaintiff must have a direct interest in the case,

and there must be a concrete claim, a factual basis and a cause for the suit. However, it would be difficult for foreign shareholders to establish sufficient nexus to China by virtue only of holding our ADSs or Ordinary Shares.

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

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the ADSs offered hereby. A related registration statement on Form F-6 will be filed with the SEC to register the ADSs. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the ADSs offered hereby, please refer to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act and will be required to file reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). We intend to furnish the depositary with our annual reports, which will include a review of operations and annual audited consolidated combined financial statements prepared in conformity with GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

We also maintain a website at [www.lianbio.com](http://www.lianbio.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website or that can be accessed through our website is not a part of, and is not incorporated by reference in, this prospectus.

LIANBIO

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Financial Statements

*Index to consolidated financial statements*

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-1
<a href="#">Consolidated Balance Sheets as of December 31, 2019 and 2020 and as of June 30, 2021</a>	F-2
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the Period from July 17, 2019 (Date of Incorporation) to December 31, 2019 and the year ended December 31, 2020 and for the six months ended June 30, 2020 and 2021</a>	F-3
<a href="#">Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholders' Deficit for the Period from July 17, 2019 (Date of Incorporation) to December 31, 2019 and the year ended December 31, 2020 and for the six months ended June 30, 2020 and 2021</a>	F-4
<a href="#">Consolidated Statements of Cash Flows for the Period from July 17, 2019 (Date of Incorporation) to December 31, 2019 and the year ended December 31, 2020 and for the six months ended June 30, 2020 and 2021</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-8

## 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, 2019 and 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholders' deficit, and cash flows for the period from July 17, 2019 (date of incorporation) to December 31, 2019 and the year ended December 31, 2020 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, 2019 and 2020, and the results of its operations and its cash flows for the period from July 17, 2019 (date of incorporation) to December 31, 2019 and the year ended December 31, 2020, 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  
June 24, 2021, except for Note 2(Q), as to which the date is October 20, 2021

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

	December 31, 2019	December 31, 2020	June 30, 2021 (unaudited)
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 43,300	\$ 254,350	\$ 142,624
Prepays expenses and other current assets	47	2,396	3,751
Other receivable	—	20,000	—
Total current assets	43,347	276,746	146,375
Restricted Cash, non-current	—	—	20,000
Property and equipment, net	—	822	759
Operating lease right-of-use assets	532	1,706	1,500
Other non-current assets	—	12	11
Total assets	<u>\$ 43,879</u>	<u>\$ 279,286</u>	<u>\$ 168,645</u>
<b>Liabilities, Redeemable Convertible Preferred Shares and Shareholders' Deficit</b>			
Current liabilities:			
Accounts payable	\$ —	\$ 4,329	\$ 30,424
Accrued expenses	318	998	9,210
Related party payable	2,845	—	—
Current portion of operating lease liabilities	182	539	403
Other current liabilities	—	360	2,047
Total current liabilities	3,345	6,226	42,084
Operating lease liabilities	350	1,341	1,233
Nonrefundable research deposit	—	20,000	20,000
Total liabilities	3,695	27,567	63,317
Commitments and contingencies (Note 7)			
Redeemable convertible preferred shares, \$0.0001 par value. Authorized 5,500,00 shares, 10,971,231 shares and 11,024,178 shares as of December 31, 2019, December 31, 2020 and June 30, 2021 (unaudited) respectively; 5,500,00 shares, 10,971,231 shares and 11,024,178 shares issued and outstanding as of December 31, 2019, December 31, 2020 and June 30, 2021 (unaudited) respectively;.	55,000	349,789	352,729
Shareholders' deficit:			
Ordinary shares, \$0.000017100448 par value. Authorized 2,891,737,100 shares as of December 31, 2019; 10,265,811 shares issued and outstanding at December 31, 2019; Authorized 2,859,742,435 shares as of December 31, 2020; 20,477,338 shares issued and outstanding at December 31, 2020. Authorized 2,859,432,812 shares as of June 30, 2021 (unaudited); 20,477,338 shares issued and outstanding at June 30, 2021 (unaudited).	—	—	—
Additional paid-in capital	8,516	31,132	34,249
Accumulated other comprehensive (loss) income	—	(40)	90
Accumulated deficit	(24,331)	(163,935)	(325,928)
Total LianBio shareholders' deficit	(15,815)	(132,843)	(291,589)
Non-controlling interest	999	34,773	44,188
Total shareholders' deficit	(14,816)	(98,070)	(247,401)
Total liabilities, redeemable convertible preferred shares and shareholders' deficit	<u>\$ 43,879</u>	<u>\$ 279,286</u>	<u>\$ 168,645</u>

See accompanying notes to the consolidated financial statements

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

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
<b>Operating expenses:</b>				
Research and development	\$ 22,624	\$ 120,885	\$ 1,258	\$ 146,383
General and administrative	1,713	13,984	5,363	13,607
Total operating expenses	24,337	134,869	6,621	159,990
Operating loss	(24,337)	(134,869)	(6,621)	(159,990)
Other income (expense):				
Interest income (expense), net	11	(4,854)	13	139
Other (expense) income, net	(1)	123	(18)	(192)
Net loss before income taxes	(24,327)	(139,600)	(6,626)	(160,043)
Income taxes	4	4	2	1,950
Net loss	(24,331)	(139,604)	(6,628)	(161,993)
Other comprehensive (loss) income:				
Foreign currency translation (loss) income, net of tax	—	(40)	(53)	130
Comprehensive loss	\$ (24,331)	\$ (139,644)	\$ (6,681)	\$ (161,863)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (4.99)	\$ (11.58)	\$ (0.65)	\$ (7.91)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	4,872,447	12,051,433	10,265,811	20,477,337

See accompanying notes to the consolidated financial statements



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

	Redeemable Convertible Preferred Stock		Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Deficit	Non-Controlling Interest	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount						
Initial capitalization, July 17, 2019 (date of incorporation)	—	\$ —	5	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of ordinary shares	—	—	5,263,014	—	—	—	—	—	—	—
Issuance of ordinary shares under a licensing agreement	—	—	5,002,792	—	8,516	—	—	8,516	—	8,516
Issuance of Series Seed Preferred Shares at \$10.00 per share	5,500,000	55,000	—	—	—	—	—	—	—	—
Warrants Issued in license agreement	—	—	—	—	—	—	—	—	999	999
Net loss	—	—	—	—	—	—	(24,331)	(24,331)	—	(24,331)
Balance, December 31, 2019	<u>5,500,000</u>	<u>\$ 55,000</u>	<u>10,265,811</u>	<u>\$ —</u>	<u>\$ 8,516</u>	<u>\$ —</u>	<u>\$ (24,331)</u>	<u>\$ (15,815)</u>	<u>\$ 999</u>	<u>\$ (14,816)</u>
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	<u>10,971,231</u>	<u>\$349,789</u>	<u>20,477,338</u>	<u>\$ —</u>	<u>\$ 31,132</u>	<u>\$ (40)</u>	<u>\$ (163,935)</u>	<u>\$ (132,843)</u>	<u>\$ 34,773</u>	<u>\$ (98,070)</u>

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

	Redeemable Convertible Preferred Stock		Ordinary Shares		Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total LianBio Shareholders' Deficit	Non-Controlling Interest	Total Shareholders' 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 (unaudited)	—	—	—	—	1,875	—	—	1,875	—	1,875
Beneficial conversion feature on issuance of convertible notes (unaudited)	—	—	—	—	2,439	—	—	2,439	—	2,439
Net Loss (unaudited)	—	—	—	—	—	—	(6,628)	(6,628)	—	(6,628)
Comprehensive loss (unaudited)	—	—	—	—	—	(53)	—	(53)	—	(53)
Balance, June 30, 2020 (unaudited)	5,500,000	\$ 55,000	10,265,811	\$ —	\$ 12,830	\$ (53)	\$ (30,959)	\$ (18,182)	\$ 999	\$ (17,183)
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 (unaudited)	—	—	—	—	3,117	—	—	3,117	—	3,117
Issuance of Series A Preferred Shares at \$56.66, net of issuance costs (unaudited)	52,947	\$ 2,940	—	—	—	—	—	—	—	—
Warrants Issued in license agreement (unaudited)	—	—	—	—	—	—	—	—	9,415	9,415
Net Loss (unaudited)	—	—	—	—	—	—	(161,993)	(161,993)	—	(161,993)
Comprehensive Income (unaudited)	—	—	—	—	—	130	—	130	—	130
Balance, June 30, 2021 (unaudited)	11,024,178	\$ 352,729	20,477,338	\$ —	\$ 34,249	\$ 90	\$ (325,928)	\$ (291,589)	\$ 44,188	\$ (247,401)

See accompanying notes to the consolidated financial statements

**LianBio**  
**Consolidated Statements of Cash Flows**  
(In thousands)

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six months ended June 30, 2020 (unaudited)	Six months ended June 30, 2021 (unaudited)
Net loss	\$ (24,331)	\$ (139,604)	\$ (6,628)	\$ (161,993)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock consideration, issued in acquisition of IPR&D	9,515	33,774	—	9,415
Amortization of beneficial conversion feature	—	2,475	—	—
Non-cash operating lease expense	—	169	63	(40)
Depreciation expense	—	76	2	137
Share based compensation expense	—	5,177	1,875	3,117
Unrealized foreign currency transaction (gain) losses, net	—	(380)	55	(46)
Changes in operating assets and liabilities:				
Increase in prepaid expenses and other current assets	(47)	(2,327)	(883)	(1,343)
(Increase) decrease in other receivable	—	(20,000)	—	20,000
Increase in other non-current assets	—	(7)	(1)	1
Increase in accounts payable	—	4,164	429	26,094
Increase in accrued expenses	318	811	1,285	8,178
Increase in nonrefundable research deposit	—	20,000	—	—
Increase (decrease) in other current liabilities	—	375	(38)	1,704
Increase (decrease) in related party payable	2,845	(2,845)	(2,845)	—
Net cash used in operating activities	(11,700)	(98,142)	(6,686)	(94,776)
Cash flows from investing activities:				
Purchase of property and equipment	—	(886)	(322)	(67)
Net cash used for investing activities	—	(886)	(322)	(67)
Cash flows from financing activities:				
Proceeds from issuance of redeemable convertible preferred stock	55,000	310,000	—	3,000
Issuance costs related to redeemable convertible preferred stock	—	(15,211)	—	(60)
Issuance of convertible notes	—	15,000	15,000	—
Debt issuance costs related to convertible notes	—	(36)	(36)	—
Net cash provided by financing activities	55,000	309,753	14,964	2,940
Effect of exchange rate changes on cash and cash equivalents	—	325	(118)	177

**LianBio**  
**Consolidated Statements of Cash Flows**  
(In thousands)

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six months ended June 30, 2020 (unaudited)	Six months ended June 30, 2021 (unaudited)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 43,300	\$ 211,050	\$ 7,838	\$ (91,726)
Cash and cash equivalents, and restricted cash - beginning of period	—	\$ 43,300	\$ 43,300	\$ 254,350
Cash and cash equivalents, and restricted cash - ending of period	\$ 43,300	\$ 254,350	\$ 51,138	\$ 162,624
Cash and cash equivalents - end of period	\$ 43,300	\$ 254,350	\$ 51,138	\$ 142,624
Restricted cash - end of period	\$ —	\$ —	\$ —	\$ 20,000
Cash and cash equivalents, and restricted cash - ending of period	\$ 43,300	\$ 254,350	\$ 51,138	\$ 162,624
Supplemental disclosure of non-cash financing and investing activities:				
Right-of-use assets obtained in exchange for lease obligations	\$ 532	\$ 1,375	\$ 103	\$ —
Seller financing related to the MyoKardia license	—	35,000	—	—
Issuance costs in accounts payable and other accrued liabilities	—	1,152	45	1,358
Beneficial conversion feature related to convertible notes	—	2,439	2,439	—

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.

### 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 ("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.

The interim balance sheet as of June 30, 2021, and the interim consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred shares and shareholders' deficit and cash flows for the six months ended June 30, 2020 and 2021 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, which consist of only normal recurring adjustments, necessary for the fair statement of the Company's financial information. The financial data and other information disclosed in these notes related to the six-month periods are also unaudited. The interim results for the six months ended June 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods or any future year or period.

#### (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 was the fair value of warrants, share-based compensation, and stock 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 COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to material credit risk due to the financial position of the banking institution. 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.

The Company's product candidates require approvals from the National Medical Products Administration ("NMPA") 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, it could have a materially adverse impact on the business.

## ***(ii) Liquidity***

The Company has incurred operating losses since inception and had an accumulated deficit of \$163.9 million as of December 31, 2020 and \$325.9 million as of June 30, 2021. The Company expects to continue to incur net losses for at least the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt or equity financings to fund its operations. Management believes that its cash and cash equivalents of \$142.6 million at June 30, 2021 are sufficient to fund operations for at least 12 months from the date of issuance of the accompanying financial statements. Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue business strategies. The Company may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that the Company might otherwise seek to develop or commercialize independently.

## ***(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 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. The Company had no Level 2 assets or liabilities as of December 31, 2019 and 2020 and June 30, 2021.
- 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, 2019 and 2020, and June 30, 2021.

**(G) Cash and Cash Equivalents**

The Company considers all highly liquid investments with a maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are carried at cost which approximates fair value due to their short-term nature. The Company maintains cash balances at both U.S.-based and foreign- based commercial banks.

Amounts included in restricted cash represent those required to be set aside by a contractual agreement with Pfizer, 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, 2019	December 31, 2020	June 30, 2021 (unaudited)
Cash and cash equivalents	\$ 43,300	\$ 254,350	\$ 142,624
Restricted cash, non-current	—	—	20,000
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 43,300</u>	<u>\$ 254,350</u>	<u>\$ 162,624</u>

**(H) 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.

**(I) 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 loss.

**(J) 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 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.



**(K) Acquisition of In-Process Research and Development (“IPR&D”)**

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 regulatory authority in China, 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.

**(L) 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.

**(M) 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 June 30, 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.

#### **(N) Leases**

The Company adopted ASC 842, Leases ("ASC 842"), effective upon the formation of the Company on July 17, 2019.

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, the 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.

#### **(O) Share-Based Compensation**

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Shared-Based Payment Accounting, ("ASU 2018-07") which supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payments arrangements related to the acquisition of goods and services from both employees and non-employees. The Company adopted ASU 2018-07 upon the formation of the Company on July 17, 2019. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant. Share compensation for shares granted to non-employees is determined as the fair value of the equity instruments issued. Compensation expense for non-employees is recognized in the same manner as if the Company has paid cash for the goods or services and therefore will be recognized immediately.

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 stock option awards and the Monte Carlo simulation model to value the Company's performance share awards. The performance share awards vest upon meeting certain market conditions and service conditions. The stock option awards generally vest pro-rata annually. Using these option-pricing models, the fair value of each stock option award and performance share award is estimated on the grant date. The fair value of the stock options and performance share awards is expensed on a straight-line basis over the vesting period. The expected volatility assumption used in both models is based on the volatility of the share price of comparable public companies. The expected life in used in both models is determined using the "simplified method." 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.

***(P) Deferred Offering Costs***

Costs directly related to the Company's IPO are deferred for expense recognition and instead capitalized and recorded on the accompanying balance sheets. These costs consist of legal fees, accounting fees, and other applicable professional services. These deferred offering costs will be reclassified to "additional paid in capital" upon the closing of the planned IPO. In the event that the Company's plans for an IPO are terminated, all deferred offering costs will be recognized within "general and administrative" and expensed in the same period on the Company's statements of operations and comprehensive loss. There were no deferred offering costs capitalized as of December 31, 2019. As of December 31, 2020 and June 30, 2021, \$1.1 million and \$2.5 million, respectively, of deferred offering costs are reported on the accompanying balance sheets within "prepaids expenses and other current assets."

***(Q) Ordinary Share Split***

On October 7, 2021, the Company's board of directors approved a 5.8478-for-1 forward stock split, which was approved by the Company's shareholders on October 14, 2021. Effective on October 14, 2021, the Company's issued and outstanding ordinary shares were impacted by the forward stock split. All share and per share data in the consolidated financial statements and notes thereto have been retrospectively revised to reflect the forward stock split. Ordinary shares underlying outstanding stock 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.

***(R) Other Recently Adopted Accounting Pronouncements***

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements of fair value measurements. The Company adopted ASU 2018-13 effective January 1, 2020, and it did not have a material impact on the Company's consolidated financial statements.

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 had no material impact to its financial statements.

### ***(S) Recently Issued Accounting Pronouncements Not Yet Adopted***

No other new accounting pronouncement issued or effective during the periods from July 17, 2019 (date of incorporation) to December 31, 2019, the year ended December 31, 2020, and the six-month period ended June 30, 2021 had or is expected to have a material impact on the Company's consolidated financial statements or disclosures.

## **3. Material Agreements**

### ***Exclusivity Agreement with BridgeBio Pharma LLC***

In October 2019 and in connection with the Series Seed Funding by Perceptive Advisors ("Perceptive"), the Company entered into an exclusivity agreement with BridgeBio Pharma LLC ("BridgeBio") pursuant to which BridgeBio received ordinary shares in the Company, valued at approximately \$8.5 million at the time of the transaction. The equity interest was issued in exchange for the grant of certain preemptive rights. Due to the nature and size of these transactions, the Company has identified both Perceptive and BridgeBio as related parties.

### ***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 amended September 2020, 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. 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 and the underlying assumptions are discussed in further detail in Note 9. 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 we sent QED the notice of the IPO. In the event QED chooses to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant QED is entitled to receive would be 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 and as of the date of the warrant conversion. This conversion feature is not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. 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 \$45.0 million upon achievement of specified development milestones, and sales milestone payments of up to \$87.5 million upon achievement of specified commercialization milestones, in addition to tiered royalties on net sales of licensed products at the greater of (a) percentage rates in the low- to mid-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"), 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 warrants 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 9. 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. In the event MyoKardia chooses to convert the Subsidiary Warrant into Parent Company Shares, the number of Parent Company Shares MyoKardia is entitled to receive would be 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 and as of the date we sent MyoKardia the notice of the IPO. In the event MyoKardia chooses to convert the Subsidiary Warrant into the Parent Company Warrant, the number of Parent Company Shares under the Parent Company Warrant MyoKardia is 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 and as of the date of the warrant conversion. This conversion feature is not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. 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 upon achievement of specified commercialization milestones, 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 June 30, 2021, the Company recorded the first development milestone of \$8.5 million for IND acceptance in the PRC as a liability within the accounts payable line item of the balance sheet.

### ***Pfizer Strategic Collaboration***

In November 2020, the Company entered into a strategic collaboration agreement (the "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 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 Agreement terminates. Under the Agreement, Pfizer and LianBio will form a joint collaboration committee to discuss potential third party in-license opportunities and development and commercialization of our products in Greater China. In the event the Company seeks 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 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 (RSV) in Mainland China, Macau, Hong Kong, and Singapore. Under the license agreement, ReViral received a nonrefundable upfront payment of \$14.0 million. Additionally, ReViral is entitled to receive payments from the Company totaling an aggregate of up to \$105.0 million upon the



achievement of specified development and commercial milestones, up to \$45.0 million and \$60.0 million, respectively, plus tiered royalties on net sales ranging from ten to the low-teens.

### ***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 warrants to purchase 125,000 ordinary shares in Lian Ophthalmology, a subsidiary of LianBio, valued at \$9.4 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 9. 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. The warrant agreement also provides Tarsus with the option to convert the warrants into ordinary shares or parent company warrants of the Company based on appreciation of the value in the Lian Ophthalmology since the inception of the Tarsus License Agreement. This conversion feature is not required to be bifurcated as it is clearly and closely related to the equity host instrument, pursuant to ASC 815. 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. As of June 30, 2021, the Company was notified that Tarsus had dosed the first patient in the Saturn-2 Clinical Trial and achievement of the primary endpoint of the Saturn-1 Clinical Trial. Accordingly, the Company recorded a liability within accounts payable for the \$20.0 million milestone in the accompanying balance sheet as of June 30, 2021.

### ***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 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. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2021	December 31, 2020	June 30, 2021 (unaudited)
Leasehold improvements	\$ —	\$ 693	\$ 673
Furniture and fixtures	—	7	7
Computer equipment and software	—	180	264
Construction in progress	—	18	23
	—	898	967
Accumulated depreciation	—	(76)	(208)
Property and equipment, net	\$ —	\$ 822	\$ 759

Total depreciation related to property and equipment was \$0.0 thousand, \$76.0 thousand, \$2.0 thousand and \$137.0 thousand for the period from July 17, 2019 (date of incorporation) to December 31, 2019, the year ended December 31, 2020, the six-month period ended June 30, 2020 (unaudited) and the six-month period ended June 30, 2021 (unaudited), respectively.

## 5. Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	December 31, 2021	December 31, 2020	June 30, 2021 (unaudited)
Advance payments to suppliers and rent deposit	\$ 47	\$ 1,070	\$ 555
Prepaid insurance	—	74	64
Deferred costs	—	970	2,652
VAT receivable	—	261	432
Other prepaid expenses	—	21	48
Total prepaid expenses and other current assets	\$ 47	\$ 2,396	\$ 3,751



## 6. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2021	December 31, 2020	June 30, 2021 (unaudited)
Employee compensation and related benefits	\$ —	\$ 236	\$ 2,284
Professional fees	288	683	3,408
Consulting and contracted research	—	49	3,463
Other	30	30	55
Total accrued expenses	<u>\$ 318</u>	<u>\$ 998</u>	<u>\$ 9,210</u>

## 7. 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 in Princeton, New Jersey, effective June 18, 2020 and for office space 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 (consistent with the 9th floor lease) with an option to renew for one additional period of 24 months.

The components of total lease costs were as follows:

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year ended December 31, 2020
Operating lease cost	\$ —	\$ 425
Short-term lease cost	16	132
Total lease cost	<u>\$ 16</u>	<u>\$ 557</u>

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

	December 31, 2019	December 31, 2020
Weighted-average remaining lease terms—operating leases (years)	2.30	3.28
Weighted-average discount rate—operating leases	10.55%	11.57%

Supplemental cash flow information related to leases was as follows:

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ —	\$ 274
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ 532	\$ 1,375

**Commitments**

As of December 31, 2020, future minimum lease payments, were as follows:

	<b>Operating Leases</b>
2021	\$ 681
2022	623
2023	659
2024	137
Total	\$ 2,100
Less imputed interest	(220)
Present value of lease liabilities	<u>\$ 1,880</u>

There are no material changes for the six months ended June 30, 2021 as compared to the year ended December 31, 2020.

**(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, 2020 and June 30, 2021, there have been no such matters identified. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within the range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. The Company is not currently party to any material legal proceedings.

**8. Stock-Based Compensation**

The Company has one active shareholder-approved share-based compensation plan (the "2019 Plan"), which was adopted in December 2019, and permits the granting of incentive stock options, nonqualified stock options, stock awards and certain other awards to its employees, members of its Board of Directors, and consultants.

The stated maximum availability of ordinary shares under the 2019 Plan is 11.7 million shares. Through June 30, 2021, there were awards issued for 11.7 million ordinary shares under this plan.

**Stock Option Awards**

Stock 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 stock option exercise price per share is the fair market value of the Company's ordinary shares on the date of the grant of the stock option. The stock options generally have a vesting period of four years.

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. There were no stock options issued or outstanding at any time during the period from July 17, 2019 (date of incorporation) to December 31, 2019.

During the six months ended June 30, 2020, the Company issued 2,999,920 ordinary shares to senior management at an exercise price of \$1.71.

## Table of Contents

During the six months ended June 30, 2021, the Company issued 5,758,787 ordinary shares to senior management at exercise prices ranging from \$6.49 to \$6.90.

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:

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Expected Dividend Yield	—	0.00%	0.00%	0.00%
Expected Volatility	—	60.00%—75.00%	75.00%	60.00%
Expected Term (years)	—	5.39—6.25	6.00	0.50—6.25
Risk Free Interest Rate	—	0.41%—1.73%	1.73%	0.09%—1.22%
Exercise Price	—	\$ 1.71—\$6.49	\$ 1.71	\$ 6.49—\$6.90
Weighted Average grant date fair value per stock option	—	\$ 2.67	\$ 1.13	\$ 3.51

The Company anticipates no dividend payouts. Volatility was determined based on that of comparable public companies, given the lack of any definitive history regarding the Company's ordinary shares. The expected term of the awards were calculated using the simplified method. The risk-free interest rates are derived from the U.S. Treasury yield curve in effect on the date of grant for instruments with a remaining term similar to the expected term of the options.

A summary of stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Terms in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2020	—	—	—	—
Granted	8,374,034	\$ 4.78	9.62	—
Exercised	—	—	—	—
Expired or forfeited	—	—	—	—
Outstanding at December 31, 2020	8,374,034	\$ 4.78	9.62	\$ 14,323
Vested or expected to vest at December 31, 2020	2,666,596	\$ 2.91	9.25	\$ 9,549
Exercisable at December 31, 2020	2,666,596	\$ 2.91	9.25	\$ 9,549
Outstanding at December 31, 2020	8,374,034	\$ 4.78	9.62	\$ 14,323
Granted (unaudited)	3,820,173	\$ 6.84	—	—
Exercised (unaudited)	—	—	—	—
Expired or forfeited (unaudited)	2,461,920	\$ 5.84	—	—
Outstanding at June 30, 2021 (unaudited)	9,732,287	\$ 5.32	9.35	\$ 15,415
Vested or expected to vest at June 30, 2021 (unaudited)	3,422,908	\$ 3.70	8.94	\$ 10,965
Exercisable at June 30, 2021 (unaudited)	3,422,908	\$ 3.70	8.94	\$ 10,965

As of December 31, 2020, \$17.2 million of total unrecognized expense related to non-vested stock option is expected to be recognized over a weighted average period of 3.41 years from the date of grant. Options granted to senior management vest in annual increments, over two years; options granted to employees and members of the Board of Directors vest in equal annual increments over four years. Stock options vest based on continued service only and are not subject to performance-based criteria.

As of June 30, 2021, \$19.8 million of total unrecognized expense relates to non-vested stock option is expected to be recognized over a weighted average period of 3.56 years from the date of

grant. Options granted to senior management and employees vest in equal annual increments over four years.

### Performance Share Awards

In May 2021, we 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 (unaudited)	—	—	—	—
Granted (unaudited)	1,938,615	\$ 6.90	9.88	—
Vested (unaudited)	—	—	—	—
Exercised (unaudited)	—	—	—	—
Expired or forfeited (unaudited)	—	—	—	—
Outstanding at June 31, 2021 (unaudited)	1,938,615	\$ 6.90	9.88	—
Non-vested share units as of June 30, 2021 (unaudited)	1,938,615	\$ 6.90	9.88	—

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 share units along with the weighted-average grant date fair value for awards granted in the periods presented are as follows:

Expected volatility	47.07%
	80.64%
Dividend Yield	0%
Risk-free interest rate	0.81%
	—1.63%
Expected term, in years	4.87
	10.00
Weighted average grant date fair value per share	\$ 4.72

As of June 30, 2021, there was \$8.9 million of total unrecognized of compensation cost related to the performance share units.

## 9. Equity

### Ordinary Shares

Prior to October 2019, 100% of the 2,392,282 outstanding shares of the Company, on a post-split basis, were owned by Perceptive Life Sciences Master Fund Ltd. The outstanding shares were voting ordinary shares with par value and initial purchase price of \$0.000017100448 per share.

On October 16, 2019, the Company entered into an exclusivity agreement with BridgeBio. As payment in kind, BridgeBio was issued 584,780 ordinary shares. Simultaneously, the Company entered into a series seed preferred share subscription agreement with each of Perceptive Life Sciences Master Fund, LTD, LEV LB Holdings, LP and Perceptive Xontogeny Venture Fund, LP. BridgeBio was issued voting ordinary shares of 4,418,012 with no additional cash consideration to avoid dilution of its ownership.

As of December 31, 2020, the Company was authorized to issue up to 2,923,900,005 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.

As of June 30, 2021, the Company was authorized to issue up to 2,923,900,005 shares, of which 2,859,432,812 were authorized as ordinary shares with a par value of \$0.000017100448, 5,500,000 were authorized Series Seed Preferred Shares with par value of \$0.0001, and 5,524,178 were authorized Series A Preferred Shares with a par value of \$0.0001.

### Preferred Shares

The authorized, issued and outstanding shares, issue price, conversion price, liquidation preference and carrying value of the Company's redeemable convertible preferred shares as of the dates indicated were as follows (in thousands, except for share and per share data):

	<u>December 31, 2019</u>					
	<u>Shares Authorized</u>	<u>Shares Issued and Outstanding</u>	<u>Issue Price</u>	<u>Per Share Conversion Price</u>	<u>Liquidation Preference</u>	<u>Carrying Value</u>
Series Seed	5,500,000	5,500,000	\$ 10.00	\$ 1.72	\$ 55,000	\$ 55,000
					<u>\$ 55,000</u>	<u>\$ 55,000</u>
	<u>December 31, 2020</u>					
	<u>Shares Authorized</u>	<u>Shares Issued and Outstanding</u>	<u>Issue Price</u>	<u>Per Share Conversion Price</u>	<u>Liquidation Preference</u>	<u>Carrying Value</u>
Series Seed	5,500,000	5,500,000	\$10.00	\$ 1.72	\$ 55,000	\$ 55,000
Series A	5,471,231	5,471,231	\$56.66	\$ 9.69	294,789	294,789
					<u>\$ 349,789</u>	<u>\$ 349,789</u>
	<u>June 30, 2021 (unaudited)</u>					
	<u>Shares Authorized</u>	<u>Shares Issued and Outstanding</u>	<u>Issue Price</u>	<u>Per Share Conversion Price</u>	<u>Liquidation Preference</u>	<u>Carrying Value</u>
Series Seed	5,500,000	5,500,000	\$10.00	\$ 1.72	\$ 55,000	\$ 55,000
Series A	5,524,178	5,524,178	\$56.66	\$ 9.69	297,729	297,729
					<u>\$ 352,729</u>	<u>\$ 352,729</u>

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 stock 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, 2020 and June 30, 2021, no dividends have been declared or paid.

### ***Liquidation Preference***

In the event of any liquidation, dissolution, or winding up of the Company, the holders of the then outstanding redeemable convertible preferred shares will have distribution preference over the ordinary shareholders in the amount of 100% of their original purchase price plus accrued but unpaid dividends. If the assets and funds to be distributed among the holders of redeemable convertible preferred shares are insufficient to permit the full payment to which the holders are entitled, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of redeemable convertible preferred shares in proportion to the preferential amount each such holder is otherwise entitled to receive before distribution is made to the ordinary shareholders.

### ***Conversion***

The Series Seed Preferred Shares are convertible, at the option of the holder, into such number of fully paid shares of the Company's ordinary shares as is determined by dividing the original issuance price by the conversion price in effect at the time of conversion. Based on the conversion ratios in effect as of December 31, 2020 and June 30, 2021, after giving effect to the 5.8478-for-1 stock split effected October 14, 2021, the Series Seed Preferred Shares will convert into an aggregate of 32,162,900 of the Company's ordinary shares.

Based on the conversion ratios in effect as of December 31, 2020 and June 30, 2021, after giving effect to the 5.8478-for-1 stock split effected October 14, 2021, the Series A Preferred Shares will convert into an aggregate of 32,304,277 of the Company's ordinary shares.

### ***Redemption***

No redeemable convertible preferred shares are unilaterally redeemable by either the shareholders or the Company.

### ***Warrants***

In October 2019, the Company issued 100,000 warrants with performance-based vesting conditions. The warrants are equity classified and were issued by Lian Oncology, a wholly owned

## [Table of Contents](#)

subsidiary of the Company, as partial consideration to QED for the QED License Agreement. The warrants, if exercised, represent 10% of the fully diluted equity of Lian Oncology. The warrants are accounted for under ASC 718 Compensation-Stock Compensation and are fair valued on the grant date using the Black-Scholes Model, using the following assumptions:

Current Price of the Underlying Share	\$ 10.00
Exercise Price	\$ 0.0001
Expected Term	10 years
Risk Free Interest Rate	1.75%
Dividend Yield	0%
Expected Volatility	75%

In August 2020, the Company issued 170,000 warrants. The warrants are equity classified and were issued by Lian Cardiovascular, a wholly owned subsidiary of the Company, as partial consideration to MyoKardia for the MyoKardia License Agreement. The warrants, if exercised, represent 17% of the fully diluted equity of Lian Cardiovascular. The 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	\$ 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 125,000 warrants. The 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 warrants, if exercised, represent 12.5% of the fully diluted equity of Lian Ophthalmology. The 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%

### ***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 the warrants are unexercised as of December 31, 2019, December 31, 2020, and June 30, 2021, 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

## [Table of Contents](#)

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 period from July 17, 2019 (date of incorporation) to December 31, 2019, and the year ended December 31, 2020, and six months ended June 30, 2020 and 2021 diluted and basic net loss per ordinary share were identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
<b>Numerator</b>				
Net Loss attributable to ordinary shareholders	\$ (24,331)	\$ (139,604)	\$ (6,628)	\$ (161,993)
<b>Denominator</b>				
Weighted-average shares – basic and diluted	4,872,447	12,051,433	10,265,811	20,477,337
<b>Net loss per ordinary share – basic and diluted</b>	\$ (4.99)	\$ (11.58)	\$ (0.65)	\$ (7.91)

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.

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Redeemable Convertible Preferred Shares	5,500,000	10,971,231	5,500,000	11,024,178
Convertible Notes	—	10,211,527	10,211,527	—
Employee Stock Options	—	8,374,034	2,999,920	11,670,902
Warrants in Lian Oncology issued to QED	100,000	100,000	100,000	100,000
Warrants in Lian Cardiovascular issued to MyoKardia	—	170,000	—	170,000
Warrants in Lian Ophthalmology issued to Tarsus	—	—	—	125,000

## 10. 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.

## 11. Income Taxes

The Company generally records its interim tax provision based upon a projection of the Company's estimated annual effective tax rate ("EAETR"). This EAETR is applied to the year-to-date consolidated pre-tax income to determine the interim provisions for income taxes before discrete items. The effective tax rate ("ETR") each period is impacted by a number of factors, including the relative mix of domestic and international earnings, adjustments to the valuation allowances, and discrete items. The currently forecasted ETR may vary from the actual year-end due to the changes in these factors.

The Company's global ETR for the six months ended June 30, 2021 and 2020 was 1.2% and 0.0% respectively. The current year increase in the ETR was principally due to the effect of cash taxes associated with certain income that cannot be deferred for US income tax purposes.

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

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year Ended December 31, 2020
Domestic	\$ (24,333)	\$ (138,050)
Foreign	6	(1,550)
Total	<u>\$ (24,327)</u>	<u>\$ (139,600)</u>

The components of income tax expense (benefit) are as follows:

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year ended December 31, 2020
Federal	\$ —	\$ —
State and local	2	4
Foreign	2	—
Total current tax expense	<u>\$ 4</u>	<u>\$ 4</u>

[Table of Contents](#)

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year ended December 31, 2020
Federal	\$ —	\$ —
State and local	—	—
Foreign	—	—
Total deferred tax expense	<u>\$ —</u>	<u>\$ —</u>

	Period from July 17, 2019 (Date of Incorporation) to December 31, 2019	Year ended December 31, 2020
Total Provision	<u>\$ 4</u>	<u>\$ 4</u>

The effective income tax rate is 0.00% and 0.00% for the period from July 17, 2019 (date of incorporation) to December 31, 2019 and the year ended December 31, 2020, respectively. The primary reconciling items between the statutory income tax rate of 21% and the effective income tax rate are the full valuation allowance recorded against its net deferred tax assets ("DTA").

The tax effects of temporary differences that give rise to deferred tax assets and liabilities are summarized as follows:

	December 31, 2019	December 31, 2020
Deferred tax assets:		
Accrued expenses	\$ —	\$ 475
Net operating loss carryforwards	706	6,328
Share based compensation	—	1,327
Right of use liability	—	426
Intangible Assets	5,652	34,900
Total Gross Deferred Tax Asset	6,358	43,456
Less: Valuation Allowance	(6,358)	(43,062)
Total Deferred Tax Asset	<u>\$ —</u>	<u>\$ 394</u>
Deferred tax liabilities:		
Property and equipment	\$ —	\$ (11)
Right of use asset	—	(383)
Total gross deferred tax liabilities	—	(394)
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

The net change in the total valuation allowance resulted in an increase of \$36.7 million in 2020. 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 DTA's 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, 2020. 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 (\$43.1) million at December 31, 2020.

At December 31, 2020, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$22.7 million which do not expire. The Company had net operating loss carryforwards for state income tax purposes of approximately \$1.2 million, which will expire if unused in years 2039 through 2040. The Company had foreign net operating loss carryforwards of \$1.4 million which will 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, 2019 and 2020. The Company has not identified nor recorded any reserves for uncertain tax positions as of December 31, 2019 and December 31, 2020. As of December 31, 2020, 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).

On March 27, 2020 the Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted and implemented certain tax legislation, among which temporarily increases the interest expense limitation pursuant to Section 163(j), allows for acceleration of refunds of alternative minimum tax (AMT) credits, and retroactively clarified the immediate recovery of qualified improvement property costs under 100% expensing rather than 39-year recovery period for assets placed in service after November 27, 2017. The provisions of the CARES Act did not impact the Company.

## **12. Subsequent Events**

### ***Lyra License***

In May 2021, the Company entered into a license and collaboration agreement with Lyra Therapeutics, Inc. ("Lyra"). Pursuant to the license agreement, Lyra granted to the Company an exclusive 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 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 the net sales.

### ***Landos License***

In May 2021, the Company entered into a license and collaboration agreement with Landos Biopharma, Inc. ("Landos"). Pursuant to the license agreement, Landos granted to the Company an exclusive license 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, BT-11 and NX-13, in the licensed territory of 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.

### ***Tarsus License***

In March 2021, the Company entered into a development and license agreement with Tarsus Pharmaceuticals, Inc. ("Tarsus"). Pursuant to the license agreement, Tarsus granted to the Company 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. Under the license agreement, Tarsus received a nonrefundable upfront payment of \$15.0 million and a subsequent payment of \$10.0 million, and was granted warrants to purchase ordinary shares in Lian Ophthalmology, a subsidiary of LianBio. The warrants were issued in three tranches with the aggregate number of shares across all tranches equaling a certain minority percentage 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. 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 ranging from the low-to high-teens on net sales.

### ***Nanobiotix License***

In May 2021, the Company entered into a license, development and commercialization agreement with Nanobiotix S.A. ("Nanobiotix"). Pursuant to the license agreement, Nanobiotix granted to the Company an exclusive license under certain patents and know-how of Nanobiotix 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 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.

### ***ReViral License***

In March 2021, the Company entered into a co-development and license agreement with ReViral Ltd. ("ReViral"). Pursuant to the license agreement, ReViral granted to the Company an exclusive license under certain patents and know-how of ReViral to develop, commercialize and otherwise exploit ReViral's proprietary compound, sisunatovir, in the licensed territory of 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 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 at percentage rates ranging from ten to the low-teens on net sales.

### ***Share Split***

On October 7, 2021, the Company's board of directors approved a 5.8478-for-1 forward stock split, which was approved by the Company's shareholders on October 14, 2021. Effective on October 14, 2021, the Company's issued and outstanding ordinary shares were impacted by the forward stock split. All share and per share data in the consolidated financial statements and notes thereto have been retroactively revised to reflect the forward stock split. Ordinary shares underlying outstanding stock 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.

### **13. Subsequent Events (Unaudited)**

Subsequent events have been evaluated for recognition and measurement purposes through October 20, 2021.

**20,312,500 American Depositary Shares  
Representing 20,312,500 Ordinary Shares**

**LianBio**



**Goldman Sachs & Co. LLC**

**Jefferies**

**BofA Securities**

**Raymond James**

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**Prospectus**

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, 2021

Through and including , 2021 (25 days after the commencement of this offering), all dealers that effect transactions in our Ordinary Shares or ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

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**PART II INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the expenses payable by the registrant in connection with the issuance and distribution of the securities being registered hereby (other than underwriting discounts and commissions). All such expenses are estimates, except for the Securities and Exchange Commission (the "SEC") registration fee, the Financial Industry Regulatory Authority ("FINRA") filing fee and Nasdaq Global Market listing fee.

SEC registration fee	\$ 36,813
FINRA filing fee	60,067
Nasdaq Global Market listing fee	295,000
Printing fees and expenses	507,000
Legal fees and expenses	3,600,000
Accounting fees and expenses	750,000
Miscellaneous expenses	201,120
Total	<u>\$5,450,000</u>

**Item 14. Indemnification of Directors and Officers.**

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The post-offering amended and restated memorandum and articles of association that will become effective immediately upon the completion of this offering provide that we shall indemnify our directors and officers (each an indemnified person) against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such person's own willful neglect or default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

We have entered into indemnification agreements with each of our directors and executive officers, pursuant to which we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer. In addition, we have entered into an indemnification agreement with Perceptive, certain of Perceptive's affiliates, and Konstantin Poukalov, in his role as Executive Chairman of our board of directors and as a Managing Director at Perceptive. The indemnification agreement provides that, among other things, Mr. Poukalov, Perceptive and its affiliates party to the agreement will be entitled to indemnification by us for claims related to actions taken on behalf of the Company in their capacities as agents.

The underwriting agreement, the form of which is filed as Exhibit 1.1 to this registration statement, will also provide for indemnification by the underwriters of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### **Item 15. Recent Sales of Unregistered Securities.**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. We believe that 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.

1. In October 2019, we issued 5,500,000 Series Seed Preferred Shares in a private placement transaction.
2. In October 2019, we issued 10,265,811 Ordinary Shares in a private placement transaction.
3. In October 2019, we issued three warrants exercisable for 100,000 ordinary shares of Lian Oncology, one of our subsidiaries, in a private placement transaction. In October 2021, these warrants were converted into 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 warrants exercisable for 100,000 ordinary shares of Lian Oncology were terminated.
4. In August 2020, we issued one warrant exercisable for 170,000 ordinary shares of Lian Cardiovascular, one of our subsidiaries, in a private placement transaction.
5. In October 2020, we issued 4,765,266 Series A Preferred Shares in the Series A Financing, a private placement transaction.
6. In October 2020, we issued 10,211,526 Ordinary Shares as a result of a conversion of convertible notes in a private placement transaction.
7. In December 2020, we issued 705,965 Series A Preferred Shares in the Series A Financing, a private placement transaction.
8. In March 2021, we issued and sold an additional 52,947 Series A Preferred Shares to AEG 2021 TRUST, whose trustee and beneficiary is Tassos Gianakokos, a director of the Company.
9. 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, pursuant to an option agreement by and between LianBio, Lian Ophthalmology and the holder, we issued 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 and, concurrently with such issuances, the warrants exercisable for 125,000 ordinary shares of Lian Ophthalmology were terminated.
10. In September 2021, Bing Li exercised certain of his vested options in accordance with their terms for 1,309,907 of the Company's Ordinary Shares.



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[Table of Contents](#)

In addition to the above, since July 17, 2019 (date of incorporation), we have granted stock options to purchase (i) an aggregate of 2,999,920 Ordinary Shares, each at an exercise price of \$1.71 per share, (ii) an aggregate of 5,374,114 Ordinary Shares, each at an exercise price of \$6.49 per share, (iii) an aggregate of 87,717 Ordinary Shares, each at an exercise price of \$6.85 per share, and (iv) an aggregate of 5,109,682 Ordinary Shares, each at an exercise price of \$6.90 per share, to our employees and directors. These grants were made pursuant to written compensatory plans or arrangements with our employees and directors in reliance upon the exemption provided by Rule 701 promulgated under the Securities Act 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.

**Item 16. Exhibits and Financial Statement Schedules.**

**(a) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
1.1 <sup>^</sup>	<a href="#">Form of Underwriting Agreement.</a>
3.1 <sup>^</sup>	<a href="#">Fourth Amended and Restated Memorandum and Articles of Association of LianBio, as currently in effect.</a>
3.2 <sup>^</sup>	<a href="#">Form of Fifth Amended and Restated Memorandum and Articles of Association of LianBio, to be effective upon consummation of this offering.</a>
4.1 <sup>^</sup>	<a href="#">Form of Deposit Agreement.</a>
4.2 <sup>^</sup>	<a href="#">Form of American Depositary Receipt (included in Exhibit 4.1).</a>
4.3 <sup>^</sup>	<a href="#">Second Amended and Restated Shareholders Agreement dated October 28, 2020, by and among LianBio and the investors party thereto.</a>
4.4 <sup>^</sup>	<a href="#">Specimen Certificate evidencing the Ordinary Shares.</a>
4.5 <sup>^</sup>	<a href="#">Information Rights Letter of BridgeBio Pharma LLC, dated October 16, 2019, by and between the Company and BridgeBio Pharma LLC.</a>
4.6 <sup>^</sup>	<a href="#">Amended and Restated Option Agreement, dated as of August 10, 2020, by and among LianBio and MyoKardia, Inc. and QED Therapeutics, Inc.</a>
4.7 <sup>^</sup>	<a href="#">Equity Holders Agreement, dated August 10, 2020, by and among LianBio, Lian Cardiovascular and MyoKardia, Inc.</a>
4.8 <sup>^</sup>	<a href="#">Form of Warrant to Purchase Ordinary Shares, dated October 16, 2019, issued by Lian Oncology.</a>
4.9 <sup>^</sup>	<a href="#">Lian Cardiovascular Warrant to Purchase Ordinary Shares, dated August 10, 2020, issued by Lian Cardiovascular.</a>
4.10 <sup>^</sup>	<a href="#">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.</a>
4.11 <sup>^</sup>	<a href="#">Form of Warrant to Purchase Ordinary Shares, dated October 18, 2021, issued by LianBio.</a>
4.12 <sup>^</sup>	<a href="#">Option Agreement, dated October 18, 2021, by and among LianBio, LianBio Ophthalmology and Tarsus Pharmaceuticals, Inc.</a>
4.13 <sup>^</sup>	<a href="#">Joinder Agreements to Second Amended and Restated Shareholders Agreement.</a>
4.14 <sup>^</sup>	<a href="#">Warrant to Purchase Ordinary Shares, dated October 18, 2021 issued by LianBio.</a>
5.1 <sup>^</sup>	<a href="#">Opinion of Travers Thorp Alberga regarding the validity of the Ordinary Shares being registered.</a>
8.1 <sup>^</sup>	<a href="#">Opinion of Travers Thorp Alberga regarding certain Cayman Islands tax matters (included in Exhibit 5.1).</a>
8.2 <sup>^</sup>	<a href="#">Opinion of Zhong Lun Law Firm regarding certain People's Republic of China tax matters (included in Exhibit 99.1).</a>
10.1 <sup>^†</sup>	<a href="#">Exclusive License Agreement, dated August 10, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc.</a>

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
10.2 <sup>†</sup>	<a href="#"><u>Amendment to the Exclusive License Agreement, dated October 8, 2020, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc.</u></a>
10.3 <sup>†</sup>	<a href="#"><u>Second Amendment to the Exclusive License Agreement, dated January 4, 2021, by and among LianBio, LianBio Licensing LLC and MyoKardia, Inc.</u></a>
10.4 <sup>†</sup>	<a href="#"><u>Exclusivity Agreement, dated October 16, 2019, by and between LianBio and BridgeBio Pharma LLC.</u></a>
10.5 <sup>†</sup>	<a href="#"><u>Exclusive License Agreement, dated October 16, 2019, by and between LianBio and QED Therapeutics, Inc.</u></a>
10.6 <sup>†</sup>	<a href="#"><u>Amendment to the Exclusive License Agreement, dated September 26, 2020, by and between LianBio and QED Therapeutics, Inc.</u></a>
10.7 <sup>†</sup>	<a href="#"><u>Novation Agreement, dated October 11, 2020, by and among LianBio, LianBio Licensing LLC and QED Therapeutics, Inc.</u></a>
10.8 <sup>†</sup>	<a href="#"><u>Exclusive License Agreement, dated August 9, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc.</u></a>
10.9 <sup>†</sup>	<a href="#"><u>First Amendment to the Exclusive License Agreement, dated September 23, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc.</u></a>
10.10 <sup>†</sup>	<a href="#"><u>Second Amendment to the Exclusive License Agreement, dated September 28, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc.</u></a>
10.11 <sup>†</sup>	<a href="#"><u>Third Amendment to the Exclusive License Agreement, dated December 17, 2020, by and among LianBio, LianBio Licensing LLC and Navire Pharma, Inc.</u></a>
10.12 <sup>†</sup>	<a href="#"><u>Strategic Collaboration Agreement, dated November 17, 2020, by and between LianBio and Pfizer Inc.</u></a>
10.13 <sup>†</sup>	<a href="#"><u>Development and License Agreement, dated March 26, 2021, by and between LianBio Ophthalmology Limited and Tarsus Pharmaceuticals, Inc.</u></a>
10.14 <sup>†</sup>	<a href="#"><u>License, Development and Commercialization Agreement, dated May 11, 2021, by and between Nanobiotix S.A. and LianBio Oncology Limited.</u></a>
10.15 <sup>†</sup>	<a href="#"><u>License and Collaboration Agreement, dated May 14, 2021, by and between LianBio Respiratory Limited and Landos BioPharma, Inc.</u></a>
10.16 <sup>†</sup>	<a href="#"><u>License and Collaboration Agreement, dated May 31, 2021, by and among LianBio Inflammatory Limited, LianBio and Lyra Therapeutics, Inc.</u></a>
10.17 <sup>†</sup>	<a href="#"><u>Co-Development and License Agreement, dated March 1, 2021, by and between LianBio Respiratory Limited and ReViral Ltd.</u></a>
10.18 <sup>^</sup>	<a href="#"><u>Lease and Lease Agreement, dated June 18, 2020, by and between LianBio dba Lian Pharma and Carnegie 103 Associates, LLC.</u></a>
10.19 <sup>^</sup>	<a href="#"><u>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.</u></a>
10.20 <sup>^</sup>	<a href="#"><u>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.</u></a>

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
10.21^	<a href="#"><u>Form of Indemnification Agreement.</u></a>
10.22^	<a href="#"><u>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.</u></a>
10.23^	<a href="#"><u>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.</u></a>
10.24^	<a href="#"><u>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.</u></a>
10.25^	<a href="#"><u>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.</u></a>
10.26^	<a href="#"><u>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.</u></a>
10.27^	<a href="#"><u>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.</u></a>
10.28^	<a href="#"><u>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.</u></a>
10.29^	<a href="#"><u>Amendment No. 1 to Lease and Lease Agreement, dated as of July 1, 2021, between Carnegie 103 Associates, LLC and LianBio, LLC.</u></a>
10.30^#	<a href="#"><u>Executive Employment Agreement, dated as of September 26, 2019, by and between LianBio and Bing Li.</u></a>
10.31^#	<a href="#"><u>Separation Agreement, dated as of February 24, 2021, by and between LianBio and Bing Li.</u></a>
10.32^#	<a href="#"><u>Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Debra Yu, M.D.</u></a>
10.33^#	<a href="#"><u>Amended and Restated Executive Employment Agreement, dated as of September 14, 2021, by and among LianBio, LianBio, LLC and Brianne Jahn.</u></a>
10.34^#	<a href="#"><u>LianBio 2019 Equity Incentive Plan.</u></a>
10.35^#	<a href="#"><u>LianBio 2021 Equity Incentive Plan, to be in effect upon completion of this offering.</u></a>
10.36^#	<a href="#"><u>Form of Non-Statutory Share Option Agreement (Non-Employee Directors).</u></a>
10.37^#	<a href="#"><u>Form of Non-Statutory Share Option Agreement (Employees).</u></a>

## Table of Contents

Exhibit No.	Description
10.38^#	<a href="#">Form of Restricted Share Unit Agreement (Employees).</a>
10.39^#	<a href="#">LianBio 2021 Cash Incentive Plan, to be in effect upon completion of this offering.</a>
10.40^#	<a href="#">LianBio Non-Employee Director Compensation Policy, to be in effect upon completion of this offering.</a>
21.1^	<a href="#">Subsidiaries of the Registrant.</a>
23.1	<a href="#">Consent of KPMG LLP.</a>
23.2^	<a href="#">Consent of Travers Thorp Alberga (included in Exhibit 5.1).</a>
24.1^	<a href="#">Powers of Attorney.</a>
24.2^	<a href="#">Powers of attorney of Susan Silbermann and Jesse Wu.</a>
99.1^	<a href="#">Opinion of Zhong Lun Law Firm regarding certain People's Republic of China law matters.</a>

^ Previously filed.  
# Management contract or compensatory plan or arrangement.  
† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks [\*\*\*] as the identified confidential portions (i) are not material and (ii) the Registrant customarily and actually treats that information as private or confidential.

### **(b) Financial Statement Schedules**

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

### **Item 17. Undertakings.**

The undersigned Registrant hereby undertakes:

(1) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(4) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for

indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Princeton, New Jersey, on October 28, 2021.

LianBio

By: /s/ Yizhe Wang  
Name: Yizhe Wang, Ph.D.  
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following person in the capacities indicated on October 28, 2021.

Signature	Capacity
<u>/s/ Yizhe Wang</u> Yizhe Wang, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Yi Larson</u> Yi Larson	Chief Financial Officer (Principal Financial and Accounting Officer)
<u>*</u> Konstantin Poukalov	Chairman of the Board
<u>*</u> Adam Stone	Director
<u>*</u> Neil Kumar	Director
<u>*</u> Tassos Gianakokos	Director
<u>*</u> Susan Silbermann	Director
<u>*</u> Jesse Wu	Director

\*By: /s/ Yizhe Wang  
Yizhe Wang, Ph.D.  
Attorney-in-Fact

**AUTHORIZED REPRESENTATIVE**

Pursuant to the requirements of Section 6(a) of the Securities Act of 1933, the undersigned has signed this registration statement, solely in its capacity as the duly authorized representative of LianBio, in Princeton, New Jersey, on October 28, 2021.

By: /s/ Yizhe Wang  
Name: Yizhe Wang, Ph.D.  
Title: Authorized Representative of LianBio



**Consent of Independent Registered Public Accounting Firm**

We consent to the use of our report dated June 24, 2021, except as to Note 2(Q), which is as of October 20, 2021, with respect to the consolidated financial statements of LianBio included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP  
New York, New York  
October 28, 2021