Filed Pursuant to Rule 424(b)(4)
Registration No. 333-264134

6,000,000 American Depositary Shares

Belite Bio, Inc

Representing 6,000,000 Ordinary Shares

We are selling American depositary shares, or ADSs. Each ADS represents one ordinary share, par value US$0.0001 per share.

This is an initial public offering in the United States of Belite Bio, Inc, a Cayman Islands exempted holding company with headquarters in San Diego, California and operations in the United States and Australia.

Prior to this offering, there has been no public market for our ordinary shares or ADSs. The ADSs have been approved for listing on the Nasdaq Capital Market under the symbol "BLTE."

Throughout this prospectus, unless the context indicates otherwise, references to "Belite" refer to Belite Bio, Inc, a holding company, together as a group with our subsidiaries, including our operating subsidiaries. Belite Bio, LLC and RBP4 Pty Ltd, our U.S. and Australia-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 operating subsidiaries in the United States and Australia. In the normal course of our business, Belite would evaluate the financial condition and capital needs of our subsidiaries periodically and then provide funding for their operations via equity investments and intercompany loans. As of the date of this prospectus, we have provided US$10.06 million to our subsidiaries via capital contribution, including US$0.5 million intercompany loans that have been repaid by the subsidiary via the issuance of ordinary shares, among which we have provided US$60,000 to our Hong Kong subsidiary via capital contribution which further invested US$50,000 to our PRC subsidiary via capital contribution. None of our subsidiaries have declared or paid any dividends or distributions on equity to their respective holding companies as of the date of this prospectus. We have not relied, and do not expect to rely, on dividends or other distributions on equity from any of our subsidiaries for our cash requirements. We have no plans to declare cash dividends in the near term, but as a holding company, we may depend on receipt of funds from one or more of our subsidiaries if we determine to pay cash dividends to holders of our ordinary shares in the future. While our PRC subsidiary has no operations and generates no revenue as of the date of this prospectus, should it generate revenue in the future, restrictions on currency exchanges in China may limit our ability to freely convert such Renminbi to fund any future business activities outside China or other payments in U.S. dollars, and capital control measures imposed by the Chinese government may limit our ability to use capital from our PRC subsidiary for business purposes outside of China. See "Prospectus Summary — Cash Transfers and Dividend Distribution" for a more detailed description.

All of our operations are outside of PRC as of the date of this prospectus although we have established a subsidiary in each of Hong Kong and China. We do not expect the listing of our ADSs to be materially affected by recent statements by the Chinese government indicating an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, including, but not limited to, the cybersecurity review and other regulatory reviews of overseas listing through an offshore holding company. However, due to the extraterritorial reach (the so-called "long arm provisions") under the current PRC laws and regulations, there remains regulatory uncertainty with respect to the implementation and interpretation of laws in China.

In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future (see "Business" beginning on page 111 for our current plans for future clinical trials), there may be certain legal and operational risks associated with having certain 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 may significantly limit or completely hinder our ability to offer or continue to offer our ADSs to investors, and may cause the value of our ADSs to significantly decline or become worthless. For more information on these risks and other risks you should consider before buying our ADSs, see "Risk Factors" beginning on page 15.

Furthermore, as more stringent criteria, including the Holding Foreign Companies Accountable Act, or the HFCAA, have been imposed by the SEC and the Public Company Accounting Oversight Board, or the PCAOB, recently, our ADSs may be prohibited from trading in the United States if our auditor cannot be fully inspected. Our auditor, Friedman LLP, the independent registered public accounting firm that issued the audit report included in this prospectus, is a firm registered with the PCAOB. Friedman LLP is headquartered in Manhattan, New York and has been inspected by the PCAOB on a regular basis. Therefore, we believe that, as of the date of this prospectus, our auditor is not subject to the determinations announced by the PCAOB on December 16, 2021 relating to the PCAOB's inability to inspect or investigate completely registered public accounting firms headquartered in mainland China of the PRC or Hong Kong because of a position taken by one or more authorities in the PRC or Hong Kong. For more information on these risks and other risks you should consider before buying our ADSs, see "Risk Factors " beginning on page 17. We cannot assure you whether Nasdaq or other regulatory authorities will apply additional or more stringent criteria to us. Such uncertainty could cause the market price of our ADSs to be materially and adversely affected.

Upon the completion of this offering, Lin Bioscience International Ltd., our principal shareholder, will hold more than 50% of the shareholder voting power of our outstanding share capital, as further described under "Principal Shareholders" in this prospectus. As a result, our principal shareholder could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, strategic collaborations or other business combination transactions. As a result, we are a "controlled company" as defined under the Nasdaq Stock Market Rules. For so long as we remain a controlled company as defined under that rule, we are exempt from, and our shareholders generally are not provided with the benefits of, some of the Nasdaq Stock Market corporate governance requirements.

We are an "emerging growth company" and a "foreign private issuer" under applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements.

Lin Bioscience International Ltd., our principal shareholder, has purchased US$15.0 million of ADSs in this offering, which represents no more than 50% of the total ADSs in this offering such that we still meet the un-affiliated float listing criteria of the Nasdaq Capital Market.

Investing in the ADSs involves risks. See "Risk Factors" beginning on page 17 for factors you should consider before buying the ADSs.

PRICE US$6.00 PER ADS

Neither the United States Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per ADS	Total
Initial public offering price	US$6.00	US$36,000,000
Underwriting discounts and commissions[(1)]	US$0.45	US$ 2,700,000
Proceeds, before expenses, to us	US$5.55	US$33,300,000

(1) See "Underwriting" for additional information regarding compensation payable by us to the underwriters.

In addition to the underwriting discounts and commissions referred to in the table above, we have agreed to issue, upon closing of this offering, warrants to the representative of the underwriters to purchase 2.5% of the total number of ADSs sold in this offering at a per ADS price equal to $7.50 (the "Representative's Warrants"). The registration statement of which this prospectus is a part also covers the Representative's Warrants and the ADSs issuable upon the exercise thereof. See section entitled "Underwriting" on page 211 for more information.

We have granted to the underwriters an option, for a period of 30 days after the date of this prospectus, to purchase up to an additional 900,000 ADSs from us at the public offering price per ADS, less underwriting discounts and commissions.

The underwriters expect to deliver the ADSs to purchasers on or about May 3, 2022.

Sole Book-Running Manager

The Benchmark Company

The date of this prospectus is April 29, 2022.

TABLE OF CONTENTS

Until May 24, 2022 (the 25th day after the date of this prospectus), all dealers that effect transactions in these ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus or in any free writing prospectus that we authorize to be distributed to you. We and the underwriters have not authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you, and neither we, nor the underwriters, take responsibility for any other information others may give you. We are offering to sell, and seeking offers to buy the ADSs, only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or the time of any sale of the ADSs. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor any of the underwriters has taken any action to permit a public offering of the ADSs outside the United States or to permit the possession or distribution of this prospectus or any filed free writing prospectus outside the United States. Persons outside the United States who come into possession of this prospectus or any filed free writing prospectus must inform themselves about and observe any restrictions relating to the offering of the ADSs and the distribution of the prospectus or any filed free writing prospectus outside the United States.

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements appearing elsewhere in this prospectus. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks of investing in the ADSs discussed under "Risk Factors" and information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in the ADSs.

Overview

We are a clinical stage biopharmaceutical drug development company focused on novel therapeutics targeting currently untreatable eye diseases involving retinal degeneration such as atrophic age-related macular degeneration (commonly known as dry AMD) and autosomal recessive Stargardt disease, or STGD1, both of which progressively lead to permanent blindness, and metabolic diseases such as non-alcoholic fatty liver disease, or NAFLD, nonalcoholic steatohepatitis, or NASH, type 2 diabetes, or T2D, and gout.

LBS-008

We believe our lead product candidate, LBS-008, or Tinlarebant, if approved, would provide a novel treatment option where there currently is none. LBS-008 is an oral once-a-day treatment that can reduce and maintain the delivery of vitamin A (retinol) to the eye as a means to reduce the accumulation of toxic vitamin A by-products in ocular tissue. This effect is achieved through the ability of LBS-008 to reduce and maintain the level of serum retinol binding protein 4, or RBP4, which carries retinol from the liver to the eye. In clinical trials, LBS-008 has demonstrated its target specificity and potency that we believe could be clinically meaningful to treat STGD1 patients. We initiated an open-label, dose-finding Phase 1b/2 clinical trial in adolescent STGD1 patients in mid-2020 in Australia and Taiwan. The study design includes two portions: Phase 1b and Phase 2. We have completed the Phase 1b portion of this study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Australia and Taiwan. The preliminary data from the Phase 1b portion has shown that LBS-008 can achieve a mean RBP4 reduction of > 70%, relative to baseline values. We are currently conducting the Phase 2 portion of this study. See "—Phase 1b/2 Clinical Trial in STGD1" below for more information.

As of the date of this prospectus, we have initiated our Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions.

STGD1 is a rare monogenetic juvenile-onset macular dystrophy that is characterized by the aberrant and excessive accumulation of toxic vitamin A by-products known as bisretinoids and cellular debris, or lipofuscin, which precedes the death of retinal tissue and loss of vision. Although an orphan disease, STGD1 is the most common juvenile macular degeneration. Dry AMD is a heterogenous condition that arises from a complex interplay between age, genetics and environmental factors, such as diet and smoking, but has a pathology and course of disease that strongly resembles that of STGD1, particularly in intermediate and advanced stages. There are no approved therapies for STGD1 or dry AMD.

Developed from our RBP4 intellectual property portfolio, or RBP4 IP Portfolio, LBS-008 was designed to be a potent and reversible RBP4 antagonist. As an RBP4 antagonist, LBS-008 reduces the amount of retinol entering the visual cycle thereby reducing the formation of bisretinoid toxins which will ultimately preserve the health of the retina. We hold a worldwide exclusive license of the RBP4 IP Portfolio from Columbia University, which contains disclosure directed to over 400 structurally distinct RBP4 antagonists under patent protection in major pharmaceutical markets worldwide, including the United States, the European Union, China, Australia, Japan, South Korea and India.

LBS-008 has received orphan drug designation for the treatment of STGD1 in the United States, which entitles it to market exclusivity such that the U.S. Food and Drug Administration, or FDA, may not approve any other applications for the same product for the same indication for 7 years, except in very limited circumstances. See "Regulations — U.S. Regulation — NDA Submission and Review — Orphan Drug

Designation and Exclusivity" for more information. LBS-008 has also received orphan designation for the treatment of STGD1 in Europe, which entitles it to a 10 year period of market exclusivity, which may be reduced in certain circumstances. During this market exclusivity period, neither the European Medicines Agency, or EMA, nor the European Commission or the member states can accept an application for, or grant a marketing authorization for, a "similar medicinal product." See "Regulations — European Regulation — Orphan Designation and Exclusivity" for more information. Additional benefits of an orphan drug designation include a tax credit of 50% of the qualified clinical testing expenses for the relevant taxable year and a waiver of the new drug application, or NDA, application fee (which is approximately $3.1 million for fiscal year 2022).

LBS-008 has also received rare pediatric disease designation in the United States and may be eligible for a priority review voucher. A priority review voucher may be awarded to a sponsor if it develops a drug for a rare pediatric disease and the drug is approved. The priority review voucher allows the sponsor of a subsequent NDA or Biologic License Application for any product candidate to expedite the FDA's review goal from 10 months to 6 months. The priority review voucher may be sold to other companies that seek to expedite drug reviews. See "Regulations — U.S. Regulation — NDA Submission and Review — Rare Pediatric Disease Designation and Priority Review Vouchers" for more information. In the last three years, priority review vouchers have sold in a price range between $80-125 million. In the event that we or a sublicensee chooses to sell a priority review voucher, we or such sublicensee would be obligated to pay Columbia University a percentage of revenue in the low double-digits that we or such sublicensee receives from any such sale pursuant to the Columbia License Agreement. In the event that we or a sublicensee does not sell a priority review voucher within one year of receipt, the earned royalties that we would be obligated to pay to Columbia University based on net sales of licensed products would increase by 1%. See "Business — Intellectual Property — Patents — Patent License Agreement with The Trustees of Columbia University in the City of New York" for more information.

LBS-008 is the only drug candidate within the current drug development projects of the National Institute of Health (NIH) Blueprint Neurotherapeutics Network, or the BPN, that is intended to treat dry AMD. The BPN was launched in 2004 to foster small-molecule neurotherapeutic development, bringing together a unique blend of grant dollars, industry-standard scientific expertise, and contract resources under a milestone-driven cooperative agreement program. The BPN criteria for selection of clinical drug candidates are based on multiple features of an applicant's drug development program including the following: 1) strong biological rationale, 2) novel target for the disease, 3) strong data linking target to disease, 4) demonstration of preclinical pharmacodynamic effect and efficacy, 5) feasible path to clinic, and 6) IP free of roadblocks. LBS-008 was selected by the BPN in 2011 and, as of the date of this prospectus, is the only drug candidate within the current drug development projects of the BPN that is intended to treat dry AMD.

The mechanism of action utilized by LBS-008 has been recognized and recommended as a priority for clinical development in both STGD1 and dry AMD in a systematic review published by the U.K. National Institute for Health Research, or the NIHR, in 2018. The NIHR is funded by the U.K. Department of Health and Social Care and focuses on early translational research, clinical research and applied health and social care research for the purpose of enabling and delivering world-leading health and social care research that improves people's health and wellbeing and promotes economic growth. The NIHR screened 7,948 articles in 2018 for its systematic review on treatments for dry AMD and STGD1. Its principal findings included that research focus should be at earlier stages in both diseases (before vision is impaired) and that the most promising treatments for both diseases appear to be prevention of lipofuscin and bisretinoid accumulation. Therefore, the NIHR recommended the mechanism of RBP4 inhibition, which is utilized by LBS-008, as a promising treatment in dry AMD and STGD1.

Although there are currently no approved treatments available for STGD1 and dry AMD, our competitors for LBS-008 include several companies going through clinical development for their product candidates. Based on publicly available information, we understand that there is one Japan-based pharmaceutical company that has an asset in Phase 3 development for STGD1. There are also three U.S.-based companies advancing treatments for STGD1 and their assets are currently in Phase 2 and Phase 2b development, respectively, with the third company having recently completed their Phase 2a trial. In geographic atrophy, or GA, there are five U.S.-based companies in late-stage clinical development, three of which have assets in Phase 3 development and two of which have assets in Phase 2 development.

Clinical Trials in Healthy Adult Subjects

To support the clinical development of LBS-008, we have completed one randomized, double-blind, placebo-controlled, Phase 1 SAD study in 40 healthy adult subjects in the United States, one randomized, double-blind, placebo-controlled, Phase 1 single ascending dose, or SAD, study in 39 healthy adult subjects and one randomized, double-blind, placebo-controlled, Phase 1 multiple ascending dose, or MAD, study in 32 healthy adult subjects in Australia. These studies were conducted to confirm the safety, toxicity, pharmacokinetics, or PK, and pharmacodynamics, or PD of LBS-008 on a range of single ascending dose (10-50 mg in the US; 25-400 mg in Australia) / multiple ascending dose (5-25 mg in Australia) levels in heathy adult subjects in fasted / fed conditions.

In the US SAD study, we found that single doses of 10–50 mg LBS-008 were well tolerated and reduced mean serum RBP4 level by around 70% from baseline. The degree of lowering of RBP4 plasma concentrations increased with increasing LBS-008 dose. This study also compared doses of LBS-008 taken with and without food, which did not show a food effect with dosing.

In the Australian SAD study, we found that single doses of 25-400 mg LBS-008 were well tolerated and reduced mean RBP4 level by > 70% from baseline. One subject in the 100 mg cohort experienced a drug-related adverse event of mild transient xanthopsia. That event was resolved within 48 hours. A direct correlation between the LBS-008 plasma concentration and RBP4 suppression was observed.

In the Australian MAD study, we found that all dose levels were well tolerated and have identified an optimal daily dose to reduce serum RBP4 by > 70% from baseline. Most drug-related adverse events reported were mild in severity, and the most frequently reported drug-related adverse event was asymptomatic Delayed Dark Adaptation, or DDA, which did not show dose proportionality and reflects a reduction in vitamin A levels in the eye, which is the intended effect of LBS-008. No deaths, serious or severe adverse events were reported. The Safety Review Committee, or SRC, approved dose escalations after reviewing the safety data profile at each dose level.

Stargardt Disease

In STGD1, we are developing LBS-008 as an oral daily treatment to target RBP4 by disrupting vitamin A (retinol) binding to RBP4 which leads to reduced delivery of retinol to the eye and reduced accumulation of toxic vitamin A by-products.

STGD1 is an inherited juvenile form of macular degeneration and currently, there is no approved treatment available. The disease is caused by a mutation in the ABCA4 gene, which leads to the accelerated formation and accumulation of toxic vitamin A by-products known as bisretinoids. The most prominent bisretinoid identified in human tissues is known as A2E (*N*-retinylidene-*N*-retinylethanolamine). The accumulation of A2E in ocular tissues causes progressive retinal cell death and permanent loss of vision. More than 500 mutations in the ABCA4 gene have been identified in STGD1 patients. Some STGD1 patients suffer severe visual impairment by the age of 20. The prevalence rate of STGD1 is estimated to be 1 in 10,000 people. Based on this estimate, approximately 30,000 US citizens are affected by STGD1. This estimate includes both adults and children. Although comprehensive epidemiological data on the prevalence of STGD1 in other countries is not available, the epidemiological literature from other countries, such as Europe and Asian countries, cite the 1 in 10,000 estimate for the prevalence of STGD1.

Phase 1b/2 Clinical Trial in STGD1

We have completed the Phase 1b portion of a Phase 1b/2 open-label, dose-finding study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Taiwan and Australia. The Phase 1b portion is a dose-finding study designed to determine the optimal dose of LBS-008 and to evaluate safety, tolerability, PK and PD in adolescent STGD1 patients for a treatment period of 2 cycles of 14-day daily dosing of LBS-008 (28 days of daily treatment) and a 14-day follow-up period. Upon completion of Phase 1b, an optimal daily dose was identified and which was able to achieve a mean RBP4 reduction of > 70%, relative to baseline values.

The preliminary data shows that most frequently reported drug-related adverse events reported to date included DDA and transient xanthopsia, which were all graded as mild. Reports of transient DDA/night

vision impairment and xanthopsia were anticipated and are consistent with LBS-008's mechanism of action. It is notable that in most incidences of DDA, it was confirmed by laboratory measure (dark adaptometry) as the majority of patients were asymptomatic. No deaths or serious or severe Treatment-emergent adverse events, or TEAEs, were reported. In addition, there were no clinically significant findings in relation to vital signs, physical exams, or electrocardiograms, or ECGs.

The Phase 2 portion consists of a 2-year treatment period with a follow-up period of one month. In the Phase 2 portion of the study, in addition to monitoring the safety and tolerability, we aimed to monitor PK and PD biomarkers (RBP4 and retinol) and the effects of treatment using various retinal imaging modalities (including definitely decreased autofluorescence, or DDAF, questionably decreased autofluorescence, or QDAF, Spectral-domain optical coherence tomography, or SD-OCT, and microperimetry), change in best-corrected visual acuity, or BCVA, and the relationship between the change in RBP4 levels and rate of lesion growth.

We are currently conducting the Phase 2 portion of this study. A total of 13 adolescent STGD1 patients were enrolled in the Phase 2 portion of the Phase 1b/2 study. As of the date of this prospectus, all 13 patients have received at least 6 months of treatment and completed the scheduled assessments at the first 6 month interval. Change in BCVA (early treatment diabetic retinopathy study, or ETDRS letter score), and fundus autofluorescence, or FAF, imaging results at 6-months are compared to the baseline measurements at the start of Phase 2. The preliminary data shows that 8 of the 13 patients (or 61.5%) recorded a gain in BCVA (ETDRS letter score) in at least one eye, including 2 patients who recorded a gain in BCVA in both eyes. The average BCVA from the 13 patients was an average loss of 2.8 letters in the right eye, and an average gain of 1.9 letters in the left eye. On FAF retinal imaging, 8 of the 13 patients (or 61.5%) had a reduction or no change in their QDAF area size in at least one eye, including 5 patients who had a reduction or no change in QDAF area size in both eyes. There was an average gain in QDAF area in the right eye of $0.2 \pm 0.09mm^2$ (Mean ± standard error of the mean, or SEM) and in the left eye of $0.1 \pm 0.09mm^2$ (Mean ± SEM). While 12 of the 13 patients had no DDAF lesion measured at the start of Phase 2 and at 6-months, 1 of the 13 patients had a DDAF lesion growth of $0.3mm^2$ in both eyes during the 6-month period. On SD-OCT imaging, a gradual thinning with an average of approximately 7 to 10 microns (on total retinal thickness by ETDRS regions) was observed in both eyes. In the Ellipsoid Zone (EZ), an average increase in defect width of 0.26mm in the right eye and 0.61mm in the left eye were observed. However, 6 patients had a reduction in EZ defect width in at least 1 eye (including 3 patients in both eyes). Additional interim data read-outs will be captured at Months 12, 15, 18 and 21, and a final data read-out will be captured at Month 24.

Phase 3 Clinical Trial in STGD1

As of the date of this prospectus, we have initiated a randomized, double-masked, placebo-controlled, global, multi-center, Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. This study consists of a screening period, a treatment period of 2 years, and a follow-up period of one month. Approximately 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). See "Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us."

We intend to focus on adolescent patients in our ongoing clinical trials due to several benefits afforded by utilizing this patient population — namely, establishing proof-of-concept in the context of a more severe and rapidly progressing disease (i.e., STGD1 disease progression is faster in adolescent patients compared to adults or later-onset patients), and the ability to readily expand into the larger adult STGD1 population upon approval (i.e., drug approvals for pediatrics and/or adolescents are accepted for adults but drug approvals for adults are not accepted for pediatrics and/or adolescent populations due to safety concerns).

Dry AMD

Due to the strong pathophysiologic similarities between STGD1 and intermediate to advanced stages of dry AMD, we expect LBS-008 to have a similar treatment effect on this population of dry AMD patients.

AMD is an age-related form of macular degeneration. The most commonly used classification system for AMD is the Age-Related Eye Disease Study, or AREDS, classification system, which designates the following categories:

- Category 1 is designated as "No AMD," although there may be a few small (<63µm in diameter) yellowish subretinal deposits (i.e., drusen beneath the retina).
- Category 2 is designated as "Early AMD" and is characterized by multiple small drusen (<20µm in diameter), a few intermediate drusen (63-124µm in diameter), and abnormalities of the retinal pigment epithelium, or RPE, a monolayer of epithelial cells that lies beneath the retina and provides trophic and metabolic support to photoreceptor cells of the retina.
- Category 3 is designated as "Intermediate AMD," where there is extensive intermediate drusen, large drusen (>125µm in diameter), or geographic atrophy (i.e., localized atrophy of the retina), or GA, and increased lipofuscin in the RPE.
- Category 4 is designated as "Advanced AMD" and is characterized by GA or neovascular maculopathy (i.e., 'wet' AMD).

The only approved therapies for AMD are for 'wet' AMD which represents approximately 10% of all AMD cases. There are no approved therapies for the other stages of AMD, including GA, secondary to advanced AMD, which are collectively referred to as dry AMD and represents approximately 90% of all AMD cases. Importantly, dry AMD is a leading cause of vision loss in older adults. Thus, there is a significant unmet medical need in treating dry AMD patients. There are an estimated 11 million dry AMD patients in the United States and over 196 million patients worldwide with an estimated global direct healthcare cost of US$255 billion.

Disease progression in early dry AMD is very slow. The American Optometric Association reports that most people move through the process from diagnosis to legal blindness in about 10 years. Therefore, investigational therapies have been directed at the treatment of intermediate and advanced stages of dry AMD, which progress more rapidly than earlier stages. Unlike STGD1, dry AMD is believed to have a very heterogenous etiology, and various therapeutic approaches have been explored to slow disease progression in dry AMD. An important feature of Intermediate AMD is the aberrant and excessive accumulation of lipofuscin and bisretinoid toxins, similar to STGD1. In these stages of dry AMD, retinal lesions (i.e., GA) are bordered on all sides by an annulus of autofluorescence which expands in a centrifugal manner followed by lesion expansion into the autofluorescent area. *In vivo* analyses of the autofluorescent area in Intermediate AMD eyes revealed an excitation maxima and fluorescence emission that is consistent with the spectral properties of bisretinoid toxins. Thus, the clinical presentation and biochemical features of intermediate and advanced dry AMD suggest that a therapy directed at reducing the level of bisretinoid toxins may be effective to slow disease progression.

We are currently evaluating our plan to initiate, in 2022, a randomized, double masked, placebo-controlled, Phase 2 or Phase 3 trial, in the United States, Europe, and Asia Pacific. See "Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us." Our objective is to evaluate the efficacy and safety of LBS-008 in the treatment of dry AMD over the course of a two-year treatment period.

LBS-009

LBS-009 is an anti-RBP4 oral therapy targeting liver disease, including NAFLD, NASH, and T2D.

NAFLD occurs when an excess accumulation of fat damages the liver. Currently, it is estimated that approximately 1.9 billion patients suffer from NAFLD worldwide. Over time, the liver damage and the associated inflammation can lead to the development of NASH, which impacts an estimate of more than 9 million patients in the United States alone. As the disease progresses, it can lead to cirrhosis and eventually, complete liver failure. NAFLD and NASH are a growing unmet need for which no FDA-approved treatments are currently available.

T2D is a chronic disease that occurs when the body cannot effectively use insulin, the hormone that regulates blood sugar levels. The health impact of T2D is profound, potentially causing damage to the eyes, heart, blood vessels, kidneys, and nerves. T2D is on the rise, with approximately 422 million patients globally.

LBS-009 is a small molecule designed to compete with retinol for RBP4 binding. When bound to LBS-009, RBP4 can no longer form a large molecular weight complex with transthyretin. Consequently, the RBP4/LBS-009 complex will be removed from circulation by renal filtration. We believe that modulating RBP4 concentrations systemically with LBS-009 has a significant therapeutic potential for treating patients suffering from metabolically associated diseases, including NAFLD, NASH and T2D.

LBS-009 is currently in preclinical development.

Our Management and Clinical Advisory Board

Our management team and ophthalmology clinical advisory board have deep experience and capabilities in ophthalmology, neurology, immunology and immunotherapy, cardiovascular and renal medicine, oncology, neurobiology, biochemistry, drug discovery, clinical development, manufacturing, and commercialization. Our ophthalmology clinical advisory board includes key opinion leaders in the macular degeneration space, including Quan Nguyen, M.D., Professor of Ophthalmology at Stanford University, Hendrik P.N. Scholl, M.D., Professor and Chairman of the Department of Ophthalmology at University of Basel and Co-Director of the Institute of Molecular and Clinical Ophthalmology in Basel, Michel Michaelides, M.D., Consultant Ophthalmologist at Moorfields Eye Hospital and Professor of Ophthalmology, UCL Institute of Ophthalmology, Robyn Guymer, M.D., Professor of Ophthalmology, University of Melbourne and Deputy Director of the Centre for Eye Research Australia and Frank Holz, M.D., Chairman of Ophthalmology, University of Bonn. Together, our management team and ophthalmology clinical advisory board, in connection with our exclusive technology platform, will allow our drugs to be tailored to target at-risk patients across the United States and worldwide, who lack access to necessary treatment in the macular degeneration space.

Our Program

Our lead product candidate, LBS-008, is an RBP4 antagonist. We are developing LBS-008 as an oral daily treatment for STGD1 and dry AMD.

The following table summarizes key information about our clinical program for LBS-008:

Indication	Clinical Trials	Trial Participants	Estimated Timeline
STGD1	Phase 1 single and multiple ascending dose trial	Healthy adult subjects	Completed
	Phase 1b trial	Adolescent patients with STGD1	Completed
	Phase 2 trial	Adolescent patients with STGD1	Ongoing, with interim data read-outs expected to be captured at Months 12, 15, 18 and 21, and a final data read-out to be captured at Month 24.
	Phase 3 trial	Adolescent patients with STGD1	Initiated
Dry AMD	Phase 1 single ascending dose trial	Healthy adult subjects	Completed
	Phase 2 or Phase 3 trial	Patients with dry AMD	2022

Our ongoing and planned development plans and clinical trials may potentially be adversely impacted if the COVID-19 pandemic continues in the future. Specifically, the COVID-19 pandemic may lead to (i) delays in patient enrollment for our clinical trials and/or other services provided by the CROs, laboratories or hospitals engaged by or collaborated with us due to lockdown measures in various countries, (ii) delays or significant increase in expenses for obtaining and shipment of our drug candidates due to congestion at port or increased freight and (iii) delays in the FDA or other regulatory agencies review and approval processes as the FDA or other regulatory agencies may prioritize and focus on the approval of therapeutics treating COVID-19 than those treating other indications.

Our Strengths

We believe we are well placed to accomplish our mission due to the following strengths:

- Novel oral therapy to tap into a niche market for significant unmet medical needs.
- Pre-clinically and clinically demonstrated mechanism of action.
- Receipt of Orphan Drug Designation in the United States and Europe.
- Receipt of Rare Pediatric Disease Designation in the United States with Eligibility for Priority Review Voucher if approved.
- National Institute of Health Blueprint Neurotherapeutics Network sponsored and endorsed.
- U.K. National Institute for Health Research endorsed the mechanism of action utilized by LBS-008.
- Potential to treat intermediate to advanced-stage dry AMD with oral therapy for lifetime.
- Highly experienced senior management team supported by world-renowned advisory board and influential key opinion leaders.

Our Strategies

Our goal is to become a leading biopharmaceutical company with an aim to develop the first approved treatment on STGD1 and dry AMD globally. We intend to accomplish our mission by pursuing the following growth strategies:

- Efficiently advance our lead product candidate, LBS-008, through Phase 2 and Phase 3 clinical development in adolescent STGD1 patients and regulatory approval, with the potential to establish a new standard of care for STGD1 patients.
- Leverage the promising clinical data of LBS-008 in adolescent STGD1 patients to initiate Phase 2 or Phase 3 clinical development in dry AMD.
- Potentially advance LBS-009 through clinical development for the treatment of NAFLD and NASH.
- Continue to leverage our exclusive RBP4 IP Portfolio, and look for additional in-licensing or collaboration arrangements, to identify novel candidates to further expand our product pipeline and utilize our global organizational structure to advance programs into clinical development in a capital efficient manner.
- Evaluate strategic collaborations to maximize the value of our product candidates.

Summary of Risk Factors

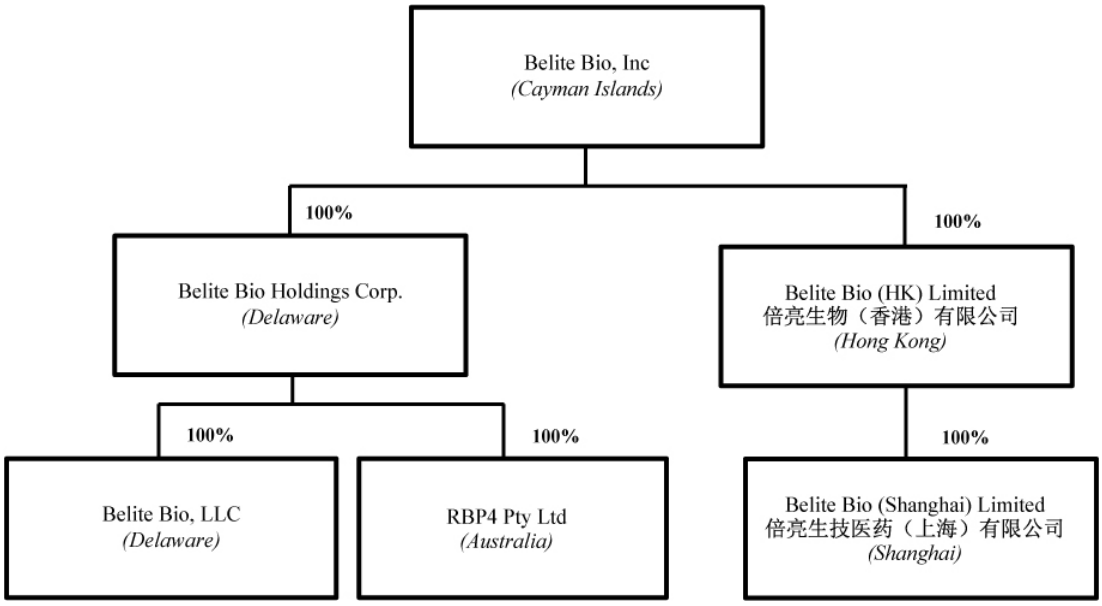
There are a number of risks that you should understand before making an investment decision regarding this offering. These risks are discussed more fully in the section entitled “Risk factors” following this prospectus summary. These risks include, but are not limited to:

- Our business is highly dependent on the success of our lead product candidate, LBS-008. If we are unable to develop, obtain marketing approval for or successfully commercialize LBS-008, either alone or through a collaboration, or if we experience significant delays in doing so, our business could be harmed;

- All of our product candidates are in preclinical or clinical development. If we are unable to complete clinical development and obtain regulatory approval to ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed;
- We have recorded net cash outflow from operating activities since our inception. Even if we consummate this offering, we will need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates;
- There is uncertainty regarding our ability to continue as a going concern, indicating the possibility that we may be required to curtail or discontinue our operations in the future;
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;
- The regulatory approval processes of the FDA, the TGA, the NMPA, the EMA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed;
- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated;
- If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected;
- We depend on intellectual property licensed from third parties, and our current and future licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business;
- If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence and the market price of our ADSs may be materially and adversely affected;
- Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees;
- As we rely on third parties to conduct our preclinical studies, clinical trials, contract manufacture drug substances and drug products, and provide other important services related to product development, regulatory submissions, and commercialization, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, 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 expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans; and
- As a result of our principal shareholder, Lin Bioscience International Ltd.'s significant share ownership position in us, it is able to influence corporate matters and a conflict of interest may arise between our principal shareholder and us.

Corporate Structure

The chart below sets forth our corporate structure and identifies our significant subsidiaries and their significant subsidiaries, as of the date of this prospectus:



Cash Transfers and Dividend Distribution

Our cash is primarily held by the holding company, Belite, and has been raised primarily through the issuance and sale of ordinary shares, convertible bonds, or convertible preferred shares in private placement transactions conducted by Belite.

Belite is permitted under the laws of the Cayman Islands to provide funding to our subsidiaries through capital contributions or loans, and there are currently no restrictions on transferring funds between our Cayman Islands holding company and subsidiaries in the U.S., Australia and Hong Kong. Our ability to make loans and additional capital contribution to our PRC subsidiary might be restricted by PRC law.

In the normal course of our business, Belite would evaluate the financial condition and capital needs of our subsidiaries periodically and then provide funding for their operations via equity investments and intercompany loans. As of the date of this prospectus, we have provided US$10.06 million to our subsidiaries via capital contribution, including US$0.5 million intercompany loans that have been repaid by the subsidiary via the issuance of ordinary shares, among which we have provided US$60,000 to our Hong Kong subsidiary via capital contribution which further invested US$50,000 to our PRC subsidiary via capital contribution. No other transfer of cash or other types of assets has been made between our Cayman Islands holding company and subsidiaries as of the date of this prospectus.

Our subsidiaries outside mainland China are permitted, under the respective laws of the U.S., Australia and Hong Kong, to provide funding to Belite through dividend distribution without restrictions on the amount of the funds. Our PRC subsidiary has no operations and generates no revenue as of the date of this prospectus, but should it generate revenue in the future, its ability to distribute dividends to us will be limited by foreign exchange restrictions. In addition, restrictions on currency exchanges in China may limit our ability to freely convert Renminbi to fund any future business activities outside China or other payments in U.S. dollars, and capital control measures imposed by the Chinese government may limit our ability to use capital from our PRC subsidiary for business purposes outside of China. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can not be made in currencies other than Renminbi without complying with certain procedural requirements of the State Administration of Foreign Exchange, or SAFE. Specifically, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into another currency and remitted out of China to pay

capital expenses, such as the repayment of loans denominated in currencies other than Renmibi. As a result, we may need to obtain SAFE approval to use cash generated from the operations of our PRC subsidiary to pay off its debt in a currency other than Renminbi owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than Renminbi. On the other hand, the PRC Enterprise Tax Law (EIT Law) and its implementation rules provide that a withholding tax rate of up to 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC-resident enterprises are incorporated. As of the date of this prospectus, we have not received nor do we have any present plan to receive dividends paid by our U.S., Australia, Hong Kong and PRC subsidiaries.

As of the date of this prospectus, we did not adopt any specific cash management policies and procedures in relation to how funds are transferred within/through our group. Our management monitors the cash position of each entity within our group regularly, and prepares budgets for our subsidiaries on a monthly basis. In the event that there is a need for cash or a potential short-term cashflow shortages, it would be reported to our chief financial officer and, subject to the approval by our board of directors, we will enter into an intercompany loan arrangement for relevant subsidiary. Other than the above, we did not adopt or maintain any cash management policies and procedures as of the date of this prospectus.

Our Board of Directors has discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, subject to the provisions in our articles of association, our shareholders may by ordinary resolution declare a dividend not exceeding the amount recommended by our Board of Directors. As of the date of this prospectus, we have not paid and do not have any present plan to declare or pay any dividends in the foreseeable future. We currently intend to retain most of our available funds and any future earnings to fund the development and growth of our business. See "Risk Factors — Risks Related to This Offering and Our ADSs — Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our ADSs for return on your investment" for more information.

Implication of Being an Emerging Growth Company

As a company with less than US$1.07 billion in revenue for our last fiscal year, we qualify as an "emerging growth company" pursuant to the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements compared to those that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting. The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. Pursuant to the JOBS Act, we have elected to take advantage of the benefits of this extended transition period for complying with new or revised accounting standards. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year during which we have total annual gross revenues of at least US$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the preceding three-year period, issued more than US$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of the ADSs that are held by non-affiliates exceeds US$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

Implication of Being a Foreign Private Issuer

We are also considered a "foreign private issuer." Accordingly, upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. This means

that, even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States.

In this prospectus, we have taken advantage of certain of the reduced reporting requirements as a result of being an emerging growth company and a foreign private issuer. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

Implications of being a Controlled Company

We are a "controlled company" as defined under the Nasdaq Stock Market Rules, because one of our shareholders holds more than 50% of our voting power. As a result, for so long as we remain a controlled company as defined under that rule, we are exempt from, and our shareholders generally are not provided with the benefits of, some of the Nasdaq Stock Market corporate governance requirements, including that:

- a majority of our board of directors must be independent directors;
- our compensation committee must be composed entirely of independent directors; and
- our corporate governance and nomination committee must be composed entirely of independent directors.

Although we intend to reconstitute our board of directors and to have a majority of independent directors, that may change in the future.

Corporate Information

Belite Bio, Inc was incorporated in the Cayman Islands on March 27, 2018 as an exempted company with limited liability. The address of our registered office in Cayman Islands is located at the Office of Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. Our principal executive offices are located at 5820 Oberlin Drive, Suite 101, San Diego, CA 92121. Our telephone number at that address is +1-858-246-6240.

Our website address is belitebio.com. Our website and the information contained on our website do not constitute a part of this prospectus. Our agent for service of process in the United States is Puglisi & Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711.

Conventions that Apply to this Prospectus

Unless otherwise indicated or the context otherwise requires, references in this prospectus to:

- "ADRs" are to the American depositary receipts that may evidence the ADSs;
- "ADSs" are to the American depositary shares, each of which represents one ordinary share;
- "AUD" are to the legal currency of Australia;

- “Belite,” “we,” “us,” “our company,” and “our” are to Belite Bio, Inc, our Cayman Islands holding company and its subsidiaries;
- “China” or the “PRC” are to the People’s Republic of China, excluding, for the purposes of this prospectus only, Hong Kong, Macau and Taiwan;
- “shares” or “ordinary shares” are to our ordinary shares, par value US$0.0001 per share; and
- “US$,” “U.S. dollars,” “$,” and “dollars” are to the legal currency of the United States.

Unless the context indicates otherwise, all information in this prospectus assumes no exercise by the underwriters of their option to purchase additional ADSs from us. The functional currency of the Company’s subsidiaries located in the United States is U.S. dollars. The functional currency of the Company’s subsidiary located in Australia is AUD. Unless otherwise noted, all translations from AUD to U.S. dollars and from U.S. dollars to AUD in this prospectus are made at a rate of AUD0.7401 to US$1.00, the exchange rate in effect as of April 15, 2022 as set forth in the H.10 statistical release of The Board of Governors of the Federal Reserve System. We make no representation that any AUD or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or AUD, as the case may be, at any particular rate, or at all.

The Offering

Offering price	US$6.00 per ADS.
ADSs offered by us	6,000,000 ADSs (or 6,900,000 ADSs if the underwriters exercise the option to purchase additional ADSs in full).
ADSs outstanding immediately after this offering	6,000,000 ADSs (or 6,900,000 ADSs if the underwriters exercise the option to purchase additional ADSs in full).
Ordinary shares issued and outstanding immediately after this offering	24,095,317 ordinary shares (or 24,995,317 ordinary shares if the underwriters exercise the option to purchase additional ADSs in full).[1]
The ADSs	Each ADS represents one ordinary share, par value US$0.0001 per share. The depositary will hold the ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time. We do not expect to pay dividends in the foreseeable future. If, however, 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 in accordance with the terms set forth in the deposit agreement. You may surrender your ADSs to the depositary for cancellation in exchange for ordinary shares. The depositary will charge you fees for any cancellation. We may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended. To better understand the terms of the ADSs, you should carefully read the “Description of American Depositary Shares” section of this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement that includes this prospectus.
Option to purchase additional ADSs	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an aggregate of 900,000 additional ADSs.
Use of proceeds	We expect that we will receive net proceeds of approximately US$32.2 million from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use approximately 2.5% of the net proceeds for our Phase 3 clinical trial of LBS-008 for STGD1, approximately 68.2% of the net proceeds for further clinical development of LBS-008 for

[1] There are 18,095,317 ordinary shares outstanding immediately prior to the offering.

	dry AMD, such as Phase 2 or Phase 3 clinical trials, and the remainder for working capital and other general corporate purposes. See “Use of Proceeds” for more information.
Lock-up	We and each of our officers, directors and shareholders beneficially holding greater than 5% of our ordinary shares have agreed with the underwriters, subject to certain exceptions, not to sell, transfer or otherwise dispose of any ADSs, ordinary shares or similar securities for a period of 180 days after the date of this prospectus. We have also agreed, subject to certain exceptions, not to file or cause to be filed any registration statement relating to the offering of any of our share capital for a period of 180 days after the date of this prospectus. See “Shares Eligible for Future Sale” and “Underwriting” for more information.
Listing	The ADSs have been approved for listing on the Nasdaq Capital Market under the symbol “BLTE.” The ADSs and our ordinary shares will not be listed on any other stock exchange or traded on any automated quotation system.
Payment and settlement	The underwriters expect to deliver the ADSs against payment therefor through the facilities of the Depository Trust Company on May 3, 2022.
Depositary	Deutsche Bank Trust Company Americas

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated statement of operations and comprehensive loss data for the years ended December 31, 2020 and 2021 and summary consolidated balance sheet data as of December 31, 2020 and December 31, 2021 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated financial statements are prepared and presented in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. Our historical results are not necessarily indicative of results expected for future periods. You should read this Summary Consolidated Financial Data section together with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	For the Years Ended December 31,	
	2020	2021
	(amounts in $ and in thousands, except for shares and per share data)	
Expenses		
Research and development	3,688	7,419
General and administrative	2,055	2,378
Total operating expenses	5,743	9,797
Loss from operations	(5,743)	(9,797)
Other income (expense):		
Interest income	12	5
Interest expense	(21)	—
Other income	—	126
Total other (expense) income, net	(9)	131
Loss before income tax	(5,752)	(9,666)
Income tax expense	(1)	—
Net loss	(5,753)	(9,666)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	6	(152)
Total comprehensive loss	$ (5,747)	$ (9,818)
Weighted average number of ordinary shares used in per share calculation:		
—Basic and Diluted	8,790,397	9,569,932
Net loss per ordinary share		
—Basic and Diluted	$ (0.65)	$ (1.01)

	As of December 31, 2020	As of December 31, 2021
	(amounts in $ and in thousands)	
Selected Consolidated Balance Sheets Data:		
Cash	$25,618	$ 17,344
Total assets	$25,741	$ 18,348
Total liabilities	$ 972	$ 1,635
Total convertible preferred shares	$31,806	$ 31,806
Total shareholders' deficit	$ (7,037)	$(15,093)
Total liabilities, convertible preferred shares and shareholders' deficit	$25,741	$ 18,348

RISK FACTORS

Investing in our ADSs involves a high degree of risk. You should carefully consider the following risks and uncertainties and all other information contained in this prospectus before investing in our ADSs. Our business, financial condition, results of operations or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material. If any of the risks actually occur, our business, financial condition, results of operations and prospects could be adversely affected. In that event, the market price of our ADSs could decline, and you could lose part or all of your investment.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our business is highly dependent on the success of our lead product candidate, LBS-008. If we are unable to develop, obtain marketing approval for or successfully commercialize LBS-008, either alone or through a collaboration, or if we experience significant delays in doing so, our business could be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. Our business and future success depends in large part on our ability to develop, obtain regulatory approval for, and then successfully commercialize our lead product candidate, LBS-008. This may make an investment in our company riskier than similar companies that have multiple product candidates in active late-stage development that may be able to better sustain the failure of a lead product candidate.

Further, if LBS-008 does not obtain approval for the treatment of autosomal recessive Stargardt disease (STGD1), which is the initial indication that we are currently exploring, we will have spent substantial time and financial resources without receiving a return on investment. As a result, if LBS-008 does not receive approval or fails to become profitable and receive market acceptance, our business, results of operations and financial condition will be adversely affected.

The success of LBS-008 will depend on several factors, including the following:

- successful completion of our ongoing clinical trials;
- initiation and successful enrollment and completion of additional clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or the FDA, , the Therapeutic Goods Administration of Australia, or the TGA, National Medical Products Administration, or the NMPA (formerly known as the China Food and Drug Administration, or the CFDA), the European Medicines Agency, or the EMA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval, and meeting all applicable postmarket commitments, obligations, and requirements;
- commercial acceptance of our products, if approved, by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize LBS-008. Even if regulatory approvals are obtained, we may never be able to successfully commercialize LBS-008. Accordingly, we may not be able to generate sufficient revenue through the sale of LBS-008 to continue our business.

We may allocate our limited resources to pursue a particular product candidate, indication, including any additional indications for LBS-008, or technology and fail to capitalize on existing or future product candidates, indications or technologies 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 intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications or technologies that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate or technology, we may relinquish valuable rights to that product candidate or technology through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or technology. For example, we are developing our lead product candidate, LBS-008, to initially treat STGD1. We are also considering a number of additional indications for LBS-008, including the treatment of nonalcoholic steatohepatitis. We cannot guarantee that the treatment of STGD1 will be the most profitable indication for LBS-008 as opposed to other contemplated indications. This could result in us failing to capitalize on the true market potential of our lead product candidate in a timely manner or at all.

Although a substantial amount of our efforts will focus on the continued clinical testing, potential approval, manufacturing and commercialization of our existing product candidates, the success of our business depends in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates or new technologies. Research efforts to identify new product candidates and technologies require substantial technical, financial, and human resources. Although we do not currently engage in such activities, we may in the future seek to expand our drug pipeline through in-licensing arrangements. We may end up focusing our efforts and resources on potential product candidates and technologies that ultimately prove to be unsuccessful. Our research and any future licensing efforts may fail to identify, discover or in-license new product candidates and technologies suitable for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates and technologies, or potential product candidates and technologies that are within our resources to license or acquire and develop;
- our potential product candidates and technologies may be shown to have adverse effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- it may take greater human, financial and/or research resources to identify additional therapeutic opportunities for our product candidates or to develop more suitable potential product candidates and technologies than what we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will successfully identify and develop new product candidates or technologies, or additional therapeutic opportunities for our product candidates, whether through internal research or future licensing efforts, which could materially adversely affect our future growth and prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

There is a risk of failure for every product candidate. Clinical testing is expensive, is difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. 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, and failure can occur at any time during the preclinical and clinical development process. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, our product candidates must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial to advanced clinical trials and despite the level of scientific rigor in the study, design and adequacy of execution. In some instances, there can be significant variability in safety and/or efficacy results among different studies of the same product candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions. Many product candidates in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. 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.

In the case of any studies we conduct, results may differ from earlier studies due to the larger number of clinical trial sites and additional countries and languages involved in such studies. Clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global studies increasingly complex. Differing regulatory approval requirements in different countries could make it more difficult for us to conduct unified global studies, which can lead to increased development costs and marketing delays or non-viability of our clinical trials. In addition, the FDA may determine that clinical trial results obtained in foreign subjects do not adequately represent the results that would be obtained in U.S. patients and are thus not supportive of an NDA approval in the United States.

In particular, if we experience delays in the start or completion of, or termination of, any clinical trial of LBS-008, the commercial prospects of LBS-008 may be harmed, and our ability to generate product revenues from LBS-008 will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for LBS-008, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of LBS-008.

All of our product candidates are in preclinical or clinical development. If we are unable to complete clinical development and obtain regulatory approval to ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed.

All of our product candidates are still in development. Our ability to generate revenue from our product candidates is dependent on receipt of regulatory approval and successful commercialization of such products. We cannot guarantee that we will be able to obtain regulatory approvals for our existing product candidates in a timely manner, or at all, and we may be unable to obtain successful commercialization of our product candidates even if we receive regulatory approval. Each of our product candidates will require additional preclinical and/or clinical development, regulatory approvals in multiple jurisdictions, development of commercial 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, but not limited to, the following:

- hiring sufficient technical experts to oversee all development and regulatory activities and meeting of safety requirements;
- successful completion of preclinical studies and clinical trials, including the successful enrollment in such clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for planned and future clinical trials, drug registration, manufacturing and commercialization;
- successful completion of all safety studies required to obtain regulatory approval in United States, Australia, Taiwan, China, the Europe and other applicable jurisdictions for our product candidates;
- our ability to establish manufacturing capabilities and capacities, whether internally or through CMOs, to the specifications of our product candidates for clinical supply;
- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- effectively competing with other therapies and alternative drugs;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the product candidates following regulatory approval, and meeting all applicable postmarket commitments, obligations, and requirements.

Any significant delays in, or an inability to, obtain regulatory approval and ultimately achieve commercial success for our existing and future product candidates in one or more jurisdictions would materially harm our business and we may not be able to generate enough revenues and cash flows to continue our operations, including delays due to COVID-19 could further materially harm our business. As a result, our financial condition, results of operations and prospects will be materially and adversely harmed.

If we encounter delays or difficulties enrolling and retaining patients in our clinical trials, our clinical development progress and our receipt of necessary regulatory approvals could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients that will remain in the study until its conclusion. 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 studies as required by the FDA, the TGA, the NMPA, the EMA and any other applicable similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. If patients are unwilling to enroll in our clinical trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies, negative publicity from adverse events related to the biopharmaceutical industry or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment could result in increased development costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of clinical trials altogether.

Patient enrollment for our clinical trials may be affected by other factors, including, but not limited to, the following:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question, including age-based eligibility criteria limiting subject enrollment to adolescent populations;
- perceived risks and benefits of the product candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients;
- our ability to maintain patient consents;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the occurrence of any pandemic, epidemic or any other public health crises, including from the COVID-19 pandemic, natural catastrophe or other disasters that may cause a delay in enrollment of patients in clinical trials.

Additionally, our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with contract research organizations, or CROs, and physicians;
- different standards for the conduct of clinical trials;
- absence in some countries of established groups with sufficient regulatory expertise for review of protocols;
- inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. For example, we have experienced delays in the enrollment of patients in our clinical trials due to government orders and site policies on account of the COVID-19 pandemic, and some patients may be unwilling or unable to travel to study sites, enroll in our studies or comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. If we have difficulty enrolling a sufficient number of patients or finding additional clinical trial sites to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, it is possible that the COVID-19 pandemic may have an impact on the workforce of the third parties and CROs on which we rely, which could adversely impact our ability to conduct preclinical studies, enroll and retain patients in our clinical trials and conduct the clinical trials of our product candidates on expected timeframes or to complete such studies, and our ability to ultimately obtain regulatory approval. As a result, the value of our Company could decline and our ability to obtain additional financing may be impaired.

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including, but not limited to, the following:

- regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective study site;
- delay in reaching, or failure to reach, agreements on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- manufacturing issues, including problems with manufacturing, supply quality, compliance with current good manufacturing practices, or cGMP, or obtaining sufficient quantities of a product candidate from third parties for use in a clinical trial;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide to conduct additional clinical trials or abandon the development of such product candidates, or regulators may require us to do so;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors used in our clinical trials, including any clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from clinical trial protocol or dropout of clinical trials, which may require that we add new clinical trial sites or clinical investigators;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response, serious adverse, undesirable or unacceptable side effects or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently plan, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these studies or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our product candidates; (ii) obtain approval for indications or patient populations that are not as broad as intended or desired; (iii) not obtain regulatory approval at all; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for use of the drug. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, the TGA, the NMPA, the EMA 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 it has reviewed and commented on the design for our clinical trials.

Our clinical trials are conducted in multiple jurisdictions, which may subject us to delays and expenses.

We are currently conducting clinical trials, through third-party CROs, in Australia and Taiwan and expect to further expand into other jurisdictions (see "Business" beginning on page 111 for our current plans for future clinical trials). There are risks inherent in conducting clinical trials in multiple jurisdictions, which may subject us to delays and expenses, such as:

- regulatory and administrative requirements of the jurisdiction where the study is conducted that could burden or limit our ability to conduct clinical trials;
- differing and conflicting regulatory requirements;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Our product candidates may cause serious adverse, undesirable or unacceptable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, and/or result in significant negative consequences following regulatory approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be serious adverse, undesirable or unacceptable side effects caused by our product candidates that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval by the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of our future preclinical studies and clinical trials could reveal a high and unacceptable severity or prevalence of steroidal adverse events. In such an event, our studies could be suspended or terminated and the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Adverse events related to our product candidates may affect patient recruitment or the ability of enrolled subjects to complete the study and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, the identification of serious adverse, undesirable or unacceptable side effects caused by any of our future approved product candidates may lead to potentially significant negative consequences, which include, but are not limited to, the following:

- suspension of our marketing of the product candidate;
- withdrawal or revocation by regulatory authorities of their approvals of or the licenses for the product candidate;
- the requirement by regulatory authorities to conduct additional clinical trials, add additional warnings to, or otherwise change, the label of the product candidate, such as a "black box" warning or contraindication, or create a medication guide outlining the risks of such side effects for distribution to patients;
- restriction on the distribution of the product candidate or imposition of burdensome implementation requirements on us through the establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy as may be required by the FDA, the TGA, the NMPA, the EMA or a comparable regulatory authority;
- the requirement by regulatory authorities to conduct specific post-marketing studies of the product candidate;
- the requirement to change the way the product candidate is distributed or administered;
- becoming subjected to regulatory investigations, government enforcement actions or litigation proceedings, and being held liable for harm caused to subjects or patients;

- the product becoming less competitive;
- removal of product candidates from the marketplace; and
- harm to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular product candidate that is approved and could significantly harm our business, results of operations and prospects.

Further, the use of our product candidates in conjunction with other therapies, may result in unique adverse events that could be exacerbated compared with adverse events from the use of our product candidates alone. Results of our studies could reveal a high and unacceptable severity or prevalence of adverse events. These types of adverse events could be caused by our product candidates and could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive indication or the delay or denial of regulatory approval by the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authority.

Results of preclinical studies and earlier clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and earlier clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authority may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different 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 dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

The manufacture of biopharmaceutical products is a complex process which requires significant expertise and capital investment, and if we encounter problems in establishing our manufacturing capabilities for clinical or commercial scale or in the manufacture of our future products, our business could suffer.

We currently do not have cGMP manufacturing capabilities and we are entirely dependent on third-party contractors to manufacture our product candidates for our clinical trials. The manufacture of biopharmaceutical products is a complex process, in part due to strict regulatory requirements. If we are unable to identify an appropriate production site or a suitable collaborator to develop our manufacturing infrastructure, or fail to do so in a timely manner, this may lead to significant delays in the clinical supply of our product candidates as well as the commercial manufacturing of our product candidates once regulatory and marketing approvals have been obtained. In turn, this could delay our clinical trials, negatively impact our ability to ultimately obtain regulatory approval and materially harm any future commercialization plans.

In addition, problems may arise during the manufacturing process for a variety of reasons, including, but not limited to, equipment malfunction, failure to follow specific protocols and procedures, problems with (including shortage of) raw materials, global supply chain issues, delays related to the construction of new facilities or expansion of any future manufacturing facilities, including changes in manufacturing

production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, increases in the prices of raw materials, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. For example, although we have not experienced material supply disruptions due to the COVID-19 pandemic, we cannot guarantee that we will not experience supply disruptions in the future due to COVID-19 or any other pandemic, epidemic or other public health crises, natural catastrophe or other disasters. If problems arise during the production of a batch of future products, that batch of future products may have to be discarded and we may experience product shortages or incur added expenses. This, as well as problems that may arise during the manufacturing process, could, among other things, lead to significant additional costs and/or delays, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before such product is released to the market, recall and product liability costs may also be incurred.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authority may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authority does not accept or approve our NDAs for any of our product candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other required trials or studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authority to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if any of our product candidates receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any future collaborators, to market the product.

Clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any future collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;

- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations, and could negatively impact our price of our ADS.

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, patient advocacy groups, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, patient advocacy groups and others in the medical community. Efforts to educate physicians, patients, patient advocacy groups and third-party payors on the benefits of our product candidates may require significant resources and may not be successful, and physicians and patients may prefer other drugs or product candidates to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or product candidates and may not become profitable.

The degree of market acceptance of our product candidates, if and only when they are approved for commercial sale, will depend on a number of factors, including, but not limited to, the following:

- the clinical indications for which our product candidates are approved;
- the degree to which physicians, hospitals, patient advocacy groups and patients consider our product candidates as safe and effective treatments;
- whether our product candidates have achieved the perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any adverse effects;
- product labeling or package insert requirements of the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities;
- timing of market introduction of our product candidates as well as competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement from third-party payors and government authorities in the United States, Australia, China or any other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

We face substantial competition, rapid technological change and the possibility that our competitors may discover, develop or commercialize drugs before we do or more successfully than we do, or develop therapies that are similar, more advanced or more effective than ours, each of which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidate.

The development and commercialization of new drugs is highly competitive and the biopharmaceutical industry is subject to rapid and significant technological change. We face competition with respect to our

product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from companies of all sizes around the world, including major and specialty pharmaceutical companies and generic drug companies. Specifically, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as LBS-008. Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of our competitors have significantly greater financial, technical, human and other resources, such as larger research and development staff and experienced marketing and manufacturing departments, and more experience in the development and regulatory approval process than we have. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval from the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products as well. For example, the NMPA has recently accelerated market approval of drugs for diseases with high unmet medical need. In particular, the NMPA may review and approve drugs that have gained regulatory market approval in the United States, the European Union or Japan in the recent ten years without requiring further clinical trials in China. This may lead to potential increased competition from drugs that have already obtained approval in other jurisdictions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our drug development programs.

Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective, safer or less costly than any product candidate that we may develop, or may achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. 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 product candidates that we may develop and commercialize.

While certain of our employees have limited experience in launching and marketing product candidates, we may not be able to effectively build and manage a sales network or benefit from the sales network of third-party collaborators.

We currently have no sales, marketing or commercial product distribution capabilities. Over time, we intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the drugs we develop or in particular regions or markets, we may pursue collaborative arrangements regarding the sales and marketing of such drugs into such regions or markets. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates, which may result in collaborative arrangements with less than optimal terms.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Even if we are able to commercialize any approved product candidates, reimbursement may be limited or unavailable in certain market segments for our product candidates, and we may be subject to unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for certain of our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved product candidates, and coverage may be more limited than the purposes for which the product candidates are approved by the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, 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 weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved product candidates could have a material adverse effect on our business, our operating results, and our overall financial condition.

Preliminary interim or "top-line" data that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish preliminary interim or "top-line" data from clinical trials. Positive preliminary data from such interim analyses may not be predictive of such trial's subsequent or overall results. Preliminary data are subject to the risk that one or more of the outcomes may materially change as more data become available. Additionally, preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Therefore, positive preliminary results in any ongoing clinical trial may not be predictive of such results in the completed 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 evaluate all data. As a result,

preliminary data that we report may differ from future results from the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary 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, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could significantly harm our business prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising product candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, often incomplete and rapidly evolving, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our product candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our product candidates, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on CROs and other third parties to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical studies and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, see "— Risks Related to Our Reliance on Third Parties — As we rely on third parties to conduct our preclinical studies, clinical trials, contract manufacture drug substances and drug products, and provide other important services related to product development, regulatory submissions, and commercialization, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, 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" below.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. The market opportunities for our product candidates, if approved, may be smaller than we anticipate.

We expect to initially seek approval of LBS-008 for the treatment of STGD1. Our projections of the number of patients with STGD1 and the portion of those patients that would benefit from treatment with LBS-008 are based on our beliefs and estimates, including data published by third parties, including scientific literature, patient foundations and publicly available databases, and on internally generated data and assumptions. While we believe our market size information is generally reliable, such information is inherently imprecise, and relies on our and third parties' projections, assumptions and estimates within our target market, which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors,

including those described in this prospectus. If such third-party or internally generated data prove to be inaccurate or we make errors in our projections, assumptions or estimates based on that data, our addressable target market opportunity and/or our future growth rate may be less than we currently estimate. Further, new sources may reveal a change in the estimated number of patients, and the number of patients may turn out to be lower than expected. Additionally, the potential addressable patient population for our current programs or future product candidates may be limited. Accordingly, the information regarding the size of our addressable market opportunity included in this prospectus should not be taken as indicative of our future growth.

The ultimate market opportunity for our product candidates will depend on, among other things, the final labeling for such product candidates as agreed with the FDA, the TGA, the NMPA, the EMA and any other applicable comparable foreign regulatory authorities, acceptance by the medical community and patient access, potential competition and drug pricing and reimbursement. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, which may significantly harm our business, financial condition, results of operations and prospects.

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

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates.

Regardless of the merits or eventual outcome, liability claims may result in significant negative consequences to our business and prospects, including, but not limited to:

- decreased demand for our product candidates or any resulting products;
- injury to our reputation;
- withdrawal of other clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management’s time and resources;
- substantial monetary awards to study participants or patients; and
- a decline in the market price of our ADSs.

We currently carry liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or which is in excess of the limits of our insurance coverage. Our insurance policies also contain various exclusions, and we may be subject to particular liability claims for which we have no coverage. We will have to pay any amount awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, if we cannot successfully defend ourselves against such claims, we may incur substantial liabilities and be required to suspend or delay our ongoing clinical trials. Even a successful defense would require significant financial and management resources.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved product candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved

product candidates and, in turn, may adversely affect our sales and profitability in the United States, China and other countries where we plan to commercialize our products. Unapproved foreign imports of prescription drugs are illegal under the current laws of the United States, Australia and China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside the United States, Australia, China or other countries where we operate or expect to operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside the United States, China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products could quickly erode the demand for our future approved product candidates.

In addition, counterfeit pharmaceutical products are not expected to meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have recorded net cash outflow from operating activities since our inception. Even if we consummate this offering, we will need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates.

Since our inception, our operations have consumed substantial amounts of cash. We raised a total of approximately $40.6 million in pre-IPO financing in the past three fiscal years and the net cash used in our operating activities was approximately $4.4 million for the year ended December 31, 2020 and approximately $7.5 million for the year ended December 31, 2021.

We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. Furthermore, following the completion of this offering, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our financing to fund our operations may be adversely affected, delayed or fail to raise because of capital market environment, valuation of our company or the progress of our competitors. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

The net proceeds of this offering and our existing cash on hand will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all.

Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our existing cash on hand will not be sufficient to enable us to meet our short-term obligations or long-term plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future clinical trials. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the number of future product candidates that we pursue and their development requirements;
- the scope, progress, timing, results and costs of discovering, researching and developing product candidates, and conducting preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with expanding our supply chain;
- 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 establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such collaborations and arrangements;
- the extent to which we acquire or in-license other product candidates and technologies;
- our headcount growth and associated costs;
- the costs, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- the impact of COVID-19 on the initiation or completion of preclinical studies or clinical trials and the supply of our product candidates;
- costs required to ensure that our and any of our partners' business arrangements with third parties comply with applicable healthcare laws and regulations; and
- the costs of operating as a public company in the United States.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We are a global clinical-stage biopharmaceutical company with a limited operating history and no history of commercializing pharmaceutical products. Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and clinical trials for our product candidates. We have not yet demonstrated an ability to successfully obtain marketing approvals for or commercialize our product candidates or manufacture our product candidates on a scale sufficient to supply the commercial markets. We have no products approved for commercial sale and have not generated any revenue from product sales. Consequently, any predictions about our future success 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 and the fact that we have yet to commercialize a pharmaceutical product, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our

prospects for future performance. As a result, any assessment of our future performance or viability is 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.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability. If we are unable to achieve or sustain profitability, the market value of our ADSs will likely decline.

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. Our net losses were approximately $5.8 million and $9.7 million for the years ended December 31, 2020 and 2021, respectively. As of December 31, 2021, we had an accumulated deficit of approximately $27.2 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of our preferred stock. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our lead product candidate, LBS-008;
- initiate and continue research, preclinical and clinical development efforts for any future product candidates;
- seek regulatory approvals for our product candidates;
- commercialize our product candidates once we have obtained marketing approval;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- hire additional clinical, operational, financial and administrative, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;
- seek to identify additional product candidates and technologies;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend any intellectual property-related claims;
- acquire or in-license other product candidates, intellectual property and technologies;
- enter into out-licensing and co-development collaborations consistent with our global strategy;
- add equipment and physical infrastructure to support our research and development
- incur setbacks or delays to the initiation or completion of preclinical studies, drug development and/or clinical trials due to COVID-19; and
- incur any disruption or delays to the supply of our product candidates due to COVID-19.

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, and obtaining marketing approval for, our product candidates, manufacturing, marketing and selling, either directly or through collaborations, those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may not 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. In the process of attempting to become and remain profitable, 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 partially on the rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of payments that we receive from or pay to third parties. If any of our product candidates fails during preclinical studies or clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and the value of our Company. This could impair our ability to raise future capital, maintain our research and development efforts, proceed with commercialization efforts, expand our business or otherwise continue our operations, and could harm our competitive position in the marketplace. A decline in the value of our Company also could cause you to lose all or part of your investment.

Our recurring losses from operations could continue to raise substantial doubt regarding our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

We have incurred significant operating losses since our inception and have never generated product revenue, and it is possible we will never generate product revenue or profit. Accordingly, we have concluded that substantial doubt exists regarding our ability to continue as a going concern. Meaningful revenues will likely not be available until and unless any current or future product candidate is approved by the FDA, the NMPA, the EMA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. Our financial statements appearing at the end of this prospectus have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of these uncertainties related to our ability to operate on a going concern basis. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our independent registered public accounting firm included an explanatory paragraph in its audit report on our financial statements as of and for the year ended December 31, 2021, stating that we have an accumulated deficit, incurred recurring losses from operations, have an expectation of continuing operating losses for the foreseeable future, and need to raise capital to finance our future operations, which raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Further, if we cannot continue as a going concern, we may be forced to discontinue operations and liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, which would cause holders of our ADSs and our shareholders to lose all or a part of their investment.

Our ability to use our net operating loss carry forwards may be subject to limitation.

As of December 31, 2020 and 2021, our subsidiaries had U.S. net operating loss carryforwards for federal and state tax purposes of approximately $3.7 million and $4.0 million, respectively. If not utilized, the federal and state net operating loss carryforwards incurred before January 1, 2018 will begin to expire in 2036, and the remaining can be carried forward indefinitely but utilization is limited to 80% of our taxable

income in any given tax year based on current federal tax laws. The timing and manner in which we may utilize net operating losses may be limited by tax rules regarding changes in ownership and a lack of future taxable income could adversely affect our ability to utilize our net operating losses before they expire. In general, net operating losses in one country cannot be used to offset income in any other country and net operating losses in one state cannot be used to offset income in any other state. Accordingly, we may be subject to tax in certain jurisdictions even if we have unused net operating losses in other jurisdictions. Furthermore, each jurisdiction in which we operate may have its own limitations on our ability to utilize net operating losses or tax credit carryovers generated in that jurisdiction. These limitations may increase our U.S. federal, state or foreign income tax liability.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances, government grants or subsidies. 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 additional indebtedness or the issuance of certain equity securities could give rise to increased fixed payment obligations and also result in certain 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.

If we were to enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party certain of our rights to technologies, future revenue streams, research programs or product candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize on our own or reserve for future potential arrangements when we might be more likely to achieve more favorable terms.

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

The regulatory approval processes of the FDA, the TGA, the NMPA, the EMA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain the approval of the FDA, the TGA, the NMPA, the EMA and other comparable regulatory authorities is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain following the commencement of preclinical studies and clinical trials and timing can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, each of which may cause delays in regulatory review. However, we cannot guarantee that we will be able to obtain regulatory approvals in a timely manner, or at all, for our existing product candidates or any product candidates that we may discover, in-license or acquire and seek to develop in the future. Our product candidates may not be effective, may be only moderately effective or may prove to have serious adverse, undesirable or unacceptable side effects, toxicities or other characteristics that may preclude regulatory approval or prevent or limit commercial use.

Our product candidates could be delayed in receiving or fail to receive regulatory approval of the FDA, the TGA, the NMPA, the EMA or a comparable regulatory authority for many reasons, including, but not limited to, the following:

- disagreement with the number, design, size, conduct or implementation of our clinical trials; For example, the regulatory authorities may disagree with our clinical trial endpoints, the subjects of our clinical trials, the number of patients enrolled, or the disease we choose to treat with our product candidates;

- delays in obtaining regulatory approval or ethics committee approval to commence a clinical trial;
- failure to demonstrate that a product candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our CROs, clinical trial sites or investigators to comply with relevant current good clinical practice, or cGCP, requirements or failure of our clinical trial process to pass GCP inspections;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from animal testing or preclinical studies or clinical trials;
- insufficient data collected from the clinical trials of our product candidates to support the submission and filing of an NDA, or other submissions or to obtain regulatory approval;
- failure of our product candidates to pass current good manufacturing practice, or cGMP, inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the FDA, the TGA, the NMPA, the EMA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the FDA, the TGA, the NMPA, the EMA or comparable regulatory authorities of deficiencies related to our manufacturing processes or the facilities of third-party CMOs with whom we contract for preclinical, clinical and commercial supplies;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval;
- our CROs taking actions that materially and adversely impact our clinical trials; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The FDA, the TGA, the NMPA, the EMA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials or approve a product candidate with an indication that is not desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We initially intend to focus our activities on our primary markets of the United States, Australia, Taiwan, Europe and China. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; voluntary or mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions; fines; refusals of government contracts; providing restitution; undergoing disgorgement; or other civil or criminal penalties. Failure to comply with these regulations could have a material adverse effect on our business.

The FDA, the TGA, the NMPA, the EMA and any other regulatory agencies may actively enforce the laws and regulations prohibiting the promotion of drugs for off-label uses.

If any of our product candidates is approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, the TGA, the NMPA, the EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the TGA, the NMPA, the EMA or such other regulatory agencies as reflected in the product's approved labeling in applicable jurisdiction(s). If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. For example, the U.S. federal government has successfully pursued judgments for large civil and criminal fines and penalties against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The U.S. federal government has also successfully pursued consent decrees, deferred prosecution agreements, and injunctions under which specified promotional conduct is changed or curtailed, and compliance is closely monitored. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if we obtain approval of our product candidates in one jurisdiction, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize the maximum market potential of our product candidates.

We cannot commercialize product candidates in the United States, Australia, China, Europe or another jurisdiction outside of the United States without first obtaining regulatory approval from the FDA, the TGA, the NMPA, the EMA or 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 the United States 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 regulatory approval in one jurisdiction, we would still need to seek approval in any other jurisdictions where we plan to market the product. Any safety issues, product recalls or other incidents related to products approved and marketed in one jurisdiction may impact approval of those products in other jurisdictions. Further, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere.

Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and the majority of our employees have limited experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, the target market for our product candidates will be reduced and our ability to realize the maximum market potential of any product candidate that we develop will be adversely affected.

The applicability of clinical data generated outside the United States is subject to FDA concurrence for its suitability in supporting approval in the United States. If the FDA or comparable regulatory agencies do not accept data from such trials, our development plans may be delayed, which could materially harm our business.

Certain of our clinical trials supporting our lead product candidate were, and continue to be, conducted outside the United States in foreign countries such as Australia and Taiwan, and we, or any future collaborators, may choose to conduct one or more clinical trials or a portion of such clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may

be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with cGCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. LBS-008 has received Orphan Drug Designation in the United States and Europe, which provides for 7 years and 10 years, respectively, of market exclusivity from approval for STGD1. LBS-008 has also received Rare Pediatric Disease Designation in the United States. We, or any future collaborators, may seek orphan drug designations for other product candidates and may be unable to obtain such designations.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA will be precluded from approving another marketing application for the same product for that indication and the EMA will be precluded from accepting an application for, or granting a marketing authorization for, a “similar medicinal product” for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. In addition, if a competitor’s drug receives marketing approval earlier than us in Europe which is deemed by the EMA as a “similar medicinal product” of any of our product candidates, then we may not be able to obtain orphan drug exclusivity for that product candidate. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, in both the U.S. and Europe, if a different drug is subsequently approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity, which only protects against approval of the “same” drug for the same indication.

Although we may pursue expedited regulatory approval pathways in the United States for certain of our product candidates, they may not qualify for expedited development or, if they do qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA's expedited programs and we may pursue one or more of these expedited programs, we cannot be certain that any of such product candidates will qualify for such programs or that we will be able to maintain such qualifications.

If we apply for any expedited program for any of our product candidates, the FDA may determine such product candidate, its proposed indication or other aspects of our clinical development plans do not qualify for such an expedited program. Even if we are successful in obtaining a designation or access to any expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data from our clinical development programs or if the FDA otherwise finds that relevant criteria are no longer being met. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for any of our product candidates.

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

Even after obtaining regulatory approval from the FDA, the TGA, the NMPA, the EMA or a comparable regulatory authority, our product candidates will be subject to, among other things, ongoing regulatory requirements governing the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, recordkeeping data management and submission of safety, efficacy and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any CMC, variations, continued compliance with cGMPs, and cGCPs and potential post-approval studies for the purposes of license renewal. Violations of the Federal Food, Drug, and Cosmetic Act, or the FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

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 studies, including Phase 4 studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the FDA, the TGA, the NMPA, the EMA 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 CMOs 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;
- fines, warning letters or holds on our clinical trials;
- refusal by the FDA, the TGA, the NMPA, the EMA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the FDA, the TGA, the NMPA, the EMA or comparable regulatory authorities to accept any of our IND approvals or NDAs;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

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 slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and prospects.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable regulatory authorities (in some jurisdictions, the hospitals) to accept application, review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and comparable regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign manufacturing facilities and products, postponed routine surveillance inspections of domestic manufacturing facilities and is conducting only teleconference meetings. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict post-approval activities and affect our ability to sell profitably any product candidates for which we obtain marketing approval.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability to utilization covered by Medicaid managed care plans;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report to the Centers for Medicare & Medicaid Services, or the CMS, financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report to the FDA drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative and regulatory proposals have been made to expand post-approval requirements, to restrict sales and promotional activities for pharmaceutical products and to control rising market prices for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, what the impact of such changes on the marketing approvals, if any, of our product candidates may be, or whether pricing strategies may be constrained. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to protect our proprietary technology and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of April 20, 2022, our portfolio of owned, co-owned, and in-licensed patents consisted of 19 issued U.S. patents (inclusive of allowed applications), 8 pending U.S. patent applications, 14 issued foreign patents (inclusive of allowed applications) and 29 pending foreign patent applications, providing protection in the United States and China, among other regions. We seek to protect and intend to seek to protect the product candidates and technology that we consider commercially important by filing patent applications and requiring our licensor to file licensed patent applications in the United States, European Union, China, Japan, South Korea, Taiwan, Canada, Australia, India and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our owned, co-owned, and in-licensed 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. The patent examination process may require us to narrow the scope of the claims of our owned, co-owned, and in-licensed pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure that all of the potentially relevant prior art relating to our owned, co-owned, and in-licensed 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.

Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our product candidates. We may become involved in interference, *inter partes* review, post grant review, ex parte reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. Thus, even if our owned, co-owned, and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Our competitors may be able to circumvent our owned, co-owned, and in-licensed patents by developing similar or alternative technologies or product candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned, co-owned, and in-licensed patents may be challenged in the courts or patent offices in the United States and other countries. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such assets might expire before or shortly after such assets are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned, co-owned, and in-licensed patents or narrow the scope of our patent protection. Under the America Invents Act enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. 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, co-owned, and in-licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

We depend on intellectual property licensed from third parties, and our current and future licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent on patents, know-how and proprietary technology licensed from others. We are party to an exclusive license agreement with Columbia University under which we are granted rights to intellectual property that are necessary to our business and we may enter into additional license agreements in the future. Our existing license agreement with Columbia University imposes on us, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, requiring timely achievement of development milestones for which we are obligated to report periodically on our progress and timely payment of milestone payments and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, and our licensor does not agree to adjust the deadlines by which milestones must be achieved or we are subject to bankruptcy-related proceedings, the licensor may have the right to convert our exclusive license to a nonexclusive license with no right to sublicense or terminate the license, in which event we would not be able to develop or market products covered by the license.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in accordance with our views or in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our licensor is required to consult with us and keep us informed on the status of all licensed patents and applications, so long as we do not challenge the validity, scope, or enforceability of any licensed patent or application. It is also possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests.

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 patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- 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.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on reasonable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under our patent license with a third party, we could lose license rights that are important to our business.

We are party to an exclusive license agreement with Columbia University pursuant to which we in-license key patent and patent applications necessary to pursue marketing and selling of our product candidates. Our existing license agreement with Columbia University imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensor may elect to convert the license from an exclusive license to a nonexclusive license without the right to sublicense or initiate legal proceedings against third party patent infringers or terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by our licensor have been or will

be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Intellectual property discovered through U.S. government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Our licensed and co-owned patents and pending patent applications have been generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world could be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and, further, may export otherwise infringing product candidates to territories, where we have patent protection, but enforcement rights are not as strong as those in the United States. These product candidates may compete with our product candidates, and our owned, co-owned, and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, are not as favorable as other jurisdictions with regard to the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our owned, co-owned, and in-licensed patents or marketing of competing product candidates in violation of our proprietary rights generally and specifically in certain jurisdictions. Proceedings to enforce our patent rights in other 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 and our owned, co-owned, and in-licensed patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not

prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, 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 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.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In some circumstances, we are dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our owned, co-owned, or in-licensed patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

The COVID-19 pandemic may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and product candidates.

Terms of our future owned, co-owned, or in-licensed patents may not be sufficient to effectively protect our product candidates and business in certain jurisdictions.

In many countries where we file applications for patents, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if we obtain patents covering our product candidates, we may still be open to competition from other companies, as well as generic medications once the patent life has expired for a drug. For example,

while there are patent regulations in the PRC in respect of regulatory data protection of new drugs containing new chemical components, there are currently no other clear mechanisms providing patent term extension or patent linkages for other drugs in the PRC. Therefore, it is possible that a lower-cost generic drug can emerge onto the market much more quickly. For additional information regarding generic competition for our products in China, see "— Risks Related to Our Intellectual Property — The uncertainty of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China" below. These factors may result in weaker protection for us against generic competition in jurisdictions similar to the PRC than could be available to us in other jurisdictions, such as the United States. In addition, patents which we expect to obtain in the PRC or similar jurisdictions may not be eligible to be extended for patent terms lost during clinical trials and the regulatory review process.

If we are unable to obtain patent term extensions or if such extensions are less than requested for, our competitors may obtain approval of competing products following our patent expirations and our business, financial condition, results of operations and prospects could be materially harmed as a result.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. It is unclear whether the FDA will treat the active ingredients in our product candidates as NCEs and, therefore, afford them five years of NCE data exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval, subject to the requirement that the ANDA applicant certifies to any patents listed for our products in the Orange Book. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

The uncertainty of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

In the United States, the Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act, or the Hatch-Waxman Act, provides the opportunity for patent-term restoration, meaning a patent term extension of up to five years to reflect patent term lost during

certain portions of product development and the FDA regulatory review process. The Hatch-Waxman Act also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Finally, the Hatch-Waxman Act provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the product candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

Depending upon the timing, duration and specifics of any FDA marketing approval process for any product candidates we may develop, one or more of our owned, co-owned, or in-licensed U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office, or USPTO, in conjunction with the FDA. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

In China, however, laws on patent term extension, patent linkage, and data exclusivity (referred to as regulatory data protection) are still developing. Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. According to the Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, dated January 15, 2020, the PRC government undertook to provide patent term extensions to compensate for unreasonable delays that occur in granting the patent or during pharmaceutical product marketing approvals. In October 2020, the Standing Committee of the National People's Congress, or the NPC, promulgated the newly amended PRC Patent Law, which became effective in June 2021. The newly amended PRC Patent Law includes provisions for patent linkage and patent term extension. However, considering that the newly amended PRC Patent Law is relatively new, it is unclear how it will be implemented, and there exist great uncertainties with respect to its interpretation and implementation by the authorities. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. If we are unable to 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 our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging

patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

For example, the America Invents Act includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned, co-owned, and in-licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned, co-owned and in-licensed patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Although we do not believe that our currently owned, co-owned, and in-licensed issued patents and any patents that may issue from our owned, co-owned, and in-licensed pending patent applications directed to our product candidates, if issued in their currently pending forms, will be found invalid based on any recent decisions by the U.S. Congress, federal courts and the USPTO, we cannot predict how their future decisions may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect this trade secret and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, CMOs, consultants, advisers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed. In addition, we face the risk of cybercrime. For instance, someone could hack our information networks and gain illicit access to our proprietary information, including our trade secrets. Even if we are successful in prosecuting such claims, any remedy awarded may be insufficient to fully compensate us for the improper disclosure or misappropriation. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

We also may be subject to claims that our employees, consultants, or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisers, including our senior management, were previously employed at or contracted by other biotechnology or pharmaceutical companies, including our competitors

or potential competitors. Some of these employees, consultants, and advisers, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, and furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our therapeutic programs and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. 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, intellectual property that is important to our therapeutic programs and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 research and 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 research and development activities 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 research and development activities, our ability to commercialize one or more product candidates, or both.

Most 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 clinical trials, continue our internal research activities, in-license needed technology in the future, or enter into strategic collaborations 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 not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Claims that our product candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our product candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our product candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are

issued in the future. In the event that a third party has also filed a patent application covering one of our product candidates or a similar invention, our owned, co-owned, or in-licensed patent application may be regarded as a competing application and may not be issued in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights is likely to be costly and time-consuming, regardless of the outcome. 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. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated losses. Any claims of infringement, misappropriation or other violation of intellectual property made against us could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering one or more of our product candidates 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. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our owned, co-owned, or in-licensed patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, non-enablement, lack of sufficient written description or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, the State Intellectual Property Office, or the SIPO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we and our licensor 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. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our owned, co-owned, or in-licensed 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, the court 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 owned, co-owned, or in-licensed patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future product candidates. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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 common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. 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.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Because the development of certain of our product candidates may in the future involve the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights.

We may be unable to acquire or in-license any compositions, methods of use, or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights 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. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

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 the date of this prospectus, we had one registered trademark in the United States, one registered trademark in EU, two registered trademarks in China, one registered trademark in Hong Kong, and one registered trademark in Japan, and one trademark application pending in Canada. 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.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own, co-own or exclusively license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, co-own or exclusively license, which could result in the patents applied for not being issued or being invalidated after issuing;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our 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 our intellectual property rights;
- it is possible that the pending and future patent applications that we own, co-own, or in-license will not lead to issued patents;
- issued patents that we own, co-own or in-license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- we or our licensors 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 out 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 drugs for commercialization in our major markets;
- we may fail to 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; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business and future prospects.

Risks Related to Our Industry, Business and Operations

If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence and the market price of our ADSs may be materially and adversely affected.

Prior to this offering, we have been a private company with limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. However, in connection with the audit of our consolidated financial statements for the year ended December 31, 2021, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting as well as other control deficiencies.

As defined in the standards established by the United States Public Company Accounting Oversight Board of the United States (PCAOB), a “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness identified is related to our lack of formal policies and procedures to

establish risk assessment process and internal control framework. We are currently in the process of implementing a number of measures to address the material weakness and deficiency that has been identified. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Internal Control Over Financial Reporting." However, we cannot assure you that these measures may fully address the material weakness and deficiency in our internal control over financial reporting or that we may conclude that they have been fully remediated.

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

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to anticipate and identify accounting issues, or other risks critical to financial reporting that could materially impact the consolidated financial statements. Generally, if we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations and lead to a decline in the trading price of our shares. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management. We have entered into employment agreements with our executive officers, but each of them may terminate their employment with us at any time with or without prior written notice. In addition, we currently do not have "key-man" insurance for any of our executive officers or other key personnel.

Recruiting, retaining and motivating qualified management, scientific, clinical, manufacturing and sales and marketing 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 research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, 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. 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 biopharmaceutical 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 public company, which may require us to recruit more management personnel.

Competition for skilled personnel is intense, particularly in the biotechnology industry. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. This competition may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed or may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business will be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, the TGA, the NMPA, the EMA and comparable regulatory authorities in other jurisdictions, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to

comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide accurate information to the FDA or comparable non-U.S. regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

In order to execute our business plans, we expect that we will need to significantly increase the number of our employees and consultants and the scope of our operations, particularly in the areas of research and development, regulatory affairs and business development. We currently rely on some of the employees of our ultimate controlling shareholder to administer and supervise some of the clinical operations of our Company. See “Related Party Transactions — Other Transactions with Related Parties.” Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage our anticipated future growth, we will need to 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, 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 our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a material adverse effect on our business.

In addition, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed or that we can find qualified replacements. Furthermore, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

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

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under applicable laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain liability insurance covering our clinical trials as well as certain other types of insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors including, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

In addition, there is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa and over the conflicts involving Ukraine, Syria and North Korea. There have also been concerns relating to trade disputes between the United States and China and regarding the relationship among China and other Asian countries, which may result in or intensify potential conflicts in relation to territorial disputes among such countries. In addition, the United Kingdom held a referendum on June 23, 2016 on its membership in the European Union, in which a majority of voters in the United Kingdom voted to exit the European Union (commonly referred to as "Brexit"). Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets. More recently, the occurrence of the COVID-19 pandemic has caused volatility in the global financial markets and threatened a slowdown in the global economy. For a detailed discussion regarding the potential impact of the COVID-19 pandemic, see "— Risks Related to Our Industry, Business and Operations — Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses" below. It is unclear whether these challenges and uncertainties and the issues arising from the COVID-19 pandemic will be contained or resolved, and what effects they may ultimately have on the global political and economic conditions in the long term.

Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business.

We lease properties for our offices and laboratories. See "Business — Facilities" for more details of our leased properties. We may not be able to successfully extend or renew such leases upon expiration of the current term on commercially reasonable terms or at all, and may therefore be forced to relocate our affected operations. This could disrupt our operations and result in significant relocation expenses, which could adversely affect our business, financial condition and results of operations. In addition, we compete with other businesses for premises at certain locations or of desirable sizes. As a result, even though we could extend or renew our leases, rental payments may significantly increase as a result of the high demand for the leased properties. In addition, we may not be able to locate desirable alternative sites for our current leased properties as our business continues to grow and failure in relocating our affected operations could adversely affect our business and operations.

Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the Trade Laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with the Trade Laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government

healthcare programs, as well as reputational harm. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

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

We may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic collaboration may entail numerous risks, including, but not limited to:

- increased operating expenses and working capital and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- challenges with assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such a strategic merger or acquisition;
- the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs;
- material weakness arising in our internal control over financial reporting because of a weaknesses in the acquired company's financial systems and controls; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

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

The tax laws of the jurisdictions in which we operate may adversely affect our business and our tax results.

The tax laws applicable to our business activities are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, laws, practices, treaties or regulations or changes in the interpretation thereof by the authorities in jurisdictions in which we do business.

Moreover, we conduct operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. 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 jurisdiction in which we operate 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. Furthermore, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. Such circumstances could adversely affect our financial condition, results of operations and cash flows.

If we, our CROs or our other contractors or consultants fail to comply with 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 and third parties, such as our CROs or other contractors or consultants, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and

the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our development of our product candidates.

Despite the implementation of security measures, our internal information technology systems and those of our 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. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. 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. Likewise, we partially rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, personally identifiable information about our employees, intellectual property, and proprietary business information. Additionally, our CROs will collect and store sensitive data, such as legally protected patient health information, when conducting our clinical trials. 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 system and data and leave us unable to utilize key business systems or access important data needed to operate our business, including conducting research and development, gaining regulatory approval for our product candidates or manufacturing and selling our products. Our collaborators, contractors or consultants 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. 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 may experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks, or other cyber-attacks. The number and complexity of these threats may 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 privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We are taking measures and plan to continue to take measures to develop and maintain systems and controls designed to prevent, identify and mitigate these events from occurring. The development and maintenance of these systems, controls and processes is costly and requires 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 collaborators, contractors, or our consultants' 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 cyberattack, security breach, 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.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

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 have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection. Additionally, the interpretation and application of data protection laws in jurisdictions applicable to us are often uncertain and in flux. We therefore face uncertainty as to the exact interpretation of any such requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of new laws.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels, including federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. 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.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/ 679, or the GDPR, which became effective in May 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including, but not limited to, requirements

relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (including to the United States), providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals and recordkeeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10.0 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20.0 million or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. National laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty.

We expect that we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws 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, damages, injunctive relief and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and otherwise materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical collaborators 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. In addition, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant legal and financial exposure and reputational damage that could potentially have an adverse effect on the development of our product candidates and our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Natural disasters, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business or whether our studies are conducted. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks, or public health threats and epidemics, including the global health concerns relating to the COVID-19 pandemic. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism, or public health threats, may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

For example, in March 2020, the WHO categorized COVID-19 as a pandemic. COVID-19 continues to spread throughout the United States and other countries across the world, and the duration and severity of its effects are currently unknown. The spread of COVID-19 has impacted the global economy and has had an impact on our operations, including delays in our clinical trial activities. 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 requiring many employees to work remotely. For example, we have suspended non-essential travel worldwide for our

employees. Although we believe that COVID-19 has had a limited impact on our operations as of the date of this prospectus, we have experienced delays in the enrollment of patients in our clinical trials. For example, we have experienced a few months' delay in commencement of patient enrollment in Australia that was caused by COVID-19, which was not material to the Company. Our clinical trials could be further delayed due to government orders and site policies on account of the pandemic. Some patients may be unwilling or unable to travel to study sites, enroll in our studies or comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to source or deliver components or raw materials necessary for our clinical supply on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption and in reduced operations or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

Further, as a result of the COVID-19 public health emergency, we may be required to develop and implement additional clinical trial policies and procedures based on new guidance and regulatory requirements promulgated by the FDA or other regulatory authorities. For example, the FDA issued guidance in March 2020, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Additional COVID-19 related guidance released by the FDA includes guidance addressing resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates.

We continue to assess the impact that the COVID-19 pandemic may have on our ability to advance the testing, development and manufacturing of our product candidates, including as a result of adverse impacts on the research sites, service providers, vendors, or suppliers on whom we rely, or to raise financing to support the development of our product candidates. Additionally, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations, increase the risk of a cybersecurity incident, create data accessibility concerns and make us more susceptible to communication disruptions. The COVID-19 pandemic has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. No assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, particularly in the event the current situation worsens, for example, with second or third waves of the pandemic, but if we or any of the third parties on whom we rely or with whom we conduct business, 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 adversely impacted.

The extent to which the COVID-19 pandemic or other epidemics or pandemics may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the pandemic, the severity of the COVID-19 pandemic or the effectiveness of actions to contain and treat the COVID-19 pandemic, particularly in the United States and other geographies where we or our third party suppliers, clinical trial sites, CROs and CMOs operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, 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, our results of operations and financial condition.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are or will be subject to rules and regulations by various governing bodies, including, for example, once we become a public company, the U.S. Securities and Exchange Commission, or the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded, and the various regulatory authorities in the Cayman Islands, Taiwan, the PRC and Australia, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Further, there could be unanticipated changes in existing regulatory requirements. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

We have granted, and will continue to grant, options and other types of awards under our equity incentive plans, which may result in increased share-based compensation expenses and dilution to our existing shareholders and holders of our ADSs.

We have adopted the Belite Bio, Inc Amended and Restated Share Incentive Plan, or the 2020 Share Incentive Plan, and the 2022 Performance Incentive Plan for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with ours. The 2022 Performance Incentive Plan is expected to become effective upon the completion of this offering. As of the date of this prospectus, options to purchase a total of 1,982,561 ordinary shares have been granted and are outstanding under the 2020 Share Incentive Plan. As of the date of this prospectus, no award has been granted or is outstanding under the 2022 Performance Incentive Plan. See “Management — Share Incentive Plans.”

We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations. Furthermore, the granting of share-based compensation will lead to dilution of our existing shareholders, including any holders of our ADSs. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective equity incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this offering.

If we fail to comply with certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, we could be subject to serious consequences and significant expenses that could have a material adverse effect on our business, financial condition and results of operations, and our reputation may be harmed.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, collectively, Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly,

corrupt or improper payments or anything else of value to or from recipients in the public or private sector. In particular, the FCPA generally prohibits us from making payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery and corruption laws of other jurisdictions. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also have significant non-U.S. activities that we expect to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the Trade Laws.

Our business may be exposed to foreign exchange risks.

We operate internationally and conduct clinical trials in multiple jurisdictions and thus we have expenses denominated in local currencies in multiple jurisdictions in connection with, among other things, our sponsored clinical trials, purchase of drug product for our clinical trials, process development and the prosecution and maintenance of our intellectual property portfolio. As a result, we are exposed to foreign currency exchange risk, as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. In accordance with our business decisions, our exposure to this type of risk could change depending on:

- the currencies chosen when agreements are signed, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on product candidates; and
- our policy for insurance coverage.

Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of 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.

We currently have no operations in China although we have established a subsidiary in each of Hong Kong and China. However, we may in the future elect to conduct clinical trials for our product candidates in China or expand our operations into China (see “Business” beginning on page 111 for our current plans for future clinical trials), and therefore our financial condition and results of operations may be affected by economic, political and legal developments in China. The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industrial development by imposing industrial policies, and change of enforcement practice of such rules and policies can occur quickly with little advance notice. The PRC government also exercises significant control over China’s economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past four decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. Our

business, financial condition and results of operations could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us.

In addition, the PRC government had, in the past, 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. 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. In July 2021, the Chinese government provided new guidance on strengthening supervision on China-based companies raising capital outside of China. In addition, the Chinese government further issued certain drafts of regulations regarding internet data security which require certain China-based data processors to conduct a cyber security review before their overseas listing. 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 believe we are not regarded as such data processors currently, as we expect to expand our operations in China (see "Business" beginning on page 111 for our current plans for future clinical trials), 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.

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 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. 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 variable interest entities ("**VIEs**") structures. We do not have a VIE structure and are not in a restricted foreign investment industry. 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 "it 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.

We currently have no operations in China although we have established a subsidiary in each of Hong Kong and China. However, due to the extraterritorial reach (the so-called "long arm provisions") under the current PRC laws and regulations, 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 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. Although as of the date of this prospectus, we do not expect to be materially affected by the foregoing statements, 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.

In the event that we elect to carry out clinical trials in China and/or to expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations promulgated by the PRC government may adversely affect our profitability or impose additional compliance burdens on us.

As required under the NMPA regulations, we established a subsidiary in China with an aim to serve as the applicant for the planned clinical trials relating to our drug candidates in China. Our PRC subsidiary currently has no substantive operations, and no clinical trial for our drug candidates may be conducted in China until relevant approvals from the NMPA are obtained. There is no indication as to whether the NMPA would approve our proposed application for clinical trial or when such NMPA approval could be obtained. In addition, our PRC subsidiary is not required to obtain any specific license or permits other than the NMPA approval to conduct clinical trials in China. In the event that we elect to carry out clinical trials in China after relevant NMPA approval is obtained (see "Business" beginning on page 111 for our current plans for future clinical trials) and/or expand our operations into China in the future, we would be required to comply with relevant PRC laws and regulations in relation to our clinical trials and operations.

The PRC pharmaceutical industry is subject to extensive government regulation and supervision as well as monitoring by various government authorities. In particular, the current regulatory framework addresses substantially all aspects of a pharmaceutical company's operations, including approval, production, licensing, certification requirements and procedures, periodic renewal and reassessment processes, registration of new drugs, quality control, pricing of pharmaceutical products and environmental protection. There can be no assurance that the legal framework, licensing and certification requirements or enforcement trends in our industry will not change in a manner that may result in increased costs of compliance, or that we will be successful in responding to such changes. We may also be subject to the risk of adverse changes to favorable governmental policies, and the introduction of unfavorable governmental policies on the pharmaceutical industry. The costs we incur to comply with these laws and regulations may materially increase our total costs and decrease any potential profits. Any violation of these laws, rules or regulations or our failure to obtain any required approvals or permits may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligations to take rectification measures.

Other than the industry specific laws and regulations that are applicable to the biotechnology or pharmaceutical companies, we may also be subject to laws and regulations promulgated or implemented by

other regulatory authorities in China concerning cyber security and data protection. Regulatory authorities in China have implemented and may consider to implement additional legislation concerning data protection. For example, China's Cyber Security Law, which became effective in June 2017, created China's first national-level data protection for "network operators," which may include all organizations in China that provide services over the Internet or another information network. Various regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Drafts of some of these measures have now been published, including the draft rules on cross-border transfers published by the China Cyberspace Administration in 2017 and 2019, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, the Standing Committee of the National People's Congress of the People's Republic of China, or SCNPC, promulgated the Data Security Law of the People's Republic of China, or 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. A similar security assessment mechanism was also included in the Personal Information Protection Law, or the Personal Information Protection Law, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

Under the Cyber Security Law and Data Security Law, in the event that we elect to carry out clinical trials in China and/or to expand our operations into China in the future, (i) we may be 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; (ii) we may need to classify and take appropriate measures to address risks created by our data processing activities and use of networks; and (iii) we may 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. We may also be required to disclose to regulators businesssensitive 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 disclosing such data may be subject to security review or prior approval by relevant PRC government authorities, 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, on December 28, 2021, the Cybersecurity Administration of China, China's highest cyberspace regulator, and other twelve authorities of the PRC jointly issued the amended Cybersecurity Review Measures, or the Amended Cybersecurity Review Measures, which became effective on February 15, 2022. Under the Amended Cybersecurity Review Measures, 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 Amended Cybersecurity Review Measures requires 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. 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.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

Certain of our clinical research and development activities are expected to be supervised by relevant regulatory authorities in China if we elect to conduct clinical trials in China for our product candidates in the future (see "Business" beginning on page 111 for our current plans for future clinical trials). The PRC legal

system is a civil law system based on written statutes and, unlike the common law system, prior court decisions can only be cited as reference and have limited precedential value. Additionally, written statutes in the PRC are often principle-oriented and require detailed interpretations by the enforcement bodies to further apply and enforce such laws. Since 1979, the PRC government has developed a comprehensive system of laws, rules and regulations in relation to economic matters, such as foreign investment, corporate organization and governance, commerce, taxation and trade. However, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and may not be as consistent or predictable as in other more developed jurisdictions. As these laws and regulations are continually evolving in response to changing economic and other conditions, and because of the limited volume of published cases and their non-binding nature, any particular interpretation of PRC laws and regulations may not be definitive. Moreover, we cannot predict the effect of future developments in the PRC legal system and regulatory structure. Such unpredictability towards our contractual, property and procedural rights as well as our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis, if at all, and which may have a retroactive effect. Hence, we may not be aware of violation of these policies and rules until after such violation has occurred. Further, the legal protections available to us and our investors under these laws, rules and regulations may be limited.

In addition, any administrative or court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC 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 the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce various contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

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

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

Risks Related to Our Reliance on Third Parties

As we rely on third parties to conduct our preclinical studies, clinical trials, contract manufacture drug substances and drug products, and provide other important services related to product development, regulatory submissions, and commercialization, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, 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 have relied on and plan to continue to rely on third-party CROs to monitor and manage data for some of our ongoing preclinical studies and clinical trials. We rely on these parties for the execution of our

preclinical studies and clinical trials, and 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 the CROs does not relieve us of our regulatory responsibilities.

Our CROs have the right to terminate their agreements with us in the event of an unrectified material breach. If any of our relationships with our third-party CROs is terminated, we may not be able to (i) enter into arrangements with alternative CROs or do so on commercially reasonable terms or (ii) meet our desired clinical development timelines. 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 and data from our clinical trials may be compromised as a result. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines.

Except for remedies available to us under our agreements with our CROs, we cannot control whether or not our CROs devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical studies. If our 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, the impacts of COVID-19 on their operations, 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 and our costs could increase. In turn, 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 certain risks 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 third parties, which could increase the risk that such information will be misappropriated. We currently have a limited number of employees, which limits the internal resources we have available to identify and monitor our third-party service 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 similar challenges or delays in the future, and such challenges or delays could have a material adverse impact on our business, financial condition and prospects.

As we rely on third parties to conduct our preclinical studies and clinical trials, our business could be harmed if those third parties fail to comply with the applicable regulatory requirements.

We and our CROs are required to comply with cGCP, current good laboratory practices, or cGLP, and other regulatory regulations and guidelines enforced by the FDA, the TGA, the NMPA, the EMA, the International Conference on Harmonization, or ICH, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these cGCP, cGLP or other regulatory requirements through periodic inspections of study sponsors, investigators and study sites. If we or any of our CROs fail to comply with applicable cGCP, cGLP or other regulatory requirements, the relevant data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the TGA, the NMPA, the EMA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP requirements. In addition, our clinical trials must be conducted with product candidates or products 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.

We rely on third parties to supply the drug raw materials for our manufacturing activities. Lack of availability or significant increases in cost of such drug raw materials could harm our business.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Currently, our drug raw materials for our manufacturing activities are supplied by multi-source suppliers

and we entered into long-term capacity arrangements with one of our suppliers. We believe our suppliers have sufficient capacity to meet our demands for drug materials. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted or if the costs of such drug materials were to significantly increase, our business would be materially harmed. For example, the COVID-19 pandemic could have a broad impact on the production and supplies of active ingredients or other raw materials and result in a potential shortage of supply. If we or our third-party manufacturers experience a shortage in supply of active ingredients or other raw materials, whether due to COVID-19 or otherwise, we may not be able to continue to supply adequate levels of our drugs to our customers, which would have a negative impact on our business and results of operations.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur recurring or non-recurring expenses and other charges, increase our near and long-term expenditures, issue securities that dilute the value of our ADSs, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic collaboration or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party.

Further, collaborations involving our product candidates are subject to additional risks, which include, but are not limited to, the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our product candidates or may elect not to continue or renew the development or commercialization programs based on clinical trial results, change in their strategic focus due to the acquisition of competitive drugs, increased competition, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our product candidates or future drugs;
- collaborators with marketing and distribution rights to one or more of our product candidates or future drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may own or co-own intellectual property covering our product candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- we may not be able to receive agreed development fees, royalties or milestone payments we expected when seeking collaborations.

As a result, if we enter into collaboration agreements or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate these collaborations or licenses with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to This Offering and Our ADSs

Although the audit report included in this prospectus is issued by an independent registered public accounting firm that is subject to inspections by the Public Company Accounting Oversight Board, or the PCAOB, and has been inspected by the PCAOB on a regular basis, there is no guarantee that future audit reports will be prepared by auditors or their international affiliates in jurisdictions where the PCAOB is able to fully inspect their work, 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 HFCAA, 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 HFCAA 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 currently provided by the HFCAA.

Our auditor, Friedman LLP, an independent registered public accounting firm with the PCAOB, 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 a subsidiary

within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our auditor is currently subject to inspection by the PCAOB and has been inspected by the PCAOB on a regular basis. However, recent developments would add uncertainties to our offering, and we cannot assure you whether Nasdaq or regulatory authorities would apply additional and more stringent criteria to us after considering the effectiveness of our auditor's audit procedures and quality control procedures, adequacy of personnel and training, or sufficiency of resources, geographic reach or experience as it relates to the audit of our financial statements.

Inspections of an independent registered public accounting firm 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 the law in China, 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, or the HFCAA, 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 HFCAA on December 2, 2020, and the HFCAA 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 HFCAA. A company will be required to comply with these rules if the SEC identifies it 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 HFCAA, including the listing and trading prohibition requirements described above.

Under the HFCAA, 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 HFCAA 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, or 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.

Because our initial public offering price is substantially higher than our net tangible book value per share, you will experience immediate and substantial dilution.

If you purchase 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 $4.00 per ADS (assuming that no outstanding options to acquire ordinary shares are exercised), representing the difference between (i) the initial public offering price of $6.00 per ADS, and (ii) our pro forma as adjusted net tangible book value per ADS as of $2.00, after giving effect to our sale of the ADSs offered in this offering. In addition, you may experience further dilution to the extent that our ordinary shares are issued upon the exercise of share options. See “Dilution” for a more complete description of how the value of your investment in the ADSs will be diluted upon completion of this offering.

If we fail to establish and maintain proper internal controls over financial reporting, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, reporting companies are generally required to file a report by their management on such company’s internal control over financial reporting, including an attestation report on internal control over financial reporting issued by the company’s independent registered public accounting firm. 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. 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 the 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, the ADSs may not be able to remain listed on Nasdaq Capital Market.

Our corporate actions are substantially controlled by our directors and executive officers, who can exert significant influence over important corporate matters, which may reduce the price of the ADSs and deprive you of an opportunity to receive a premium for your ADSs.

As of the date of this prospectus and on an as-converted basis, the chairman of the board of directors, Dr. Lin, beneficially owned approximately 13.61% of our outstanding ordinary shares and our directors and executive officers beneficially owned approximately 18.37% of our outstanding ordinary shares, collectively. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, strategic collaborations or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of

our Company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their ordinary shares as part of a sale of our Company and reducing the price of the ADSs. These actions may be taken even if they are opposed by our other shareholders, including the holders of the ADSs. In addition, these persons could divert business opportunities away from us to themselves or others.

As a result of our principal shareholder, Lin Bioscience International Ltd.'s significant share ownership position in the Company, the company is able to influence corporate matters and conflict of interest may arise between our principal shareholder and us.

As of the date of this prospectus and on an as-converted basis, our principal shareholder, Lin Bioscience International Ltd., beneficially owned approximately 76.97% of our outstanding ordinary shares. As a result of significant share ownership position in our Company, our principal shareholder could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, strategic collaborations or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their ordinary shares as part of a sale of our Company and reducing the price of the ADSs. These actions may be taken even if they are opposed by our other shareholders, including the holders of the ADSs. In addition, these persons could divert business opportunities away from us to themselves or others.

Conflicts of interest may arise between our principal shareholder and us in a number of areas relating to our ongoing relationships. Our financial contribution to our principal shareholder was not material during the periods presented in this prospectus, and our principal shareholder may from time to time make strategic decisions that it believes are in the best interests of its business as a whole, which may be different from the decisions that we would have made on our own. our principal shareholder's decisions with respect to us or our business may favor our principal shareholder and therefore our principal shareholder, which may not necessarily be aligned with our interests and the interests of our other shareholders. Our principal shareholder may make decisions, or suffer adverse trends, that may disrupt or discontinue our collaborations with our principal shareholder. Although we will become a stand-alone public company upon the completion of this offering and will have an audit committee, consisting of independent non-executive directors, to review and approve all proposed related party transactions including those between our principal shareholder and us, we may not be able to resolve all potential conflicts of interest, and even if we do so, the resolution may be less favorable to us than if we were dealing with a non-controlling shareholder.

There has been no public market for our ordinary shares or ADSs prior to this offering, and you may not be able to resell our ADSs at or above the price you paid, or at all.

Prior to this initial public offering, there has been no public market for our ordinary shares or ADSs. We have applied to list the ADSs on Nasdaq Capital Market. Our ordinary shares will not be listed on any exchange or quoted for trading on any over-the-counter trading system.

Negotiations with the underwriters will determine the initial public offering price for our ADSs which may bear no relationship to their market price after the initial public offering. 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. Investors in the ADSs may experience a significant decrease in the value of the ADSs regardless of our operating performance of prospects. 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 of our ADSs may be volatile, which could result in substantial losses to you.

The market price of our ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your ADSs at or above the initial public offering price and you may lose some or all of your investment.

In addition to market and industry factors, the price and trading volume for our ADSs may be highly volatile due to specific business reasons, including, but not limited to:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for a drug's use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors;
- regulatory developments affecting us, our patients, our customers, our suppliers or our competitors, including adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to research and develop additional product candidates or otherwise acquire or license additional product candidates;
- entering into out-licensing or collaborations and any subsequent changes in the terms or structure of these licenses or collaborations;
- appointments of key vendors, including CMOs;
- variations in the level of expenses related to our existing drugs and product candidates or preclinical, clinical development and commercialization programs;
- any litigation or administrative proceedings in which we may become involved, including any intellectual property infringement actions;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our revenue, operating expenses and profitability, and any other variations in our results of operations;
- manufacture, supply or distribution shortages;
- announcements about our results of operations that are not in line with analyst expectations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- media reports, whether or not true, about our business, our competitors or our industry;
- additions to or departures of our management;
- foreign exchange fluctuations;
- release or expiration of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and directors or our shareholders;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles; and
- changes or developments in the United States, Australia, Taiwan, PRC or global regulatory environment.

We expect that, until we are able to commercialize our drug pipeline, the primary drivers of the market price of our ADSs will likely be the results of our research and development efforts, the outcome of our various testing, studies and our overall clinical performance. Nevertheless, the stock market, in general, and pharmaceutical and biotechnology companies have from time to time experienced extreme price and

trading volume fluctuations that have often been unrelated or disproportionate to the clinical and/or operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the market price of our ADSs to decline rapidly and unexpectedly.

After the completion of this offering, we may face an increased risk of securities class action litigation, which is expensive and could divert management's attention.

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 to us because biotechnology and biopharmaceutical companies have experienced significant share price volatilities in recent years. If we were to face such lawsuits, it will likely result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding the ADSs, the market price for the ADSs and trading volume could decline.

The trading market for the ADSs will be influenced by research or reports that industry or securities analysts publish about our business. If one or more analysts who cover us downgrade the ADSs, the market price for the ADSs would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the ADSs to decline.

Techniques employed by short sellers may drive down the market price of our ADSs.

Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market.

Much of the scrutiny and negative publicity has centered on allegations of a lack of effective internal control over financial reporting resulting in financial and accounting irregularities and mistakes, inadequate corporate governance policies or a lack of adherence thereto and, in many cases, allegations of fraud. As a result, many of these companies are now conducting internal and external investigations into the allegations and, in the interim, are subject to shareholder lawsuits and/or SEC enforcement actions.

It is not clear what effect such negative publicity, if it would occur, could have on us. If we were to become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we could have to expend a significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which it can proceed against the relevant short seller by principles of freedom of speech, applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could distract our management from growing our business. Even if such allegations are ultimately proven to be groundless, allegations against us could severely impact its business operations and stockholders equity, and any investment in our ADSs could be greatly reduced or rendered worthless.

The sale or availability for sale, or perceived sale or availability for sale, of substantial amounts of our ADSs could adversely affect their market price.

Sales of substantial amounts of our ADSs in the public market after the completion of this offering, or the perception that these sales could occur, could adversely affect the market price of our ADSs and could

materially impair our ability to raise capital through equity offerings in the future. The ADSs sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, and ordinary shares held by our existing shareholders may also be sold in the public market in the future subject to the restrictions in Rule 144 and Rule 701 under the Securities Act and the applicable lock-up agreements. There will be ADSs (equivalent to ordinary shares) outstanding immediately after this offering. We, our officers, directors, and shareholders holding greater than 5% of our ordinary shares have agreed not to sell any of our ordinary shares or our ADSs or are otherwise subject to similar lockup restrictions for 180 days after the date of this prospectus without the prior written consent of the representative of the underwriters, subject to certain exceptions. However, the representative of the underwriters may release these securities from these restrictions at any time. 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. See "Underwriting" and "Shares Eligible for Future Sale" for a more detailed description of the restrictions on selling our securities after this offering.

The ADSs are equity and are subordinate to our existing and future indebtedness and any preferred stock we may issue in the future.

The ADSs are our equity interests and do not constitute indebtedness. As such, ADSs will rank junior to all indebtedness and other non-equity claims on us with respect to assets available to satisfy claims on us, including in a liquidation of us. Additionally, holders of our ADSs may be subject to prior dividend and liquidation rights of any holders of our preferred stock or depositary shares representing such preferred stock then outstanding.

Our board of directors is authorized to issue additional classes or series of preferred stock without any action on the part of the shareholders. The board of directors also has the power, without shareholder approval, to set the terms of any such classes or series of preferred stock that may be issued, including voting rights, dividend rights, and preferences over our ADSs with respect to dividends or upon our dissolution, winding-up and liquidation and other terms. If we issue preferred stock in the future that has a preference over our ADSs with respect to the payment of dividends or upon our liquidation, dissolution, or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our ADSs, the rights of holders of our ADSs or the market price of our ADSs could be adversely affected.

Holders of ADSs have fewer rights than shareholders and the voting rights of holders of ADSs are limited by the terms of the deposit agreement.

Holders of 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. As a holder of our ADSs, you will not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. As an ADS holder, you will only be able to exercise the voting rights carried by the underlying ordinary shares indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement, you may vote only by giving voting instructions to the depositary in the manner set forth in the deposit agreement. Upon receipt of your voting instructions, the depositary will try, as far as is practicable, to vote the ordinary shares underlying your ADSs in accordance with your instructions. If we ask for your instructions, then upon receipt of your voting instructions, the depositary will try to vote the underlying ordinary shares in accordance with these instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with instructions you give, but it is not required to do so. You will not be able to directly exercise your right to vote with respect to the underlying ordinary shares unless you withdraw the shares, and become the registered holder of such shares prior to the record date for the general meeting. Under our third amended and restated memorandum and articles of association, which will become effective immediately prior to completion of this offering, the minimum notice period required for convening a general meeting is seven (7) calendar days; provided that a general meeting may be called on short notice under specified circumstances. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to withdraw the ordinary shares underlying your ADSs and become the registered holder of such shares to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. In addition, under our

third amended and restated memorandum and articles of association, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may fix the date notice is given of a general meeting as the record date, and the setting of such a record date may prevent you from withdrawing the ordinary shares underlying your ADSs and becoming the registered holder of such shares prior to the record date, so that you would not be able to attend the general meeting or to vote directly. If we ask for your instructions, the depositary will notify you of the upcoming vote and will arrange to deliver our voting materials to you. We have agreed to give the depositary notice of shareholder meetings sufficiently in advance of such meetings. Nevertheless, we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the underlying shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the ordinary shares underlying your ADSs are voted and you may have no legal remedy if the ordinary shares underlying your ADSs are not voted as you requested. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. Except in limited circumstances, the depositary for our ADSs will give us a discretionary proxy to vote the ordinary shares underlying your ADSs if you do not give voting instructions to the depositary, which could adversely affect your interests.

Under the deposit agreement for the ADSs, if you do not give voting instructions to the depositary, the depositary will give us a discretionary proxy to vote the ordinary shares underlying your ADSs at shareholders' meetings unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting;
- a matter to be voted on at the meeting would have an adverse impact on shareholders; or
- the voting at the meeting is to be made on a show of hands.

The effect of this discretionary proxy is that you cannot prevent our ordinary shares underlying your ADSs from being voted, except under the circumstances described above. This may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares are not subject to this discretionary proxy.

Furthermore, in the event of voting by a show of hands, pursuant to the terms of the deposit agreement, the depositary will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions, which may result in the ordinary shares underlying the ADSs held by certain ADS holders being voted in a manner contrary to such ADS holders' voting instructions. See "Description of American Depositary Shares — Voting rights" for more information.

The depositary for the ADSs is entitled to charge holders of ADSs fees for various services, including annual service fees.

The depositary for the ADSs is entitled to charge holders of ADSs fees for various services, including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust Company, or the DTC, the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time. For further information, see "Description of American Depositary Shares — Fees and Charges."

We have considerable discretion to determine how to use the net proceeds from this offering and may use them in ways with which you may not agree or that may not ultimately yield a favorable return or increase 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 considerable discretion in

deciding how to apply the 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 ultimately 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, while applied in a manner consistent with the manner described in the section titled "Use of Proceeds" in this prospectus, may differ substantially from our current plans. Additionally, in utilizing the proceeds of this offering, under the PRC laws and regulations, we are only allowed to provide funding to our PRC subsidiary through loans or capital contributions. Subject to satisfaction of the applicable government registration and approval requirements, we may extend inter-company loans to our PRC subsidiary or make additional capital contributions to our PRC subsidiary to fund its research and development, capital expenditures or working capital. We cannot assure you that we will be able to obtain these government registrations or approvals in a timely manner, if at all. Further, if we choose to allocate funds to our PRC subsidiary, or if we desire to re-allocate those funds, our PRC subsidiary will have to comply with various PRC laws and regulations.

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 to assess whether the net proceeds from this offering are being used appropriately before making your investment decision. You must rely on the judgment of our management regarding the application of the net proceeds of this offering. We cannot assure you that the net proceeds will be used in a manner that will ultimately yield a favorable return or increase our ADS price, nor that these net proceeds will be placed only in investments that generate income or appreciate in value.

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 both the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Under the deposit agreement, the depositary will not make rights available to you unless both the rights and the underlying securities to be distributed to ADS holders are either registered under the Securities Act or exempt 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 and we may not be able to establish a necessary exemption from registration under the Securities Act. If the depositary does not distribute the rights, if any, 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.

You may not receive cash dividends if the depositary decides it is impractical to make them available to you.

The depositary will pay cash dividends on the ADSs only to the extent that we decide to distribute dividends on our ordinary shares, and we do not have any present plan to pay any dividends on our ordinary shares. To the extent that there is a distribution, the depositary of our ADSs has agreed to pay to you the cash dividends or any other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses pursuant to the deposit agreement. 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 to make a distribution available to any holders of ADSs. For instance, 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, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property to you. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities that may be 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 such distributions to you are illegal or impractical. These restrictions may cause a material decline in the value of our ADSs.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems it expedient in connection with the performance of its duties. The depositary may close its books from time to time for a number of reasons, including in connection with corporate events such as a rights offering, during which time the depositary needs to maintain an exact number of ADS holders on its books for a specified period. The depositary may also close its books in emergencies, and on weekends and public holidays. The depositary may refuse to deliver, transfer or register transfers of the ADSs generally when our share register or the books of the depositary are closed, or at any time if we or the depositary thinks it is 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.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are an exempted company with limited liability incorporated in the Cayman Islands. Most of our directors and executive officers, and some of the experts named in this prospectus, are nationals and/or residents of countries other than the United States, and a significant portion of the assets of these persons may be 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 United States in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. As of the date of this prospectus, none of our officers, directors or other members of our senior management are located in China. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands may render you unable to enforce a judgment against our assets or the assets of our directors and officers. For more information regarding the relevant laws of the Cayman Islands, see “Enforceability of Civil Liabilities.”

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by, among other things, our memorandum and articles of association, the Companies Act (As Revised) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary duties of our directors to us under the Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, the Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands companies like us have no general rights under the Cayman Islands law to inspect corporate records, or to obtain copies of the register of members of these companies, other than the memorandum and articles of association and any special resolutions passed by these companies, and the registers of mortgages and charges of these companies. The Registrar of Companies of the Cayman Islands shall make available the list of the names of the current directors of the Company (and where applicable the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. Our directors have discretion under our post-offering memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it

more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. We may in the future rely on home country practice with respect to our corporate governance after we complete this offering. If we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by our management, members of our board of directors or our controlling shareholders than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Act (As Revised) of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, see "Description of Share Capital — Differences in Corporate Law."

Your rights to pursue claims against the depositary as a holder of ADSs are limited by the terms of the deposit agreement.

Under the deposit agreement, any action or proceeding against or involving the depositary, arising out of or based upon the deposit agreement or the transactions contemplated thereby or by virtue of owning the ADSs may only be instituted in a state or federal court in New York, New York, and you, as a holder of our ADSs, will have irrevocably waived any objection which you may have to the laying of venue of any such proceeding, and irrevocably submitted to the exclusive jurisdiction of such courts in any such action or proceeding.

The depositary may, in its sole discretion, require that any dispute or difference arising from the relationship created by the deposit agreement be referred to and finally settled by an arbitration conducted under the terms described in the deposit agreement, although the arbitration provisions do not preclude you from pursuing claims under the Securities Act or the Exchange Act in state or federal courts. See "Description of American Depositary Shares" for more information.

ADSs 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 plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, subject to the depositary's right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the 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. 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 investing in the ADSs.

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 / or the

depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not enforced, to the extent a court action proceeds, it would proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs shall relieve us or the depositary from our respective obligations to comply with the Securities Act and the Exchange Act.

Our post-offering memorandum and articles of association contain anti-takeover provisions that could have a material adverse effect on the rights of holders of our ordinary shares and ADSs.

Our post-offering memorandum and articles of association contain certain provisions that could limit the ability of others to acquire control of our company, including a provision that grants authority to our board of directors to establish from time to time one or more series of preferred shares without action by our shareholders and to determine, with respect to any series of preferred shares, the terms and rights of that series. These provisions could have the effect of depriving our shareholders of the opportunity to sell their shares at a premium over the prevailing market price by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transactions.

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD.

We will be required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, we intend to publish our results on a quarterly basis as press releases, distributed pursuant to the rules and regulations of the Nasdaq Stock Market. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K. However, the information we are required to file with or furnish to the SEC will be less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

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

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2022. We would lose our foreign private issuer status if, for example, as of the applicable determination date, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on June 30, 2022, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2023, which are more detailed

and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq Stock Market listing rules. As a U.S. listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we would not otherwise incur as a foreign private issuer.

As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq corporate governance listing standards.

As a Cayman Islands exempted company listed on the Nasdaq, we are subject to the Nasdaq corporate governance listing standards. However, the Nasdaq permits a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards. For instance, we are not required to:

- have a majority of the board be independent (although all of the members of the audit committee must be independent under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act);
- have a compensation committee or a nominations or corporate governance committee consisting entirely of independent directors; or
- have regularly scheduled executive sessions with only independent directors each year.

We may rely on home country practice with respect to our corporate governance after we complete this offering. If we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers.

As a "controlled company", we are exempt from certain Nasdaq corporate governance requirements, which may result in our independent directors not having as much influence as they would if we were not a controlled company.

We are a "controlled company" as defined under the Nasdaq Stock Market Rules, because one of our shareholders holds more than 50% of our voting power. As a result, for so long as we remain a controlled company as defined under that rule, we are exempt from, and our shareholders generally are not provided with the benefits of, some of the Nasdaq Stock Market corporate governance requirements, including that:

- a majority of our board of directors must be independent directors;
- our compensation committee must be composed entirely of independent directors; and
- our corporate governance and nomination committee must be composed entirely of independent directors.

Although we intend to reconstitute our board of directors and to have a majority of independent directors, that may change in the future.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our ADSs for return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in the ADSs as a source for any future dividend income.

Our Board of Directors has complete discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, a Cayman Islands company may pay a dividend out of either profit or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Even if our Board of Directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board of Directors. Accordingly, the return on your investment in the ADSs will likely depend entirely upon any future price appreciation of the ADSs. There is no guarantee that the ADSs will appreciate in value after this offering or even maintain the price at which you purchased the ADSs. You may not realize a return on your investment in the ADSs and you may even lose your entire investment in the ADSs.

We may be classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to U.S. investors of our ADSs or ordinary shares.

Based on current estimates of our gross income and the value of our gross assets (including goodwill) and the manner in which we conduct our business, we do not expect to be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for the taxable year 2022. Despite our expectation, there can be no assurance that we will not be a PFIC in the current taxable year or any future taxable year as PFIC status is tested each taxable year and will depend on the composition of our assets and income and the value of our assets in each such taxable year.

A non-U.S. corporation is a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for any taxable year in which (after taking into account the income and assets of subsidiaries in which it owns at least a 25% interest by value), (i) at least 75% of its gross income is "passive" income, such as interest and income from financial investments (the "income test") or (ii) at least 50% of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce or are held to produce passive income (the "asset test"). For purposes of the asset test, any cash and cash equivalents (such as bank deposits) will count as passive assets, and goodwill should be treated as an active asset to the extent associated with activities that produce or intended to produce active income. In determining the average percentage value of our gross assets, the aggregate value of our assets will generally be deemed to be equal to our market capitalization (determined by the sum of the aggregate value of our outstanding equity) plus our liabilities. We could be a PFIC for any future taxable year if our market capitalization were to decrease significantly while we hold substantial cash and cash equivalents, or if the gross income that we and our subsidiaries earn from investing the portion of cash raised in this offering is substantial in comparison with the gross income from our business operation.

If we were treated as a PFIC for any taxable year, then U.S. investors could be subject to adverse U.S. federal income tax consequences (regardless of whether we continue to be a PFIC), including increased tax liability on disposition gains and certain "excess distributions" and additional reporting requirements. **See** "United States Federal Income Tax Considerations — Passive Foreign Investment Company" for further information. U.S. investors should consult their tax advisers regarding our PFIC status for any taxable year and the potential application of the PFIC rules to an investment in our ADSs or ordinary shares including the availability and the advisability of making certain elections under the PFIC rules.

We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from requirements applicable to other public companies that are not emerging growth companies, including, most significantly, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 for so long as we remain an emerging growth company. As a result, if we elect not to comply with such auditor attestation requirements, our investors may not have access to certain information they may deem important.

The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. Pursuant to the JOBS Act, we have elected to take advantage of the benefits of this extended transition period for complying with new or revised accounting standards. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year during which we have total annual gross revenues of at least US$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the preceding three-year period, issued more than US$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of the ADSs that are held by non-affiliates exceeds US$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

We expect to incur increased costs as a result of being a public company, and will incur further increased costs after we cease to qualify as an "emerging growth company."

We will become a public company after this offering, and expect to incur significant legal, accounting and other expenses that we would not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, impose various requirements on the corporate governance practices of public companies. As a company with less than US$1.07 billion in revenues for our last fiscal year, we qualify as an "emerging growth company" pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting and permission to delay adopting new or revised accounting standards until such time as those standards apply to private companies.

We expect these rules and regulations to increase our legal and financial compliance costs and to make some corporate activities more time-consuming and costly. After we are no longer an "emerging growth company," we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. For example, as a result of becoming a public company, we need to increase the number of independent directors and adopt policies regarding internal controls and disclosure controls and procedures. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we will incur additional costs associated with our public company reporting requirements. It may also be more difficult for us to find qualified persons to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company's securities. If we were involved in a class action suit, it could divert a significant amount of our management's attention and other resources from our business and operations, which could harm our results of operations and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Known and unknown risks, uncertainties and other factors, including those listed under "Risk Factors," may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include statements relating to:

- the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our discovery programs;
- the timing and likelihood of regulatory filings and approvals, including with respect to additional indications beyond the initial indication for which we are seeking approval for our product candidates;
- our ability to advance our product candidates into drugs, and the successful completion of clinical trials;
- the approval, commercialization, pricing and reimbursement of our product candidates;
- the competitive landscape and size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- estimates of our costs, expenses, future revenues, capital expenditures and our needs for additional financing;
- our ability to continue as a going concern;
- our ability to attract and retain senior management and key employees;
- our future business development, financial condition and results of operations;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- our strategies, plans, objectives and goals and our ability to successfully implement these strategies, plans, objectives and goals;
- costs associated with enforcing or defending against intellectual property infringement, misappropriation or violation, product liability and other claims;
- our ability to establish and maintain collaborations or licensing agreements;
- our ability to identify and integrate new product candidates, technologies and/or suitable acquisition targets;
- our ability to effectively manage our growth;
- our proposed use of proceeds;
- changes to regulatory and operating conditions in our industry and markets.
- potential impact of the COVID-19 pandemic on our current and future business development, financial condition and results of operations.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from and worse than what we expect. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all the risk factors and uncertainties, nor can we assess the impact of all factors on

our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Except as required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately US$32.2 million, or approximately US$37.2 million if the underwriters exercise their option to purchase additional ADSs, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us.

The primary purposes of this offering are to create a public market for our shares for the benefit of all shareholders, retain talented employees by providing them with equity incentives, and obtain additional capital. We plan to use the net proceeds of this offering as follows:

- approximately 2.5% for our Phase 3 clinical trial of LBS-008 for STGD1,
- approximately 68.2% for further clinical development of LBS-008 for dry AMD, such as Phase 2 or Phase 3 clinical trials, and
- the remainder for working capital and other general corporate purposes.

We estimate the net proceeds of this offering would enable us to complete our ongoing Phase 2 and Phase 3 clinical trials of LBS-008 for STGD1, and to obtain interim results of our anticipated Phase 2 or Phase 3 clinical trials of LBS-008 for dry AMD.

The foregoing represents our current intentions based upon our present plans and business conditions to use and allocate the net proceeds of this offering. Our management, however, will have broad discretion in the application of our net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of these proceeds. See “Risk Factors — Risks Related to This Offering and Our ADSs — We have considerable discretion to determine how to use the net proceeds from this offering and may use them in ways with which you may not agree or that may not ultimately yield a favorable return or increase the price of the ADSs.” Due to the many variables inherent in the development of product candidates, such as the size and timing of patient enrollment, evolving regulatory requirements and the associated costs, we cannot currently predict the stage of development that we will be able to achieve for the product candidates in our pipeline with the net proceeds of this offering. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the results of the preclinical studies and clinical trials of our product candidates, our operating costs and expenditures, any strategic collaborations that we may enter into with third parties and the amount of cash generated by our operations. If an unforeseen event occurs or business conditions change, we may use the proceeds of this offering differently than as described in this prospectus.

In using the proceeds of this offering, we are permitted as an offshore holding company to provide funding under PRC laws and regulations to our PRC subsidiary only through loans or capital contributions. Subject to satisfaction of the applicable government registration and approval requirements, we may extend inter-company loans to our PRC subsidiary or make additional capital contributions to our PRC subsidiary to fund its research and development, capital expenditures or working capital. We cannot assure you that we will be able to obtain these government registrations or approvals on a timely basis, or at all.

DIVIDEND POLICY

We have not previously declared or paid cash dividends on our ordinary shares and we have no plan to declare or pay any dividends in the near future on our ordinary shares or ADSs. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

Our Board of Directors has discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, subject to the provisions in our articles of association, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board of Directors. Even if our Board of Directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant.

We are a holding company incorporated in the Cayman Islands. We have not received and do not have any present plan to receive dividends paid by our U.S., Australia, Hong Kong and PRC subsidiaries, but we have discretion as to whether such dividends are paid, subject to applicable statutory and contractual restrictions, including PRC regulations which may govern the ability of our PRC subsidiary to pay dividends to us.

If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the underlying ordinary shares represented by the ADSs to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to the ADS holders in proportion to the underlying ordinary shares represented by the ADSs held by such ADS holders, 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 capitalization as of December 31, 2021:

- on an actual basis;
- on a pro forma basis to reflect the automatic conversion of all of the issued and outstanding preferred shares on a one-for-one basis into ordinary shares immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect (i) the automatic conversion of all of the issued and outstanding preferred shares on a one-for-one basis into ordinary shares immediately prior to the completion of this offering; and (ii) the issuance and sale of 6,000,000 ordinary shares in the form of ADSs by us in this offering at an initial public offering price of US$6.00 per ADS, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of December 31, 2021		
	Actual	Pro forma	Pro forma as adjusted
	(amounts in US$ thousands, except for shares and per share data)		
	$	$	$
Convertible preferred shares:			
Series A convertible preferred shares, US$0.0001 par value; 2,377,642 shares (actual) and no shares (pro forma and pro forma as adjusted) authorized; 2,377,642 shares issued and outstanding (actual); no shares issued and outstanding (pro forma and pro forma as adjusted)	$ 8,806	—	—
Series B convertible preferred shares, US$0.0001 par value; 5,443,272 shares (actual) and no shares (pro forma and pro forma as adjusted) authorized; 5,443,272 shares issued and outstanding (actual); no shares issued and outstanding (pro forma and pro forma as adjusted)	$ 23,000	—	—
Total convertible preferred shares	**$ 31,806**	**—**	**—**
Shareholders' deficit:			
Ordinary shares, par value of US$0.0001 per share; 492,179,086 shares authorized; 10,274,403 shares issued and outstanding (actual); 18,095,317 and 24,095,317 shares issued and outstanding (pro forma and pro forma as adjusted)	1	2	2
Additional paid-in capital	12,325	44,130	75,561
Accumulated other comprehensive loss	(196)	(196)	(196)
Accumulated deficit	(27,223)	(27,223)	(27,223)
Total shareholders' equity (deficit)	**(15,093)**	**16,713**	**48,144**

DILUTION

If you invest in the ADSs, your interest will be diluted to the extent of the difference between the initial public offering price per ADS and our net tangible book value per ADS after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the net tangible book value per ordinary share attributable to the existing shareholders for our presently outstanding ordinary shares.

Our net tangible book value as of December 31, 2021 was approximately US$15.9 million, representing US$0.88 per ordinary share on a pro forma basis and US$0.88 per ADS. Net tangible book value represents the amount of our total consolidated tangible assets less total consolidated liabilities. Pro Forma net tangible book value per ordinary share is calculated after giving effect to the automatic conversion of all of our issued and outstanding convertible preferred shares. Dilution is determined by subtracting pro forma net tangible book value per ordinary share, after giving effect to the additional proceeds we will receive from this offering, from the initial public offering price of US$6.00 per ordinary share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Without taking into account any other changes in pro forma net tangible book value after December 31, 2021, after giving effect to our sale of the ADSs offered in this offering at the initial public offering price of US$6.00 per ADS, after deduction of the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2021 would have been US$48.1 million, or US$2.00 per ordinary share and US$2.00 per ADS. This represents an immediate increase in net tangible book value of US$1.12 per ordinary share and US$1.12 per ADS to the existing shareholders and an immediate dilution in net tangible book value of US$4.00 per ordinary share and US$4.00 per ADS to investors purchasing ADSs in this offering. The following table illustrates such dilution:

	Per Ordinary Share	Per ADS
Initial public offering price	US$6.00	US$6.00
Net tangible book value as of December 31, 2021	US$1.55	US$1.55
Pro forma net tangible book value after giving effect to the conversion of our preferred shares	US$0.88	US$0.88
Pro forma as adjusted net tangible book value after giving effect to the conversion of our preferred shares and this offering	US$2.00	US$2.00
Amount of dilution in net tangible book value to new investors in this offering	US$4.00	US$4.00

If the representative of the underwriters exercise in full the option to purchase additional ADSs from us, based on the public offering price of US$6.00 per ADS, the pro forma as adjusted net tangible book value after this offering would be US$2.12 per ordinary share and US$2.12 per ADS, and the dilution to new investors purchasing ADSs in this offering would be US$3.88 per ordinary share and US$3.88 per ADS.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2021, the differences between existing shareholders and the new investors with respect to the number of ordinary shares (represented by ADSs) purchased from us, the total consideration paid and the average price per ordinary share and per ADS paid before deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The total number of ordinary shares does not include ordinary shares underlying the ADSs issuable upon the exercise of the option to purchase additional ADSs granted to the underwriters.

	Ordinary Shares Purchased		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Existing shareholders	18,095,317	75%	US$44,132,000	55%	US$2.44	US$2.44
New investors	6,000,000	25%	US$36,000,000	45%	US$6.00	US$6.00

	Ordinary Shares Purchased		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Total	24,095,317	100.0%	US$80,132,000	100.0%		

The discussion and table above assume no exercise of any share options outstanding as of the date of this prospectus. As of the date of this prospectus, there are 1,982,561 outstanding options with an average exercise price of US$0.4626 per share. To the extent that any of these options are exercised, there will be further dilution to new investors.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. 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 foreign 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 memorandum and articles of association does 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.

Most of our directors and officers are nationals or residents of jurisdictions other than the United States and most of their assets are 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 individuals, or to bring an action against us or these individuals in the United States, 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. As of the date of this prospectus, none of our officers, directors or other members of our senior management are located in China.

We have appointed Puglisi & Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711, as our agent upon whom process may be served in any action brought against us under the securities laws of the United States.

Maples and Calder (Hong Kong) LLP, our counsel as to Cayman Islands law, has advised us that there is uncertainty as to whether the courts of the Cayman Islands would (a) recognize or enforce judgments of U.S. courts obtained against us or our directors or officers that are predicated upon the civil liability provisions of the federal securities laws of the United States or the securities laws of any state in the United States, or (b) entertain original actions brought in the Cayman Islands against us or our directors or officers that are predicated upon the federal securities laws of the United States or the securities laws of any state in the United States.

Maples and Calder (Hong Kong) LLP has informed 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 (and the Cayman Islands are not a party to any treaties for the reciprocal enforcement or recognition of such judgments), the courts of the Cayman Islands would recognize and enforce a final and conclusive judgement in personam obtained in federal or state courts in the United States under which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature, a fine or a penalty or similar fiscal or revenue obligations) or, in certain circumstances, an in personam judgment for non-monetary relief, and would give a judgment based thereon provided that: (a) such courts had proper jurisdiction over the parties subject to such judgment; (b) such courts did not contravene the rules of the natural justice of Cayman Islands; (c) such judgment was not obtained by fraud; (d) such judgment 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; (e) no new admissible evidence relevant to the

action is submitted prior to the rendering of the judgment by the courts of the Cayman Islands; and (f) there is due compliance with the correct procedures under the laws of the Cayman Islands. However, the Cayman Islands courts are unlikely to enforce a punitive judgment of a United States court predicated upon the civil liability provisions of the federal securities laws in the United States without retrial on the merits if such judgment is determined by the courts of the Cayman Islands to give rise to obligations to make payments that may be regarded as fines, penalties or punitive in nature. A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

CORPORATE HISTORY AND STRUCTURE

Corporate History

The Company was incorporated under the laws of the Cayman Islands on March 27, 2018. We are engaged in research and development of novel therapeutics targeting significant unmet needs.

In June 2016, Lin BioScience, Inc., a public company in Taiwan (stock code: 6696.TW), which is our ultimate controlling shareholder (i.e., the sole shareholder of our principal shareholder, Lin Bioscience International Ltd.), established Belite Bio Holdings Corp. (formerly known as Lin BioScience Holdings Corporation) and Belite Bio, LLC (formerly known as Lin BioScience, LLC), in Delaware. Belite Bio Holdings Corp. is an intermediate holding company and owns 100% equity interests in Belite Bio, LLC, which is mainly engaged in research and development of LBS-008 and LBS-009.

In March 2018, as a part of a reorganization, Lin BioScience, Inc. established the Company (formerly known as Lin BioScience Co., Ltd.) in the Cayman Islands, as a subsidiary to its wholly-owned subsidiary Lin Bioscience International Ltd.

In June 2018, as a part of the reorganization, Lin Bioscience International Ltd., acquired the entire equity interest in Belite Bio Holdings Corp. from Lin BioScience, Inc. and then contributed the entire equity interest in Belite Bio Holdings Corp. to us in July 2018. After this contribution, Belite Bio Holdings Corp. became our wholly-owned subsidiary, which in turn owns 100% equity interests in Belite Bio, LLC.

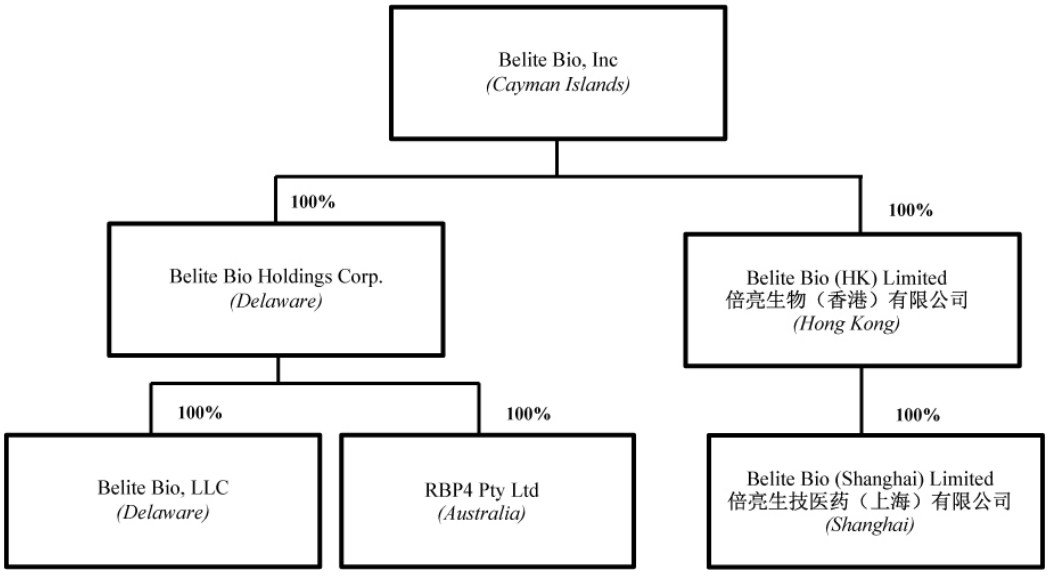
Before and after the reorganization, we were, together with our subsidiaries, effectively controlled by the same shareholders, and therefore the reorganization is considered a recapitalization of entities under common control in accordance with Accounting Standards Codification ("ASC") 805-50-25. The consolidation of us and our subsidiaries have been accounted for at historical cost in the accompanying consolidated financial statements in accordance with ASC 805-50-45-5.

In August 2018, Belite Bio Holdings Corp. established RBP4 Pty Ltd in Australia as its wholly-owned subsidiary for carrying out clinical trials in Australia and tax refund purposes.

In June 2021, we established Belite Bio (HK) Limited in Hong Kong as a wholly-owned subsidiary which established Belite Bio (Shanghai) Limited in Shanghai, China in August 2021 with an aim to carry out clinical trials of our product candidates in China in the future.

Our Corporate Structure

The chart below sets forth our corporate structure and identifies our significant subsidiaries and their significant subsidiaries, as of the date of this prospectus:



SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated statement of operations and comprehensive loss data for the years ended December 31, 2020 and 2021 and selected consolidated balance sheet data as of December 31, 2020 and December 31, 2021 have been derived from our audited consolidated financial statements included elsewhere in this prospectus.

Our consolidated financial statements are prepared and presented in accordance with U.S. GAAP. Our historical results do not necessarily indicate results expected for any future periods. You should read this Selected Consolidated Financial Data section together with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	For the Year Ended December 31,	
	2020	2021
	(In thousand US Dollars, except share and per share amounts)	
Selected Consolidated Statements of Operations and Comprehensive Loss		
Total operating expenses[(1)]	5,743	9,797
Total other (expense) income, net	(9)	131
Net loss	(5,753)	(9,666)
Total comprehensive loss	$ (5,747)	$ (9,818)
Weighted average number of ordinary shares used in per share calculation, basic and diluted	8,790,397	9,569,932
Net loss per ordinary share, basic and diluted	(0.65)	(1.01)

(1) Total share-based compensation costs were recognized as follows for the years ended December 31, 2020 and 2021:

	Year Ended	
	December 31, 2020	December 31, 2021
	(amounts in $ and in thousands)	
Research and development	$ 77	$ 52
General and administrative	1,286	1,478
Total	$1,363	$1,530

	As of December 31, 2020	As of December 31, 2021
	(amounts in $ and in thousands)	
Selected Consolidated Balance Sheets Data:		
Cash	$25,618	$ 17,344
Total assets	$25,741	$ 18,348
Total liabilities	$ 972	$ 1,635
Total convertible preferred shares	$31,806	$ 31,806
Total shareholders' deficit	$ (7,037)	$(15,093)
Total liabilities, convertible preferred shares and shareholders' deficit	$25,741	$ 18,348

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 "Selected Consolidated Financial Data," and 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. The terms "our company", "we", "our" or "us" as used herein refer to Belite Bio, Inc and its subsidiaries unless otherwise stated or indicated by context.

Overview

We are a clinical stage biopharmaceutical drug development company focused on novel therapeutics targeting currently untreatable eye diseases involving retinal degeneration such as atrophic age-related macular degeneration (commonly known as dry AMD) and autosomal recessive Stargardt disease, or STGD1, both of which progressively lead to permanent blindness, and metabolic diseases such as non-alcoholic fatty liver disease, or NAFLD, nonalcoholic steatohepatitis, or NASH, type 2 diabetes, or T2D, and gout.

We believe our lead product candidate, LBS-008, or Tinlarebant, if approved, would provide a novel treatment option where there currently is none. LBS-008 is an oral once-a-day treatment that can reduce and maintain the delivery of vitamin A (retinol) to the eye as a means to reduce the accumulation of toxic vitamin A by-products in ocular tissue. This effect is achieved through the ability of LBS-008 to reduce and maintain the level of serum retinol binding protein 4, or RBP4, which carries retinol from the liver to the eye. In clinical trials, LBS-008 has demonstrated its target specificity and potency that we believe could be clinically meaningful to treat STGD1 patients. We initiated an open-label, dose-finding Phase 1b/2 clinical trial in adolescent STGD1 patients in mid-2020 in Australia and Taiwan. The study design includes two portions: Phase 1b and Phase 2. We have completed the Phase 1b portion of this study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Australia and Taiwan. The preliminary data from the Phase 1b portion has shown that LBS-008 can achieve a mean RBP4 reduction of > 70%, relative to baseline values. We are currently conducting the Phase 2 portion of this study.

As of the date of this prospectus, we have initiated our Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. Previously, we completed a Phase 1 clinical trial of LBS-008 in healthy adult subjects in mid-2020. We are currently evaluating our plans to conduct a Phase 2 or Phase 3 trial in 2022 to evaluate the safety and efficacy of LBS-008 in the treatment of dry AMD.

Since our inception in 2016, our operations have focused on organizing and staffing our Company, business planning, raising capital, acquiring rights to product candidates, developing our product candidates, including conducting preclinical studies and clinical trials, and establishing our intellectual property portfolio. Our ultimate controlling shareholder, Lin BioScience, Inc., obtained from Columbia University an exclusive worldwide license to the RBP4 IP Portfolio, which contains disclosure directed to over 400 structurally distinct compounds including our lead product candidate, LBS-008, in September 2016, which was initially assigned to our principal shareholder, Lin Bioscience International Ltd., and subsequently assigned to us in 2018.

To date, we have not generated any revenues. We have financed our operations primarily through approximately $40.6 million in proceeds from the issuance of our ordinary shares, the private placement of shares of our convertible preferred stock and the issuance of our convertible promissory notes. We have incurred annual net operating losses in each year since our inception and expect to continue to incur net

operating losses for the foreseeable future. Our net losses were approximately $5.8 million and $9.7 million for the years ended December 31, 2020 and 2021, respectively. As of December 31, 2021, we had an accumulated deficit of approximately $27.2 million. Our independent registered public accounting firm has included in its audit report on our financial statements as of and for the year ended December 31, 2021, an explanatory paragraph regarding a substantial doubt about our ability to continue as a going concern. We expect to continue to incur significant expenses and increasing operating losses for the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year depending on the progress of our clinical trials and the payment schedule between us and the CROs engaged by us. We anticipate that our expenses will increase significantly if and as we continue to develop and conduct clinical trials in our current indications with LBS-008, including our ongoing Phase 2 and Phase 3 trials in STGD1 and an anticipated Phase 2 or Phase 3 trial in dry AMD; initiate and continue research and preclinical and clinical development efforts for any future product candidates; leverage our exclusive RBP4 IP Portfolio to identify and develop additional product candidates and/or for additional indications; further expand our product pipeline through in-licensing or collaboration arrangements; seek regulatory and marketing approvals for our product candidates and complete clinical trials, if any; establish strategic collaborations or sales, marketing distribution and other commercial infrastructure in the future to commercialize any products for which we may obtain marketing approval; require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; hire and retain additional personnel, such as clinical and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

Our ability to become and remain profitable depends on our ability to generate product revenue. We do not expect to generate product revenue unless, and until, we enter into an out-license and/or collaboration agreement with others for, or we obtain marketing approval for, and commercialize, a product candidate, and we cannot assure you that we will ever generate revenue or profits.

Our current clinical development, manufacturing and commercialization plans and any of our future strategies for growth will be based on our ongoing assessment of macroeconomic trends and the evolving regulatory landscape.

Key Factors Affecting Our Results of Operations

Our results of operations, financial condition, and the year-to-year comparability of our financial results have been, and are expected to continue to be, principally affected by the below factors:

Costs and Expenses Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and general and administrative expenses.

Research and development activities are central to our business model. We believe our ability to successfully develop product candidates will be the primary 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 investments in this area. Since our inception, we have focused our resources on our research and development activities, including developing our RBP4 IP Portfolio, conducting preclinical studies and clinical trials, and engaging in activities related to regulatory filings for our product candidates. Clinical studies become increasingly more expensive from Phase 1b/2 and onwards due to an increase in the number of subjects enrolled in such studies. Research and development costs are expensed as incurred. Costs for certain activities, such as activities performed by third-party contractors relating to the manufacturing and preclinical studies and clinical trials of our product candidates, are generally accrued based on our estimates of the actual services performed for a given period. These estimates are based on our evaluation of the progress to completion of specific tasks to be performed using information and data provided to us by our third-party contractors and vendors.

At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including, but not limited to, the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- successful completion of clinical trials, including the successful enrollment in such clinical trials, and clinical trial results;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates, whether alone or in collaboration with others;
- our ability to establish manufacturing capabilities and capacities, whether internally or through CMOs, to the specifications of our product candidates for clinical supply;
- the potential benefits of our product candidates over other therapies;
- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our product candidates;
- the terms and timing of regulatory approvals;
- successful completion of all safety studies required to obtain regulatory approval in the United States and other applicable jurisdictions for our product candidates; and
- maintaining a continued acceptable safety profile of the product candidates following regulatory approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could mean a significant change in the costs, timing and viability of the development of that product candidate. For example, if we are required to conduct additional clinical trials or other testing of any of our product candidates beyond those that are contemplated or if we experience significant delays in enrollment in any clinical trials, we could incur significant additional costs and the clinical development timeline for our product candidates may be delayed. We expect research and development costs to continue to increase for the foreseeable future as we expand our operations and our development of product candidates progresses, including as we continue to support and advance the clinical trials of our product candidates.

Our general and administrative expenses consist primarily of employee salaries and related benefit costs, including share-based compensation expenses, for personnel in executive, finance, accounting and administrative functions. Other general and administrative expenses include professional fees for financial advisory, auditing and legal services. We expect our general and administrative headcount and related expenses to increase in the future to support our clinical program and research and development efforts, and the commercialization of our product candidates in the event approval is obtained. We also anticipate that our general and administrative expenses will increase as we operate as a public company following the completion of this offering.

Funding for Our Operations

During the periods presented, we have funded our operations primarily through the issuance and sale of ordinary shares, convertible preferred shares in private placement transactions and convertible promissory notes. See “Description of Share Capital — History of Securities Issuances” for more information. However, if our business and our product candidate pipeline continue to expand, we may require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Any fluctuation in our ability to fund our operations will impact our development plan, operating plan and our results of operations. In the event of the successful development and commercialization of one or more of our product candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. In the event that we enter into out-license and/or collaboration arrangements with others, we expect to fund our operations in part with revenue received from such out-license and/or collaboration arrangements.

Our Ability to Commercialize and/or Out-License Our Product Candidates

Our business and results of operations depend on our ability to out-license our product candidates or, in the event any of our product candidates are approved for marketing by the respective regulatory authority in a country, commercialize such product candidates. Currently, our pipeline consists of our lead product candidate, LBS-008, which is currently in clinical development, and LBS-009, which is currently in preclinical development. Although we currently do not have any product approved for commercial sale and have not generated revenue from product sales or out-licensing, we expect to generate revenue either from sales of a product candidate if we complete the clinical development, obtain regulatory approval, and successfully commercialize such product candidate, or from out-licensing a product candidate if we enter into an out-license and/or collaboration agreement for any product candidate.

Key Components of Results of Operations

Revenue

To date, we have not generated any revenue. Our ability to generate revenue and to become profitable will depend upon the successful commercialization of, and/or our successful entry into out-license and/or collaboration arrangements in connection with, one or more of our product candidates. Because of the numerous risks and uncertainties associated with product development and regulatory approval, and out-license and/or collaboration arrangements, we are unable to predict the amount or timing of product revenue or out-license and/or collaboration revenue.

Research and Development Expenses

Research and development expenses consist of costs associated with planning and conducting clinical trials of our product candidates. Our research and development expenses primarily consist of:

- payroll, share-based compensation and other related costs of personnel engaged in research and development activities;
- in-licensed patent rights fee of exclusive development rights of drugs granted to us under the Columbia License Agreement;
- costs for preclinical testing of our technologies and clinical trials such as payments to CROs and CMOs, investigators and clinical trial sites that conduct the clinical studies;
- costs to develop our product candidates, including raw materials and supplies, product testing, clinical trial equipment and its depreciation, and facility related expenses; and
- other research and development expenses.

Clinical trial costs are a significant component of our research and development expenses. Our current research and development activities primarily relate to the clinical development of LBS-008 for the following indications:

- ***STGD1.*** We are developing LBS-008 as an oral once-a-day treatment for STGD1. STGD1 is an inherited juvenile form of macular degeneration. As of the date of this prospectus, we have initiated our Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. We are also currently conducting our ongoing Phase 2 clinical trial. Previously, we completed a Phase 1b clinical trial of LBS-008 in adolescent patients with STGD1 and a Phase 1 clinical trial of LBS-008 in healthy adult subjects in mid-2020.
- ***Dry AMD.*** We are developing LBS-008 as an oral once-a-day treatment for dry AMD. Age-related macular degeneration, or AMD, is a common eye disorder among people over 50. The only approved therapies for AMD are for ‘wet’ AMD, which represents approximately 10% of all AMD cases. There are no approved therapies for the other stages of AMD, which are collectively referred to as dry AMD and represents approximately 90% of all AMD cases. We are currently evaluating our

plans to conduct a Phase 2 or Phase 3 trial in 2022 to evaluate the safety and efficacy of LBS-008 in the treatment of dry AMD. Previously, we completed a Phase 1 clinical trial of LBS-008 in healthy adult subjects in mid-2020.

We incurred research and development expenses of approximately $7.4 million for the year ended December 31, 2021, representing approximately 75.7% of our total operating expenses for that period. Our research and development expenses may vary substantially from period to period according to the status of our research and development activities. The timing of expenses is impacted by the commencement of clinical trials and enrollment of patients in clinical trials. Clinical studies become increasingly expensive from Phase 1b/2 and onwards. We expect our research and development expenses to continue to increase for the foreseeable future, as we advance our lead product candidate, LBS-008, toward later stages and continue to expand our operations.

General and Administrative Expenses

Our general and administrative expenses consist primarily of employee salaries and related benefit costs, including share-based compensation expenses, for personnel in executive, finance and administrative functions. Other general and administrative expenses include professional fees for financial advisory, auditing and legal services. For the year ended December 31, 2021, our general and administrative expenses amounted to approximately $2.4 million.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, including our ongoing and planned research and development of our lead product candidate, LBS-008. We also expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

Interest Income (Expenses)

Interest income consists primarily of interest income derived from our cash. Interest expense consists primarily of accrued interest incurred pursuant to loans due to related parties.

Taxation

Cayman Islands

We are an exempted company with limited liability incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, we are not subject to tax on income or capital gain. Additionally, upon payments of dividends by us to our shareholders, no Cayman Islands withholding tax will be imposed. However, we may be subject to taxation in other jurisdictions in which we operate, in particular, the United States, Australia, Hong Kong, and/or the PRC, where five of our wholly-owned subsidiaries are incorporated, if certain conditions are met under the laws and regulations of the Cayman Islands.

United States

Our subsidiaries, Belite Bio Holdings Corp. and Belite Bio, LLC, which are both incorporated or formed in Delaware, United States, are subject to statutory U.S. Federal corporate income tax at a maximum rate of 21% for the year ended December 31, 2021. Both entities are also subject to state income tax in California at a rate of 8.84% for the year ended December 31, 2021.

Australia

Our subsidiary, RBP4 Pty Ltd, is subject to Australia profits tax on the taxable income as reported in its respective statutory financial statements adjusted in accordance with the relevant Australia tax laws. The applicable tax rate in Australia is 30%. RBP4 Pty Ltd had no taxable income for the periods presented, therefore, no provision for income taxes has been provided.

Hong Kong

Our subsidiary, Belite Bio (HK) Limited, is subject to Hong Kong profits tax at a tax rate of 8.25% for assessable profits on the first HK$2 million and 16.5% for any assessable profits in excess. No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax for the year ended December 31, 2021.

PRC

Our subsidiary, Belite Bio (Shanghai) Limited is subject to the statutory rate of 25%, in accordance with the EIT Law. Under the EIT Law, dividends, interests, rent or royalties payable by Belite Bio (Shanghai) Limited to non-PRC resident enterprises, and proceeds from any such non-PRC resident enterprise investor's disposition of assets (after deducting the net value of such assets) shall be subject to a 10% withholding income tax, unless the respective non-PRC resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with China that provides for a reduced withholding income tax rate or an exemption from withholding income tax. No provision for PRC corporate income tax has been made for the year ended December 31, 2021, as Belite Bio (Shanghai) Limited had no such assessable profit for the year then ended.

Results of Operations

Comparison of the Fiscal Years Ended December 31, 2020 and 2021

The following table sets forth a summary of our consolidated results of operations for the years ended December 31, 2020 and 2021. This information should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus. The operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	For the Years Ended December 31,		Change	
	2020	2021		
	(amounts in $ and in thousands)			(%)
Expenses				
Research and development[(1)]	3,688	7,419	3,731	101.2
General and administrative[(1)]	2,055	2,378	323	15.7
Total operating expenses	5,743	9,797	4,054	70.6
Loss from operations	(5,743)	(9,797)	(4,054)	70.6
Other income (expense):				
Interest income	12	5	(7)	(58.3)
Interest expense	(21)	—	21	100
Other income	—	126	126	
Total other (expense) income, net	(9)	131	140	1,555.6
Loss before income tax	(5,752)	(9,666)	(3,914)	168.0
Income tax expense	(1)	—	1	100
Net loss	(5,753)	(9,666)	(3,915)	168.0
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	6	(152)	(158)	(2,633.3)
Total comprehensive loss	$(5,747)	$(9,818)	$(4,071)	$ (70.8)

(1) Total share-based compensation costs were recognized as follows for the year ended December 31, 2020 and 2021:

	Years ended December 31,	
	2020	2021
Research and development	$ 77	$ 52
General and administrative	1,286	1,478
Total	$1,363	$1,530

Revenue

We did not generate any revenue during the years ended December 31, 2020 and 2021.

Research and Development Expenses

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the years ended December 31, 2020 and 2021:

(in $ thousands, except percentages)	For the Years Ended December 31,			
	2020		2021	
	$	%	$	%
Contracted research expenses and clinical trial expenses	1,979	53.7	6,384	86.0
Consultancy and professional service fees	319	8.6	492	6.6
Royalties	1,187	32.2	103	1.4
Other expenses	203	5.5	440	6.0
Total	$3,688	100	$7,419	100

Our research and development expenses increased by 101.2% from approximately $3.7 million for the year ended December 31, 2020, to approximately $7.4 million for the year ended December 31, 2021. The increase was primarily attributable to increased contracted research expenses and clinical trial expenses relating to our Phase 1b/2 and Phase 3 clinical trials to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients, which were initiated in mid-2020 and 2021, respectively.

In the year ended December 31, 2021, approximately 86.0% of our total research and development expenses were attributable to contracted research expenses and clinical trial expenses. In the year ended December 31, 2020, approximately 53.7% of our total research and development expenses were attributable to contracted research expenses and clinical trial expenses. Clinical studies become increasingly more expensive from Phase 1b/2 and onwards. LBS-008 is currently undergoing a Phase 2 clinical trial and, as of the date of this prospectus, we have initiated a global Phase 3 clinical trial in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions.

General and Administrative Expenses

Our general and administrative expenses increased by approximately $0.3 million from the year ended December 31, 2020, to the year ended December 31, 2021, which was primarily due to an increase in professional service fees incurred and an increase in our number of employees.

We expect these costs to increase materially in the near future, consistent with our plans to increase our headcount in conjunction with this offering and ongoing requirements as a public company.

Interest Expense

We recorded approximately $21,000 of interest expense for the year ended December 31, 2020, which comprised of the interest expense owing under the 2020 Lin BioScience Loan Agreement and the Cayman 2019 August Loan Agreement, and no interest expense for the year ended December 31, 2021. The change was

attributable to the loans under both the 2020 Lin BioScience Loan Agreement and the Cayman 2019 August Loan Agreement being repaid in full in July 2020.

Other Income

We did not record any other income for the year ended December 31, 2020 and recorded approximately $126,000 of other income for the year ended December 31, 2021. Other income primarily consists of foreign exchange gains resulting from transactions undertaken by our Australian subsidiary in its functional currency, the Australian dollar. The increase was attributable to the weakening of the Australian dollar against the U.S. dollar.

Foreign Currency Adjustments, Net

We recorded a net foreign currency gain of approximately $6,000 for the year ended December 31, 2020 and a net foreign currency loss of approximately $152,000 for the year ended December 31, 2021. Foreign currency gain (loss) primarily results from the translation of the Australian dollar denominated financial statements of our Australian subsidiary into the U.S. dollar for consolidation purposes. The decrease was attributable to the weakening of the Australian dollar against the U.S. dollar which negatively impacted the Australian dollar denominated assets held by our Australian subsidiary.

Liquidity and Capital Resources

To date, we have not generated any revenues. We incurred net losses of approximately $5.8 million and $9.7 million for the years ended December 31, 2020 and 2021, respectively. Our primary use of cash is funding our research and development expenses. We used approximately $4.4 million and $7.5 million in cash for our operating activities for the years ended December 31, 2020 and 2021, respectively. We have financed our operations to date primarily through the issuance of our ordinary shares, the private placement of our convertible preferred stock and the issuance of our convertible promissory notes. For more information on our equity financing, see “Description of Share Capital — History of Securities Issuances.” As of December 31, 2021, we had cash of approximately $17.3 million. Our cash consists primarily of demand deposits which is unrestricted as to withdrawal and use and have original maturities of less than three months.

Our lead product candidate, LBS-008, is still in clinical development. We expect our expenses to increase substantially as compared to prior periods in connection with our ongoing activities, particularly as we continue the development of and seek marketing approval for LBS-008 and, possibly, other product candidates. In addition, if we obtain marketing approval for LBS-008 or any other product candidate that we develop, and we choose to commercialize such product candidate ourselves, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, upon the closing of this offering we expect to incur additional costs associated with operating as a public company. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations. These factors raise substantial doubt about our ability to continue as a going concern. Our financial statements have been prepared assuming that we will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from our possible inability to continue as a going concern.

We expect that our expenses will continue to increase substantially and that we will continue to incur significant operating losses and negative operating cash flows as we fund both ongoing research and development activities and new activities as well as working capital needs. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect or on alternative uses. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our product candidates.

After this offering, we may decide to enhance our liquidity position or increase our cash reserve for future operations and investments through additional financing. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the product candidates we pursue;
- the scope, progress, timing, results and costs of discovering, researching and developing product candidates, and conducting preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with expanding our supply chain;
- 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 establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such collaborations and arrangements;
- the extent to which we acquire or in-license other product candidates and technologies;
- our headcount growth and associated costs;
- the costs, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- the impact of COVID-19 on the initiation or completion of preclinical studies or clinical trials and the supply of our product candidates; and
- the costs of operating as a public company in the United States.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing 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 of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. For additional information regarding the risks related to our need to obtain additional capital, see “Risk Factors — Risks Related to Our Financial Position and Need for Additional Capital — We have recorded net cash outflow from operating activities since our inception. Even if we consummate this offering, we will need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates” and “Risk Factors — Risks Related to Our Financial Position and Need for Additional Capital — Raising additional capital may cause dilution to holders of our ADSs and our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.”

Operating Activities

Net cash used in operating activities was approximately $4.4 million for the year ended December 31, 2020 and consisted primarily of a net loss of approximately $4.4 million, after non-cash add backs, offset

primarily by a decrease in prepayments of approximately $0.2 million and a decrease in accrued expenses of approximately $0.3 million. Net cash used in operating activities was approximately $7.5 million for the year ended December 31, 2021 and consisted primarily of a net loss of approximately $8.1 million, after non-cash add backs, offset primarily by an increase in accrued expenses of approximately $0.6 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was approximately $20,000, which was comprised of an increase in prepayments of purchases of fixed assets.

Net cash used in investing activities during the year ended December 31, 2021 was approximately $56,000, which resulted primarily from the purchase of fixed assets offset by the sale of certain fixed assets.

Financing Activities

Net cash provided by financing activities was approximately $28.1 million for the year ended December 31, 2020, which consisted primarily of proceeds from the issuance of our convertible preferred shares, the issuance of our ordinary shares and borrowings under the 2020 Lin BioScience Loan Agreement and the Cayman 2019 August Loan Agreement, partially offset by the repayment of loans due to related parties. The loans under both the 2020 Lin BioScience Loan Agreement and the Cayman 2019 August Loan Agreement were repaid in full in July 2020.

Net cash used in financing activities was approximately $0.6 million for the year ended December 31, 2021, which consisted primarily of deferred offering costs, partially offset by the exercise of stock options.

Contractual Obligations and Commitments

We are party to an exclusive license agreement with Columbia University, which has been amended five times, most recently as of February 4, 2022, under which we license specified intellectual property from Columbia University. The patent rights licensed to us by Columbia University include issued patents with claims that recite a class of compounds directed to covering our planned lead compound, LBS-008, and specifically recite LBS-008. The license agreement requires us to make minimum annual royalty payments to Columbia University of (i) $2.5 million on each of the second, third and fourth anniversaries of the first commercial sale of a licensed product and (ii) $5 million on each anniversary of the first commercial sale of a licensed product, commencing on the fifth anniversary of such sale. We will also be obligated to pay single-digit earned royalties to Columbia University based on net sales of each licensed product by us and our affiliates and sublicensees. The minimum royalty payments will be creditable against the earned royalties accrued during the same calendar year. The license agreement obligates us to use commercially reasonable efforts to research, discover, develop and market licensed products for commercial sale and distribution and achieve certain development and regulatory approval milestones within certain timeframes, if certain milestones are achieved. We are also obligated to periodically inform Columbia University of our progress in meeting such milestones. The failure to achieve any such milestone would constitute a breach of the Columbia License Agreement. If we pay Columbia University the required fee, we will be granted a 6-month extension. As of the date of this prospectus, we have complied with the development and regulatory approval milestones under the Columbia License Agreement and requested no extensions. In the event that, after completion of Phase I Trials, there are unforeseen changes in clinical or regulatory development that we believe would affect the timely achievement of any milestone, we may request an extension from Columbia University for such milestone, which will not be unreasonably withheld or delayed. In the event that Columbia University does not agree to extend the deadlines to meet the milestones, and we are in breach for failure to timely meet the milestones or to make milestone or royalty payments, Columbia University may elect to convert our license to a nonexclusive license without the right to sublicense or initiate legal proceedings against third party patent infringers or terminate our license. We are also obligated to make payments to Columbia University in an aggregate amount of up to $20 million based on achieving specified development and regulatory approval milestones and in an amount of up to $25 million based on achieving a specified cumulative sales milestone with respect to the first licensed product. In addition, we are obligated to pay Columbia University a specified portion of revenue (other than royalties) we receive from sublicensees and a percentage of revenue in the low double-digits received from any sale of a priority review voucher by us or a sublicensee. In the event that we or a sublicensee do not sell a priority review voucher within one

year of receipt, the earned royalties that we would be obligated to pay to Columbia University based on net sales of licensed products would increase by 1%. We cannot reasonably estimate whether, when and in what amount any of such payments shall be made, but believe we are in compliance with the terms of the license. From inception through December 31, 2021, we have made a payment of $1 million to Columbia University resulting from this license agreement, which was triggered by the completion of our Phase 1 clinical trial.

We also enter into cancelable contracts in the normal course of business with CROs for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. As of the date of this prospectus, the remaining contractual costs expected to be incurred in future periods for our clinical trials in STGD1 is approximately $10.0 million.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet arrangements. We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. In addition, we have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our consolidated financial statements included elsewhere in this prospectus. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

Quantitative and Qualitative Disclosures About Market Risks

Interest and Credit Risk

We are exposed to market risk related to changes in interest rates. We had cash of approximately $17.3 million as of December 31, 2021. Interest-earning instruments carry a degree of interest rate risk and we are not exposed to other interest rate risk. We have not been exposed to material risks due to changes in interest rates, and we have not used any derivative financial instruments to manage our interest risk exposure.

Our credit risk is primarily attributable to cash. We mainly place or invest cash with reputable financial institutions in the jurisdictions where we and our subsidiaries are located. We do not believe that our cash has significant risk of default or illiquidity, and we will continually monitor the credit worthiness of these financial institutions. While we believe our cash does not contain excessive risk, future investments may be subject to adverse changes in market value.

Assets that potentially subject us to significant concentration of credit risk primarily consist of cash. We expect that there is no significant credit risk associated with our cash, which were held by reputable financial institutions in the jurisdictions where we and our subsidiaries are located. We believe that it is not exposed to unusual risks as these financial institutions have high credit quality.

Foreign Currency Exchange Rate Risk

Our functional currency is U.S. dollars, but we contract with CROs and CMOs globally. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. As of December 31, 2021, substantially all of our total liabilities were denominated in the U.S. dollar.

Internal Control over Financial Reporting

Prior to this offering, we have been a private company with limited accounting and financial reporting personnel and other resources to address our internal controls and procedures. In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2021, we and our independent registered public accounting firm identified one material weakness in our internal control over

financial reporting. The material weakness identified is our lack of formal policies and procedures to establish risk assessment processes and an internal control framework.

We are currently in the process of implementing a number of measures to address the material weakness identified, including: (i) preparing comprehensive accounting policies, manuals and closing procedures to improve the quality and accuracy of our period-end financial closing process; and (ii) appointing independent directors, establishing an audit committee, and strengthening corporate governance.

We may incur significant costs in the implementation of such measures. However, we cannot assure you that all these measures will be sufficient to remediate our material weaknesses in time, or at all. Additionally, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. See "Risk Factors — Risks Related to This Offering and Our ADSs — If we fail to establish and maintain proper internal controls over financial reporting, our ability to produce accurate financial statements or comply with applicable regulations could be impaired."

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. Our most critical accounting policies are summarized below. See Note 3 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of our other significant accounting policies.

Research and Development Expenses

Research and development expenses primarily include (1) payroll, share-based compensation and other related costs of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to us, (3) costs related to preclinical testing of the Company's technologies and clinical trials such as payments to contract research organizations ("CRO") and contract manufacturing organizations ("CMO"), investigators and clinical trial sites that conduct the clinical studies; (4) costs to develop our product candidates, including raw materials and supplies, product testing, clinical trial equipment and its depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Company's research and development services and have no alternative future uses.

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses resulting from obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided under such contracts. We reflect research and development expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities and determine accrual estimates through review of the underlying contracts along with discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from our estimates. Estimates for accrued research and development expenses are classified as accrued expenses on the accompanying consolidated balance sheet.

Share-Based Compensation

Awards Granted to Employees

We grant share options to eligible employees, management and directors and accounts for these share-based awards in accordance with Accounting Standards Codification, or ASC, 718, *Compensation-Stock*

Compensation. Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses a) immediately at grant date if no vesting conditions are required; b) using graded vesting method over the requisite service period, which is the vesting period, on a straight-line basis; or c) for share-based awards granted with performance condition, using graded vesting method over the period based on the expected milestone achievement dates. Share-based compensation expense is recorded in research and development and general and administrative expenses based on the classification of the work performed by the grantees.

Our determination of the fair value of share option on the date of grant utilized the Binominal Option Pricing Model with the assistance of an independent third party valuation firm. Grant date fair value was impacted by our ordinary share price as well as changes in assumptions regarding a number of subjective variables which included, but were not limited to, the expected term that options remained outstanding, the expected ordinary share price volatility over the term of the option awards, risk-free interest rates, and expected dividends.

To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed.

Awards Granted to Non-Employees

We have accounted for equity instruments issued to non-employees in accordance with Accounting Standards Update, or ASU, No. 2018-07, *Compensation — Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*.

We recognize share-based compensation cost for equity awards to non-employees with a performance condition at the fixed fair value on date of grant over the period based on the expected milestone achievement dates as the derived service period (usually the vesting period), on a straight-line basis. We consider the probable outcome of that performance condition when determining share-based compensation expenses and will recognize a cumulative true-up adjustment if the probability of the conditions has changed.

The following table summarizes our share option activities under the 2020 Share Incentive Plan and the 2019 Share Incentive Plan for the years ended December 31, 2020 and 2021:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	1,335,794	$0.1191	$2.4720	9.96	3,301
Granted	2,807,381	$0.4386	$2.2574	—	—
Exercised	(727,676)	$0.1191	$2.4720	—	—
Forfeited or expired	(19,601)	$0.1191	$2.4733	—	—
Outstanding as of December 31, 2020	3,395,898	$0.3832	$2.2946	9.80	7,834
Granted	41,736	$4.2254	$0.4626	—	—
Exercised	(706,406)	$0.3289	$2.3311	—	—
Forfeited or expired	(748,667)	$0.4386	$2.2574	—	—
Outstanding Options, December 31, 2021	1,982,561	$0.4626	$2.2571	8.82	$4,480
Vested and Expected to Vest Options as of December 31 2021	844,774	$0.3935	$2.3052	8.58	$1,969
Exercisable Options as of December 31, 2021	356,067	$0.2291	$2.4192	7.99	$ 891

Total unrecognized employee share-based compensation expense, which may be adjusted for actual forfeitures occurring in the future, were approximately $2.6 million and $0.8 million as of December 31, 2020 and December 31, 2021, respectively. The unrecognized compensation is expected to be recognized over a weighted-average period of 1.68 years and 2.77 years as of December 31, 2020 and December 31, 2021, respectively.

The fair value of options was determined using the Binomial Option Pricing Model, with assistance from an independent third-party appraiser. The binomial model requires the input of highly subjective

assumptions, including the expected volatility, the exercise multiple, the risk-free interest rate and the expected dividend yield. For expected volatility, we have made reference to historical volatility of several comparable companies in the same industry. The exercise multiple was estimated as the average ratio of the stock price to the exercise price of when employees would decide to voluntarily exercise their vested share options. As we did not have sufficient information of past employee exercise history, the exercise multiple was based on management's estimation. The risk-free rate for periods within the contractual life of the options is based on the market yield of U.S. Government Notes with a maturity life equal to the remaining maturity life of the options as of the valuation date. The expected dividend yield is based on our expected dividend policy over the contractual life of the options.

The assumptions used to estimate the fair value of the share options on the date of grant are as follows:

	As of December 17, 2019	As of December 23, 2020	As of March 1, 2021
Risk-free interest rate	1.72% – 1.74%	0.51%	0.87%
Expected volatility range	35.50% – 35.72%	36.59%	36.75%
Exercise multiple	2.8	2.8	2.8
Expected dividend yield	—	—	—

The following table summarizes total share-based compensation cost recognized:

	Years ended December 31,	
	2020	2021
Research and development	$ 77	$ 52
General and administrative	1,286	1,478
Total	$1,363	$1,530

Recent Accounting Pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in Note 3 "Summary of Significant Accounting Policies — Recent Accounting Pronouncements" of our consolidated financial statements beginning on page F-1 of this prospectus.

JOBS Act

In April 2012, the JOBS Act was enacted. Section 107 of 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 applicable to public companies. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This transition period is only applicable under U.S. GAAP, which is the standard to which we prepare our consolidated financial statements.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we intend to rely on all of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis and (iii) complying with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common shares that are held by non-affiliates exceeds $700.0 million as of the prior June 30th.

BUSINESS

Overview

We are a clinical stage biopharmaceutical drug development company focused on novel therapeutics targeting currently untreatable eye diseases involving retinal degeneration such as atrophic age-related macular degeneration (commonly known as dry AMD) and autosomal recessive Stargardt disease, or STGD1, both of which progressively lead to permanent blindness, and metabolic diseases such as non-alcoholic fatty liver disease, or NAFLD, nonalcoholic steatohepatitis, or NASH, type 2 diabetes, or T2D, and gout.

LBS-008

We believe our lead product candidate, LBS-008, or Tinlarebant, if approved, would provide a novel treatment option where there currently is none. LBS-008 is an oral once-a-day treatment that can reduce and maintain the delivery of vitamin A (retinol) to the eye as a means to reduce the accumulation of toxic vitamin A by-products in ocular tissue. This effect is achieved through the ability of LBS-008 to reduce and maintain the level of serum retinol binding protein 4, or RBP4, which carries retinol from the liver to the eye. In clinical trials, LBS-008 has demonstrated its target specificity and potency that we believe could be clinically meaningful to treat STGD1 patients. We initiated an open-label, dose-finding Phase 1b/2 clinical trial in adolescent STGD1 patients in mid-2020 in Australia and Taiwan. The study design includes two portions: Phase 1b and Phase 2. We have completed the Phase 1b portion of this study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Australia and Taiwan. The preliminary data from the Phase 1b portion has shown that LBS-008 can achieve a mean RBP4 reduction of > 70%, relative to baseline values. We are currently conducting the Phase 2 portion of this study. See "—Phase 1b/2 Clinical Trial in STGD1" below for more information.

As of the date of this prospectus, we have initiated our Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions.

STGD1 is a rare monogenetic juvenile-onset macular dystrophy that is characterized by the aberrant and excessive accumulation of toxic vitamin A by-products known as bisretinoids and cellular debris, or lipofuscin, which precedes the death of retinal tissue and loss of vision. Although an orphan disease, STGD1 is the most common juvenile macular degeneration. Dry AMD is a heterogenous condition that arises from a complex interplay between age, genetics and environmental factors, such as diet and smoking, but has a pathology and course of disease that strongly resembles that of STGD1, particularly in intermediate and advanced stages. There are no approved therapies for STGD1 or dry AMD.

Developed from our RBP4 intellectual property portfolio, or RBP4 IP Portfolio, LBS-008 was designed to be a potent and reversible RBP4 antagonist. As an RBP4 antagonist, LBS-008 reduces the amount of retinol entering the visual cycle thereby reducing the formation of bisretinoid toxins which will ultimately preserve the health of the retina. We hold a worldwide exclusive license of the RBP4 IP Portfolio from Columbia University, which contains disclosure directed to over 400 structurally distinct RBP4 antagonists under patent protection in major pharmaceutical markets worldwide, including the United States, the European Union, China, Australia, Japan, South Korea and India.

LBS-008 has received orphan drug designation for the treatment of STGD1 in the United States, which entitles it to market exclusivity such that the U.S. Food and Drug Administration, or FDA, may not approve any other applications for the same product for the same indication for 7 years, except in very limited circumstances. See "Regulations — U.S. Regulation — NDA Submission and Review — Orphan Drug Designation and Exclusivity" for more information. LBS-008 has also received orphan designation for the treatment of STGD1 in Europe, which entitles it to a 10 year period of market exclusivity, which may be reduced in certain circumstances. During this market exclusivity period, neither the European Medicines Agency, or EMA, nor the European Commission or the member states can accept an application for, or grant a marketing authorization for, a "similar medicinal product." See "Regulations — European Regulation — Orphan Designation and Exclusivity" for more information. Additional benefits of an orphan drug

designation include a tax credit of 50% of the qualified clinical testing expenses for the relevant taxable year and a waiver of the new drug application, or NDA, application fee (which is approximately $3.1 million for fiscal year 2022).

LBS-008 has also received rare pediatric disease designation in the United States and may be eligible for a priority review voucher. A priority review voucher may be awarded to a sponsor if it develops a drug for a rare pediatric disease and the drug is approved. The priority review voucher allows the sponsor of a subsequent NDA or Biologic License Application for any product candidate to expedite the FDA's review goal from 10 months to 6 months. The priority review voucher may be sold to other companies that seek to expedite drug reviews. See "Regulations — U.S. Regulation — NDA Submission and Review — Rare Pediatric Disease Designation and Priority Review Vouchers" for more information. In the last three years, priority review vouchers have sold in a price range between $80-125 million. In the event that we or a sublicensee chooses to sell a priority review voucher, we or such sublicensee would be obligated to pay Columbia University a percentage of revenue in the low double-digits that we or such sublicensee receives from any such sale pursuant to the Columbia License Agreement. In the event that we or a sublicensee does not sell a priority review voucher within one year of receipt, the earned royalties that we would be obligated to pay to Columbia University based on net sales of licensed products would increase by 1%. See "Business — Intellectual Property — Patents — Patent License Agreement with The Trustees of Columbia University in the City of New York" for more information.

LBS-008 is the only drug candidate within the current drug development projects of the National Institute of Health (NIH) Blueprint Neurotherapeutics Network, or the BPN, that is intended to treat dry AMD. The BPN was launched in 2004 to foster small-molecule neurotherapeutic development, bringing together a unique blend of grant dollars, industry-standard scientific expertise, and contract resources under a milestone-driven cooperative agreement program. The BPN criteria for selection of clinical drug candidates are based on multiple features of an applicant's drug development program including the following: 1) strong biological rationale, 2) novel target for the disease, 3) strong data linking target to disease, 4) demonstration of preclinical pharmacodynamic effect and efficacy, 5) feasible path to clinic, and 6) IP free of roadblocks. LBS-008 was selected by the BPN in 2011 and, as of the date of this prospectus, is the only drug candidate within the current drug development projects of the BPN that is intended to treat dry AMD.

The mechanism of action utilized by LBS-008 has been recognized and recommended as a priority for clinical development in both STGD1 and dry AMD in a systematic review published by the U.K. National Institute for Health Research, or the NIHR, in 2018. The NIHR is funded by the U.K. Department of Health and Social Care and focuses on early translational research, clinical research and applied health and social care research for the purpose of enabling and delivering world-leading health and social care research that improves people's health and wellbeing and promotes economic growth. The NIHR screened 7,948 articles in 2018 for its systematic review on treatments for dry AMD and STGD1. Its principal findings included that research focus should be at earlier stages in both diseases (before vision is impaired) and that the most promising treatments for both diseases appear to be prevention of lipofuscin and bisretinoid accumulation. Therefore, the NIHR recommended the mechanism of RBP4 inhibition, which is utilized by LBS-008, as a promising treatment in dry AMD and STGD1.

Although there are currently no approved treatments available for STGD1 and dry AMD, our competitors for LBS-008 include several companies going through clinical development for their product candidates. Based on publicly available information, we understand that there is one Japan-based pharmaceutical company that has an asset in Phase 3 development for STGD1. There are also three U.S.-based companies advancing treatments for STGD1 and their assets are currently in Phase 2 and Phase 2b development, respectively, with the third company having recently completed their Phase 2a trial. In geographic atrophy, or GA, there are five U.S.-based companies in late-stage clinical development, three of which have assets in Phase 3 development and two of which have assets in Phase 2 development.

Clinical Trials in Healthy Adult Subjects

To support the clinical development of LBS-008, we have completed one randomized, double-blind, placebo-controlled, Phase 1 SAD study in 40 healthy adult subjects in the United States, one randomized, double-blind, placebo-controlled, Phase 1 single ascending dose, or SAD, study in 39 healthy adult subjects

and one randomized, double-blind, placebo-controlled, Phase 1 multiple ascending dose, or MAD, study in 32 healthy adult subjects in Australia. These studies were conducted to confirm the safety, toxicity, pharmacokinetics, or PK, and pharmacodynamics, or PD of LBS-008 on a range of single ascending dose (10-50 mg in the US; 25-400 mg in Australia) / multiple ascending dose (5-25 mg in Australia) levels in heathy adult subjects in fasted / fed conditions.

In the US SAD study, we found that single doses of 10–50 mg LBS-008 were well tolerated and reduced mean serum RBP4 level by around 70% from baseline. The degree of lowering of RBP4 plasma concentrations increased with increasing LBS-008 dose. This study also compared doses of LBS-008 taken with and without food, which did not show a food effect with dosing.

In the Australian SAD study, we found that single doses of 25-400 mg LBS-008 were well tolerated and reduced mean RBP4 level by > 70% from baseline. One subject in the 100 mg cohort experienced a drug-related adverse event of mild transient xanthopsia. That event was resolved within 48 hours. A direct correlation between the LBS-008 plasma concentration and RBP4 suppression was observed.

In the Australian MAD study, we found that all dose levels were well tolerated and have identified an optimal daily dose to reduce serum RBP4 by >70% from baseline. Most drug-related adverse events reported were mild in severity, and the most frequently reported drug-related adverse event was asymptomatic Delayed Dark Adaptation, or DDA, which did not show dose proportionality and reflects a reduction in vitamin A levels in the eye, which is the intended effect of LBS-008. No deaths, serious or severe adverse events were reported. The Safety Review Committee, or SRC, approved dose escalations after reviewing the safety data profile at each dose level.

Stargardt Disease

In STGD1, we are developing LBS-008 as an oral daily treatment to target RBP4 by disrupting vitamin A (retinol) binding to RBP4 which leads to reduced delivery of retinol to the eye and reduced accumulation of toxic vitamin A by-products.

STGD1 is an inherited juvenile form of macular degeneration and currently, there is no approved treatment available. The disease is caused by a mutation in the ABCA4 gene, which leads to the accelerated formation and accumulation of toxic vitamin A by-products known as bisretinoids. The most prominent bisretinoid identified in human tissues is known as A2E (*N*-retinylidene-*N*-retinylethanolamine). The accumulation of A2E in ocular tissues causes progressive retinal cell death and permanent loss of vision. More than 500 mutations in the ABCA4 gene have been identified in STGD1 patients. Some STGD1 patients suffer severe visual impairment by the age of 20. The prevalence rate of STGD1 is estimated to be 1 in 10,000 people. Based on this estimate, approximately 30,000 US citizens are affected by STGD1. This estimate includes both adults and children. Although comprehensive epidemiological data on the prevalence of STGD1 in other countries is not available, the epidemiological literature from other countries, such as Europe and Asian countries, cite the 1 in 10,000 estimate for the prevalence of STGD1.

Phase 1b/2 Clinical Trial in STGD1

We have completed the Phase 1b portion of a Phase 1b/2 open-label, dose-finding study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Taiwan and Australia. The Phase 1b portion is a dose-finding study designed to determine the optimal dose of LBS-008 and to evaluate safety, tolerability, PK and PD in adolescent STGD1 patients for a treatment period of 2 cycles of 14-day daily dosing of LBS-008 (28 days of daily treatment) and a 14-day follow-up period. Upon completion of Phase 1b, an optimal daily dose was identified and which was able to achieve a mean RBP4 reduction of > 70%, relative to baseline values.

The preliminary data shows that most frequently reported drug-related adverse events reported to date included DDA and transient xanthopsia, which were all graded as mild. Reports of transient DDA/night vision impairment and xanthopsia were anticipated and are consistent with LBS-008's mechanism of action. It is notable that in most incidences of DDA, it was confirmed by laboratory measure (dark adaptometry) as the majority of patients were asymptomatic. No deaths or serious or severe Treatment-emergent adverse events, or TEAEs, were reported. In addition, there were no clinically significant findings in relation to vital signs, physical exams, or electrocardiograms, or ECGs.

The Phase 2 portion consists of a 2-year treatment period with a follow-up period of one month. In the Phase 2 portion of the study, in addition to monitoring the safety and tolerability, we aimed to monitor PK and PD biomarkers (RBP4 and retinol) and the effects of treatment using various retinal imaging modalities (including definitely decreased autofluorescence, or DDAF, questionably decreased autofluorescence, or QDAF, Spectral-domain optical coherence tomography, or SD-OCT, and microperimetry), change in best-corrected visual acuity, or BCVA, and the relationship between the change in RBP4 levels and rate of lesion growth.

We are currently conducting the Phase 2 portion of this study. A total of 13 adolescent STGD1 patients were enrolled in the Phase 2 portion of the Phase 1b/2 study. As of the date of this prospectus, all 13 patients have received at least 6 months of treatment and completed the scheduled assessments at the first 6 month interval. Change in BCVA (early treatment diabetic retinopathy study, or ETDRS letter score), and fundus autofluorescence, or FAF, imaging results at 6-months are compared to the baseline measurements at the start of Phase 2. The preliminary data shows that 8 of the 13 patients (or 61.5%) recorded a gain in BCVA (ETDRS letter score) in at least one eye, including 2 patients who recorded a gain in BCVA in both eyes. The average BCVA from the 13 patients was an average loss of 2.8 letters in the right eye, and an average gain of 1.9 letters in the left eye. On FAF retinal imaging, 8 of the 13 patients (or 61.5%) had a reduction or no change in their QDAF area size in at least one eye, including 5 patients who had a reduction or no change in QDAF area size in both eyes. There was an average gain in QDAF area in the right eye of $0.2 \pm 0.09mm^2$ (Mean ± standard error of the mean, or SEM) and in the left eye of $0.1 \pm 0.09mm^2$ (Mean ± SEM). While 12 of the 13 patients had no DDAF lesion measured at the start of Phase 2 and at 6-months, 1 of the 13 patients had a DDAF lesion growth of $0.3mm^2$ in both eyes during the 6-month period. On SD-OCT imaging, a gradual thinning with an average of approximately 7 to 10 microns (on total retinal thickness by ETDRS regions) was observed in both eyes. In the Ellipsoid Zone (EZ), an average increase in defect width of 0.26mm in the right eye and 0.61mm in the left eye were observed. However, 6 patients had a reduction in EZ defect width in at least 1 eye (including 3 patients in both eyes). Additional interim data read-outs will be captured at Months 12, 15, 18 and 21, and a final data read-out will be captured at Month 24.

Phase 3 Clinical Trial in STGD1

As of the date of this prospectus, we have initiated a randomized, double-masked, placebo-controlled, global, multi-center, Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. This study consists of a screening period, a treatment period of 2 years, and a follow-up period of one month. Approximately 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). See “Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us.”

We intend to focus on adolescent patients in our ongoing clinical trials due to several benefits afforded by utilizing this patient population — namely, establishing proof-of-concept in the context of a more severe and rapidly progressing disease (i.e., STGD1 disease progression is faster in adolescent patients compared to adults or later-onset patients), and the ability to readily expand into the larger adult STGD1 population upon approval (i.e., drug approvals for pediatrics and/or adolescents are accepted for adults but drug approvals for adults are not accepted for pediatrics and/or adolescent populations due to safety concerns).

Dry AMD

Due to the strong pathophysiologic similarities between STGD1 and intermediate to advanced stages of dry AMD, we expect LBS-008 to have a similar treatment effect on this population of dry AMD patients.

AMD is an age-related form of macular degeneration. The most commonly used classification system for AMD is the Age-Related Eye Disease Study, or AREDS, classification system, which designates the following categories:

- Category 1 is designated as “No AMD,” although there may be a few small (<63µm in diameter) yellowish subretinal deposits (i.e., drusen beneath the retina).

- Category 2 is designated as "Early AMD" and is characterized by multiple small drusen (<20μm in diameter), a few intermediate drusen (63-124μm in diameter), and abnormalities of the retinal pigment epithelium, or RPE, a monolayer of epithelial cells that lies beneath the retina and provides trophic and metabolic support to photoreceptor cells of the retina.
- Category 3 is designated as "Intermediate AMD," where there is extensive intermediate drusen, large drusen (>125μm in diameter), or geographic atrophy (i.e., localized atrophy of the retina), or GA, and increased lipofuscin in the RPE.
- Category 4 is designated as "Advanced AMD" and is characterized by GA or neovascular maculopathy (i.e., 'wet' AMD).

The only approved therapies for AMD are for 'wet' AMD which represents approximately 10% of all AMD cases. There are no approved therapies for the other stages of AMD, including GA, secondary to advanced AMD, which are collectively referred to as dry AMD and represents approximately 90% of all AMD cases. Importantly, dry AMD is a leading cause of vision loss in older adults. Thus, there is a significant unmet medical need in treating dry AMD patients. There are an estimated 11 million dry AMD patients in the United States and over 196 million patients worldwide with an estimated global direct healthcare cost of US$255 billion.

Disease progression in early dry AMD is very slow. The American Optometric Association reports that most people move through the process from diagnosis to legal blindness in about 10 years. Therefore, investigational therapies have been directed at the treatment of intermediate and advanced stages of dry AMD, which progress more rapidly than earlier stages. Unlike STGD1, dry AMD is believed to have a very heterogenous etiology, and various therapeutic approaches have been explored to slow disease progression in dry AMD. An important feature of Intermediate AMD is the aberrant and excessive accumulation of lipofuscin and bisretinoid toxins, similar to STGD1. In these stages of dry AMD, retinal lesions (i.e., GA) are bordered on all sides by an annulus of autofluorescence which expands in a centrifugal manner followed by lesion expansion into the autofluorescent area. *In vivo* analyses of the autofluorescent area in Intermediate AMD eyes revealed an excitation maxima and fluorescence emission that is consistent with the spectral properties of bisretinoid toxins. Thus, the clinical presentation and biochemical features of intermediate and advanced dry AMD suggest that a therapy directed at reducing the level of bisretinoid toxins may be effective to slow disease progression.

We are currently evaluating our plan to initiate, in 2022, a randomized, double masked, placebo-controlled, Phase 2 or Phase 3 trial, in the United States, Europe, and Asia Pacific. See "Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us." Our objective is to evaluate the efficacy and safety of LBS-008 in the treatment of dry AMD over the course of a two-year treatment period.

LBS-009

LBS-009 is an anti-RBP4 oral therapy targeting liver disease, including NAFLD, NASH, and T2D.

NAFLD occurs when an excess accumulation of fat damages the liver. Currently, it is estimated that approximately 1.9 billion patients suffer from NAFLD worldwide. Over time, the liver damage and the associated inflammation can lead to the development of NASH, which impacts an estimate of more than 9 million patients in the United States alone. As the disease progresses, it can lead to cirrhosis and eventually, complete liver failure. NAFLD and NASH are a growing unmet need for which no FDA-approved treatments are currently available.

T2D is a chronic disease that occurs when the body cannot effectively use insulin, the hormone that regulates blood sugar levels. The health impact of T2D is profound, potentially causing damage to the eyes, heart, blood vessels, kidneys, and nerves. T2D is on the rise, with approximately 422 million patients globally.

LBS-009 is a small molecule designed to compete with retinol for RBP4 binding. When bound to LBS-009, RBP4 can no longer form a large molecular weight complex with transthyretin, or TTR.

Consequently, the RBP4/LBS-009 complex will be removed from circulation by renal filtration. We believe that modulating RBP4 concentrations systemically with LBS-009 has a significant therapeutic potential for treating patients suffering from metabolically associated diseases, including NAFLD, NASH and T2D.

LBS-009 is currently in preclinical development.

Our Management and Clinical Advisory Board

Our management team and ophthalmology clinical advisory board have deep experience and capabilities in ophthalmology, neurology, immunology and immunotherapy, cardiovascular and renal medicine, oncology, neurobiology, biochemistry, drug discovery, clinical development, manufacturing, and commercialization. Our ophthalmology clinical advisory board includes key opinion leaders in the macular degeneration space, including Quan Nguyen, M.D., Professor of Ophthalmology at Stanford University, Hendrik P.N. Scholl, M.D., Professor and Chairman of the Department of Ophthalmology at University of Basel and Co-Director of the Institute of Molecular and Clinical Ophthalmology in Basel, Michel Michaelides, M.D., Consultant Ophthalmologist at Moorfields Eye Hospital and Professor of Ophthalmology, UCL Institute of Ophthalmology, Robyn Guymer, M.D., Professor of Ophthalmology, University of Melbourne and Deputy Director of the Centre for Eye Research Australia and Frank Holz, M.D., Chairman of Ophthalmology, University of Bonn. Together, our management team and ophthalmology clinical advisory board, in connection with our exclusive technology platform, will allow our drugs to be tailored to target at-risk patients across the United States and worldwide, who lack access to necessary treatment in the macular degeneration space.

Our Program

Our lead product candidate, LBS-008, is an RBP4 antagonist. We are developing LBS-008 as an oral daily treatment for STGD1 and dry AMD.

The following table summarizes key information about our clinical program for LBS-008:

Indication	Clinical Trials	Trial Participants	Estimated Timeline
STGD1	Phase 1 single and multiple ascending dose trial	Healthy adult subjects	Completed
	Phase 1b trial	Adolescent patients with STGD1	Completed
	Phase 2 trial	Adolescent patients with STGD1	Ongoing, with interim data read-outs expected to be captured at Months 12, 15, 18 and 21, and a final data read-out to be captured at Month 24.
	Phase 3 trial	Adolescent patients with STGD1	Initiated
Dry AMD	Phase 1 single ascending dose trial	Healthy adult subjects	Completed
	Phase 2 or Phase 3 trial	Patients with dry AMD	2022

Our Strengths

We believe we are well placed to accomplish our mission due to the following strengths:

Novel oral therapy to tap into a niche market for significant unmet medical needs.

LBS-008 is an orally administered, non-retinoid, small molecule antagonist of RBP4 that shows nanomolar potency and a pharmacodynamic effect that is readily reversible upon drug cessation. LBS-008

is intended as a once-a-day treatment to reduce the accumulation of vitamin A-based cytotoxins known as bisretinoids and is intended to slow or halt disease progression in STGD1 and dry AMD.

Pre-clinically and clinically demonstrated mechanism of action.

The LBS-008 mechanism of action has demonstrated both preclinical and clinical proof-of-concept. In the preclinical studies, treatment with LBS-008 showed a clear correlation between reduction of serum RBP4, reduction of bisretinoid cytotoxins in the eye, and photoreceptor preservation in a relevant animal model (i.e., $Abca4^{-/-}$ / $Rdh8^{-/-}$ mice). The clinical significance of this therapeutic approach was realized in a 2-year Phase 2 clinical trial of fenretinide (a retinoid-based RBP4 antagonist) in GA secondary to dry AMD. In that study, subjects achieving a > 70% reduction of RBP4 showed a statistically significant slowing of lesion growth at the end of the study.

Receipt of Orphan Drug Designation in the United States and Europe.

LBS-008 has received orphan drug designation in the United States and Europe, which entitles it to market exclusivity such that the FDA may not approve any other applications for the same product for the same indication for 7 years, except in very limited circumstances, and the EMA, the European Commission and each of the member states may not accept an application for, or grant a marketing authorization for, a "similar medicinal product" for 10 years, which may be reduced in certain circumstances. See "Regulations — U.S. Regulation — NDA Submission and Review — Orphan Drug Designation and Exclusivity" and "Regulations — European Regulation — Orphan Designation and Exclusivity" for more information. Additional benefits of an orphan drug designation include a tax credit of 50% of the qualified clinical testing expenses for the relevant taxable year and a waiver of the NDA application fee (which is approximately $3.1 million for fiscal year 2022).

Receipt of Rare Pediatric Disease Designation in the United States with Eligibility for Priority Review Voucher if approved.

LBS-008 has received rare pediatric disease designation in the United States and may be eligible for a priority review voucher. A priority review voucher may be awarded to a sponsor if it develops a drug for a rare pediatric disease and the drug is approved. The priority review voucher allows the sponsor of a subsequent NDA or Biologic License Application for any product candidate to expedite the FDA's review goal from 10 months to 6 months. The priority review voucher may be sold to other companies that seek to expedite drug reviews. See "Regulations — U.S. Regulation — NDA Submission and Review — Rare Pediatric Disease Designation and Priority Review Vouchers" for more information. In the last three years, priority review vouchers have sold in a price range between $80-125 million. In the event that we or a sublicensee chooses to sell a priority review voucher, we or such sublicensee would be obligated to pay Columbia University a percentage of revenue in the low double-digits that we or such sublicensee receives from any such sale pursuant to the Columbia License Agreement. In the event that we or a sublicensee does not sell a priority review voucher within one year of receipt, the earned royalties that we would be obligated to pay to Columbia University based on net sales of licensed products would increase by 1%. See "Business — Intellectual Property — Patents — Patent License Agreement with The Trustees of Columbia University in the City of New York" for more information.

National Institute of Health Blueprint Neurotherapeutics Network sponsored and endorsed.

LBS-008 is the only drug candidate within the current drug development projects of the BPN that is intended to treat dry AMD. The BPN was launched in 2004 to foster small-molecule neurotherapeutic development, bringing together a unique blend of grant dollars, industry-standard scientific expertise, and contract resources under a milestone-driven cooperative agreement program. The BPN criteria for selection of clinical drug candidates are based on multiple features of an applicant's drug development program. LBS-008 was selected by the BPN in 2011 and, as of the date of this prospectus, is the only drug candidate within the current drug development projects of the BPN that is intended to treat dry AMD.

U.K. National Institute for Health Research endorsed the mechanism of action utilized by LBS-008.

The NIHR commissioned a systematic review of 7,948 articles in 2018 to identify therapeutic approaches that would have the greatest chance to provide a treatment effect in STGD1 and dry AMD. Antagonism of

RBP4, via the LBS-008 mechanism of action, was recommended as a priority for clinical development in both STGD1 and dry AMD. This decision was based upon the clear biological rationale and a well-defined mechanism of action which has demonstrated both preclinical and clinical proof-of-concept.

Potential to treat intermediate to advanced-stage dry AMD with oral therapy for lifetime.

Invasive treatments such as intravitreal injections and gene therapies pose a very high risk for early to intermediate-stage dry AMD patients as these individuals are typically asymptomatic or show very mild symptoms. The treatment modalities that are acceptable for these disease stages, i.e., prior to advanced stage AMD, are non-invasive, self-administered treatments such as oral and topical medications (such as eye drops) that are suitable as daily treatments for chronic slowly progressive diseases such as AMD. However, topical treatments are more suitable for diseases and disorders at the front of the eye as they are unlikely to reach the back of the eye where the disease is localized in dry AMD. As the accumulation of bisretinoid toxins and lipofuscin in dry AMD is a slowly evolving process, any effective treatments would need to be administered during the entire course of disease as these treatments would not be expected to be curative. LBS-008 was developed to be a potent and reversible RBP4 antagonist intended for long-term daily oral administration. Importantly, long-term (5-year) reduction of RBP4 with a retinoid-based RBP4 antagonist (fenretinide) in pre- and post-menopausal women was determined by the study authors to be well-tolerated. The strong pathophysiologic similarities between dry AMD and STGD1 (i.e., early accumulation of bisretinoid toxins which leads to dysfunction or death of the RPE, followed by photoreceptor cell death) suggests that LBS-008 would be effective in both diseases as a long-term treatment.

Highly experienced senior management team supported by world-renowned advisory board and influential key opinion leaders.

Our senior management team is comprised of highly experienced research scientists, clinician scientists, and business development experts who have decades of clinical development experience. This team is supported by a world-renowned advisory board of ophthalmologists and retinal specialists and influential key opinion leaders.

Our Strategies

Our goal is to become a leading biopharmaceutical company with an aim to develop the first approved treatment on STGD1 and dry AMD globally. We intend to accomplish our mission by pursuing the following growth strategies:

- ***Efficiently advance our lead product candidate, LBS-008, through Phase 2 and Phase 3 clinical development in adolescent STGD1 patients and regulatory approval, with the potential to establish a new standard of care for STGD1 patients.*** We are developing LBS-008 as an oral daily treatment for STGD1. The Phase 1b portion of our Phase 1b/2 clinical trial for STGD1 patients has shown that LBS-008 can achieve a mean RBP4 reduction of > 70%, relative to baseline values. We are currently conducting the Phase 2 portion of this study. See "—Phase 1b/2 Clinical Trial in STGD1" above for more information. As of the date of this prospectus, we have initiated our Phase 3 clinical trial, to evaluate the efficacy and safety of LBS-008 in adolescent STGD1 patients over the course of a two-year treatment period and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions.
- ***Leverage the promising clinical data of LBS-008 in adolescent STGD1 patients to initiate Phase 2 or Phase 3 clinical development in dry AMD.*** We have chosen to strategically prioritize our clinical development efforts in adolescent STGD1 patients before pursuing clinical development in adult patients with dry AMD. Clinical research has shown that there is a higher rate of disease progression and rapid deterioration of visual function in childhood-onset STGD1, compared to adult-onset STGD1 and GA in dry AMD. This suggests that therapeutic intervention in an adolescent population would provide an increased likelihood of observing a treatment effect, compared to adult-onset retinal degenerations. Additionally, because of the strong pathophysiologic similarities between STGD1 and dry AMD, a positive treatment effect of LBS-008 in adolescent STGD1 patients would provide a margin of de-risk for a subsequent clinical trial in GA. The Phase 1b portion of our

Phase 1b/2 clinical trial for STGD1 patients has shown that LBS-008 can achieve a mean RBP4 reduction of > 70%, relative to baseline values. Based on this clinical activity, we believe that LBS-008, if approved, will also have therapeutic value in treating dry AMD. We are currently evaluating our plans to initiate a Phase 2 or Phase 3, randomized, double masked, placebo-controlled, global, multi-center trial for dry AMD in 2022 to evaluate the efficacy and safety of LBS-008 over the course of a two-year treatment period.

- ***Potentially advance LBS-009 through clinical development for the treatment of NAFLD and NASH.*** If we obtain the necessary funding, we may develop LBS-009 as an oral treatment for NAFLD and NASH. LBS-009 is currently in preclinical development.
- ***Continue to leverage our exclusive RBP4 IP Portfolio, and look for additional in-licensing or collaboration arrangements, to identify novel candidates to further expand our product pipeline and utilize our global organizational structure to advance programs into clinical development in a capital efficient manner.*** We plan to continue to utilize our exclusive RBP4 IP Portfolio, as well as search for additional in-licensing or collaboration arrangements, to isolate promising and novel drug compounds to expand our therapeutic pipeline. Additionally, we believe our global organizational structure will ultimately lead to significant revenue and cost advantages in the discovery, development and commercialization of our innovative therapeutics.
- ***Evaluate strategic collaborations to maximize the value of our product candidates.*** We hold the worldwide development and commercial rights to our pipeline programs, and we intend to out-license our product candidates or commercialize our product candidates, if approved, in key territories. We may selectively enter into global or regionally focused strategic partnerships around certain targets, product candidates, or disease areas if we believe these collaborations could accelerate the clinical development and maximize the value of our product candidates, ultimately expanding patient access.

Research and Development and Technology

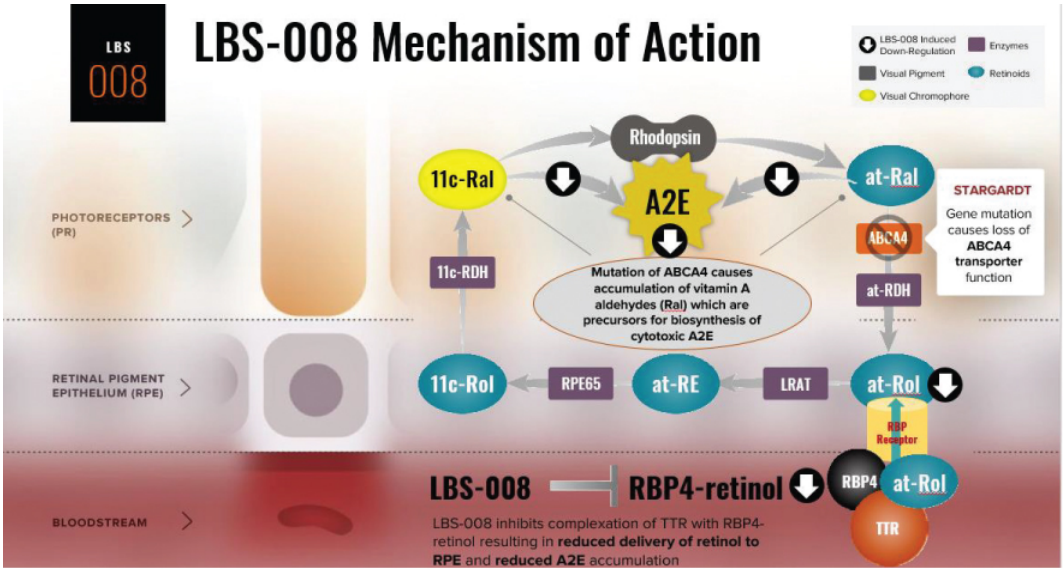
The retina is a thin sheet of nerve tissue which lies along the back inside wall of the eye. Within the retina are two types of light-sensitive cells called photoreceptors. The light-sensing chemical molecule which rods and cones depend upon for proper functioning is delivered by an underlying tissue called the retinal pigment epithelium, or RPE. The RPE maintains the health and viability of photoreceptors by providing other nutrients from the blood and by ingesting the spent distal tips of rods and cones in a process called phagocytosis. The phagocytosis process is particularly important as it facilitates removal of toxic metabolites of vitamin A and other cellular material which has become heavily oxidized due to chronic light exposure. Under normal physiologic conditions, these metabolites are removed from the photoreceptors and transferred to the RPE for detoxification and recycling. It is theorized that, within a subset group of individuals predisposed to develop AMD, the removal and/or recycling process may be compromised. In this condition, the vitamin A metabolites linger within photoreceptors and spontaneously react with other cellular material resulting in chemically stable, toxic entities. These toxins then enter the RPE through the normal physiologic process of phagocytosis and inevitably poison the RPE. The toxins which accumulate within the RPE are derived primarily from vitamin A. Therefore, reducing the level of vitamin A circulating within the eye would be expected to reduce the toxic burden placed upon the RPE. An animal model which demonstrates excess accumulation of lipofuscin and vitamin A based toxin, known as A2E was utilized to determine whether the modulation of vitamin A entering RPE would be an effective therapeutic approach.

Mechanism of Action

Both STGD1 and dry AMD are characterized by the early aberrant accumulation of lipofuscin and cytotoxic bisretinoids. The most abundant autofluorescent bisretinoid that has been identified in human lipofuscin is known as A2E (*N*-retinylidene-*N*-retinylethanolamine), a spontaneously formed complex comprised of two molecules of retinal and one molecule of ethanolamine. Investigations of the potential toxicity of A2E in cell-based assays and animal models have shown that this compound is highly toxic and can kill RPE cells in a concentration-dependent manner through myriad mechanisms. Because A2E and related bisretinoids are derived from vitamin A (i.e., they are by-products of normal visual cycle function), therapeutic approaches have focused on reducing levels of vitamin A (retinol) in the eye. One approach that

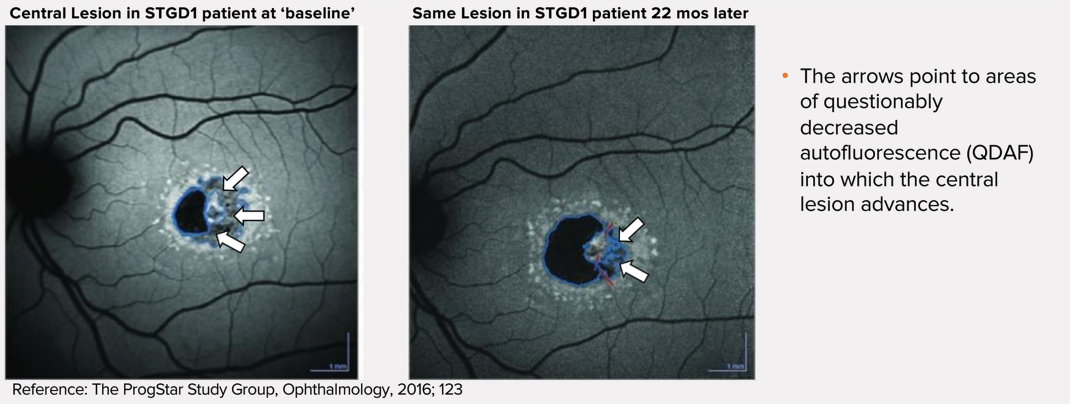
has been effective to reduce A2E and lipofuscin in a mouse model of STGD1 (i.e., Abca4$^{-/-}$ / Rdh8$^{-/-}$ mice) is based on reducing delivery of dietary retinol to the eye. In that mouse model, LBS-008 significantly reduced the accumulation of bisretinoid toxins that are known to cause STGD1 and have been implicated in progression of dry AMD. Importantly, treatment of Abca4$^{-/-}$ / Rdh8$^{-/-}$ mice with LBS-008 also prevented photoreceptor loss, which is believed to be caused by excessive levels of bisretinoid toxins.

LBS-008 is a potent, orally administered small molecule RBP4 antagonist that has been specifically designed to reduce the delivery of retinol to the eye as a therapeutic approach towards reducing the accumulation of cytotoxic bisretinoids, preserving the integrity of retinal tissues, and ultimately slowing or preventing loss of vision. The delivery of retinol to the RPE requires RBP4 and the RPE expresses a specific RBP4 receptor (STRA6) to regulate vitamin A uptake. Other extrahepatic tissues do not require delivery of retinol bound to RBP4 and do not express the RBP4 receptor. These tissues are able to take up vitamin A bound to non-specific carriers such as lipoproteins, triglycerides, and albumin.



Pathophysiologic Similarities in STGD1 and Intermediate to Advanced Dry AMD

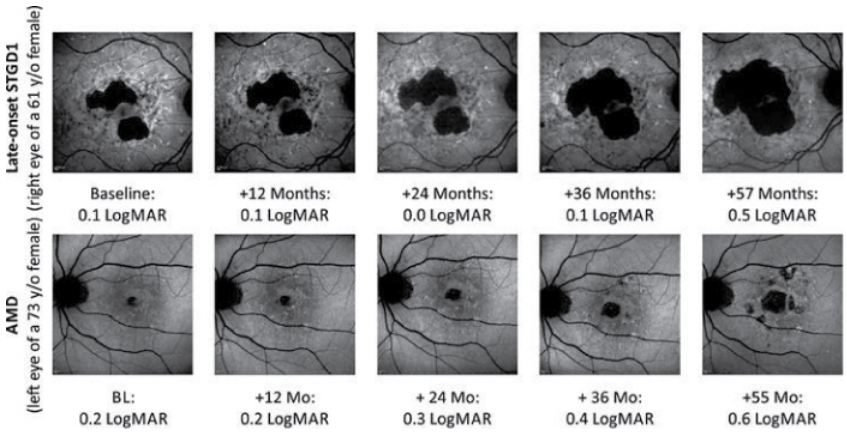
Early *in vivo* measurements of lipofuscin in STGD1 patients revealed an intrinsic autofluorescence which is localized to the RPE. A comprehensive biochemical analysis of post-mortem retinal tissue from STGD1 patients has shown a high concentration of bisretinoid compounds (vitamin A-based dimers) which would likely confer autofluorescence to lipofuscin due to the light absorbing and light emitting properties of these compounds. Thus, the intrinsic autofluorescent properties of lipofuscin in STGD1 can be attributed to the high concentrations of fluorescent vitamin A byproducts within lipofuscin particles. Importantly, this unique feature allows clinicians to diagnose and monitor the extent of retinal disease in STGD1 patients using fundus autofluorescence, or FAF, photography. In a recent prospective cohort study of childhood-onset STGD1 (n = 71 subjects; mean age of onset 9.6 ± 3.4 years), FAF photography was found to be a robust structural outcome measure. In that same study, a high rate of progression was observed in childhood-onset disease, making this subtype of STGD1 ideally suited to be considered for prioritization in clinical trials.



Reference: The ProgStar Study Group, Ophthalmology, 2016; 123

An additional indication under consideration for LBS-008 is GA in dry AMD. This additional indication was selected based upon the strong pathophysiologic similarities between STGD1 and GA, which includes the aberrant and excessive accumulation of vitamin A-based toxins and cellular debris within ocular tissue.

The figure below shows a series of FAF images from a patient with late-onset STGD1 (top panels) and a patient with GA (lower panels). The images were taken at Baseline and at 4 subsequent time points out to 57 months and 55 months, for STGD1 and GA, respectively. In each of the images for the STGD1 patient and the GA patient, the central lesion is surrounded on all sides by autofluorescence which is consistent with the excitation/emission properties of A2E and related bisretinoids. In each patient, the pattern of disease progression from Baseline shows that as the autofluorescence grows in intensity and area, the lesioned tissue follows. Additionally, in the GA patient, the 'evolution' of areas of autofluorescence into lesioned tissue can be clearly seen. It is also important to note that in each disease the loss of visual acuity does not track with the expansion of lesioned tissue. This is due to a phenomena of foveal sparing in both diseases which preserves the small area of tissue in the center of the retina that is responsible for conferring high visual acuity. In addition, as lesions encroach into the fovea, STGD1 and GA patients tend to utilize 'eccentric fixation' in which areas just peripheral to the fovea (non-lesioned retina) are used for reading and high visual acuity.



Proof of Concept from Fenretinide

Our confidence that reduction of serum RBP4 will be a viable treatment approach in STGD1 and GA comes from prospective clinical analyses of the natural history of disease progression in these diseases, and the findings from a 2-year Phase 2 proof-of-concept study that was conducted in dry AMD patients with GA. Fenretinide was selected for the study because of a prominent side effect that had been observed in subjects treated with fenretinide in various clinical oncology studies, a dose-dependent reduction in serum RBP4-retinol, due to its structural and chemical similarity to retinol.

Fenretinide (*N*-(4-hydroxyphenyl) retinamide; also known as 4-HPR) is an analog of all-*trans* retinoic acid (ATRA) first synthesized in the late 1960s as an antineoplastic drug. The Phase 2 GA fenretinide study was a randomized, double-blind, placebo-controlled study with 246 subjects randomized into one of three treatment arms: placebo, 100 mg, or 300 mg. In this study, patients in the 300 mg group who achieved RBP4 levels of ≤ 1 µM, which is equivalent to approximately 70% reduction of RBP4, showed a mean reduction of 0.33 mm^2 in the yearly lesion growth rate compared with subjects in the placebo group (1.70 mm^2/year vs. 2.03 mm^2/year, respectively). However, due to its poor bioavailability and significantly lower affinity towards RBP4 as compared to LBS-008, and therefore weaker potency, only a small subset of GA subjects achieved the criterion. Based on this data, we believe a sustained >70% reduction of RBP4 from baseline would provide the greatest potential for a treatment benefit and, therefore, represents the 'therapeutic threshold' to achieve in future clinical studies directed at reducing the accumulation of A2E and related bisretinoids as a means of preserving retinal tissue and functional vision.

Safety of Long-Term RBP4 Inhibition

In March 1987, a Phase 3 trial was initiated to assess the efficacy of a 5-year treatment regimen with fenretinide in reducing contralateral or second ipsilateral breast cancer in patients aged 30-70 years with early breast cancer, who had received no systemic treatment after primary treatment. A total of 2,867 assessable patients completed the intervention period by July 1998.

Women were randomly assigned to receive no treatment (1,435 patients) or 5-year fenretinide treatment (1,432 patients). Fenretinide was administered in a gelatin capsule (200 mg) and was taken daily at dinner with a two-day drug holiday on weekends. Compared to baseline, plasma retinol levels decreased by a mean of approximately 71% (range: 61% – 88%) during fenretinide administration (P<0.0001). Mean plasma retinol concentrations during fenretinide treatment were ≤1 µM. Following the 5-year treatment regimen, a 28-day treatment cessation period was effective to restore retinol to baseline values.

In terms of disease recurrence in the breast, the trial showed a possible beneficial effect of the compound in premenopausal women, and an opposite trend in postmenopausal women. End points considered for safety assessment were the occurrence of delayed dark adaptation, or DDA, dermatologic disorders, gastrointestinal symptoms, disorders of the ocular surface, and abnormal laboratory values.

A comprehensive analysis of the safety data showed that the most common adverse events were DDA (cumulative incidence, 19.0%) and dermatologic disorders (18.6%). Less common events were gastrointestinal symptoms (13.0%) and disorders of the ocular surface (10.9%). In comparison, incidence figures in the control arm were 2.9% for DDA, 2.9% for dermatologic disorders, 5.4% for gastrointestinal symptoms, and 3.2% for disorders of the ocular surface. Symptoms occurring during fenretinide treatment tended to recover with time. No between-group difference was observed for the occurrence of laboratory data abnormalities. Overall, only 63 (4.4%) treatment discontinuations were caused by adverse events.

The investigators of the study noted that given the large number of patients involved in the study and the prolonged (i.e., over 5 years) intake of the drug, the experience on fenretinide tolerability can be considered reasonably reassuring. The observed clinical symptoms were often of minor importance, tended to recover spontaneously, and required permanent treatment discontinuation in a minority of cases.

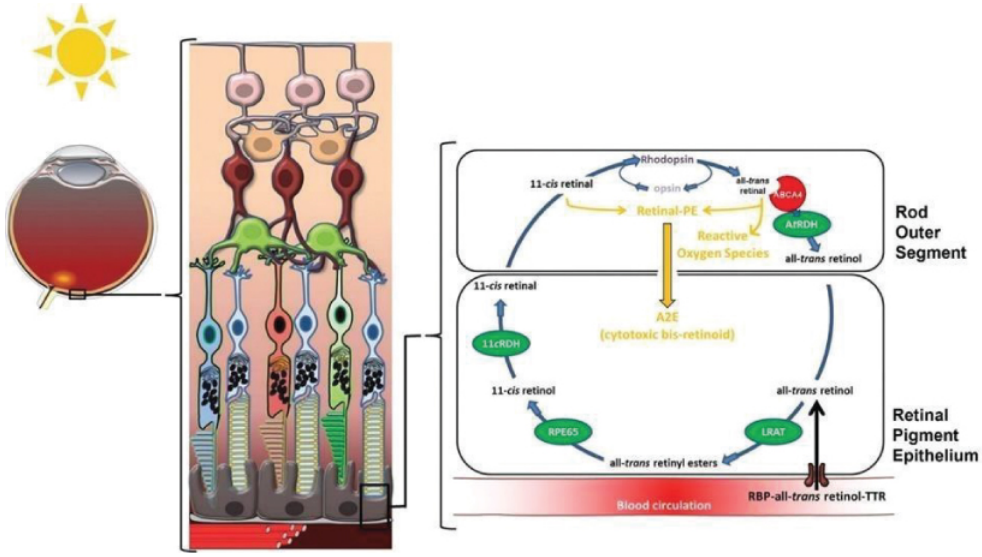
Stargardt Disease

Background

Autosomal recessive STGD1 is a rare monogenetic juvenile-onset macular dystrophy that is characterized by the aberrant and excessive accumulation of toxic vitamin A by-products and cellular debris which precedes the death of retinal tissue and loss of vision. STGD1 is the most common inherited retinal dystrophy, affecting roughly 1 in 10,000 people. This prevalence rate computes to approximately 30,000 STGD1 patients in the United States. The disease is typically diagnosed at a young age, often starting during childhood or adolescence, and is characterized by lesions within retinal tissue which cause severe and irreversible loss of visual acuity gradually leading to legally defined blindness at a very young age. Older age at onset (>20 years of age) is associated with slower disease progression. There are no FDA-approved treatments for STGD1.

Individuals affected with STGD1 harbor mutations in a retina-specific ATP-binding cassette, or ABC, transporter gene, known as *ABCA4*. The *ABCA4* gene encodes an ATP-dependent transporter, known as ABCA4, or Rim Protein. This protein resides at the rim of rod and cone photoreceptor disc membranes where it removes light-activated or 'bleached' visual chromophore (all-trans retinal) from the retina permitting detoxification by a retinal dehydrogenase (RDH8) which, in turn, allows recycling within the underlying RPE. The primary function of the RPE is to provide metabolic and trophic support to sustain health and integrity of the retina. The intimate association of the RPE with outer segments of rod and cone photoreceptors facilitates this function.

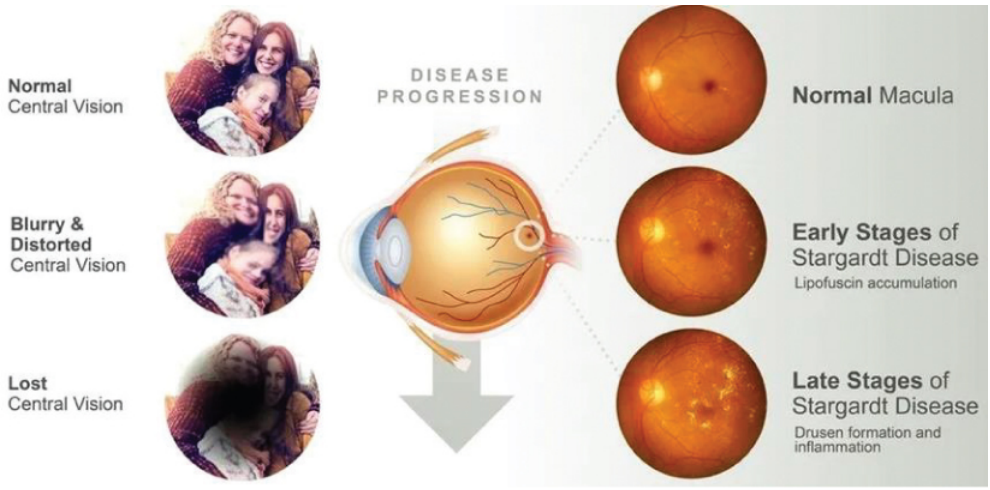
The RPE converts dietary vitamin A delivered from the blood circulation, and recycled retinol liberated from the retina following exposure to light, into visual chromophore (11-cis retinal). The visual chromophore is then transferred to the retina to maintain light sensitivity and function of the retina. The enzymatic conversion of dietary vitamin A to a light-sensitive visual chromophore is a unique process which only occurs within RPE cells and the ABCA4 protein plays a key role in this process — see figure below.



The processing of vitamin A (aka, retinol, or all-trans retinol) in the visual cycle begins with the delivery of circulating retinol to the RPE. The ternary complex of RBP4-retinol-TTR is presented to RBP4 receptors which are located on the basal surface of RPE. The RBP4-TTR vehicle serves to solubilize retinol and produce a large molecular size complex which resists elimination in the kidney. Upon entry into the RPE, retinol undergoes a series of enzymatic reactions resulting in generation of the visual chromophore, 11-cis retinal. The visual chromophore is delivered to the retina where it combines with opsin to form the light-sensitive visual pigment, rhodopsin. Photoactivation of rhodopsin liberates all-trans retinal which is transported out of the retina by the ABCA4 protein.

In the absence of a functional ABCA4 protein, retinal accumulates within photoreceptor outer segments where it generates membrane-damaging reactive oxygen species, and also spontaneously reacts with cellular lipids and other retinaldehyde molecules. These retinal-retinal species, known as bisretinoids, and oxidized membranes are taken into the RPE through normal diurnal phagocytic processing where they gradually accumulate. It is theorized that these compounds reach a critical mass within RPE phagolysosomes and cause dysfunction of the metabolic activities of the RPE leading to early accelerated accumulation of lipofuscin which severely compromises the ability of the RPE to nourish the retina.

Symptoms of STGD1

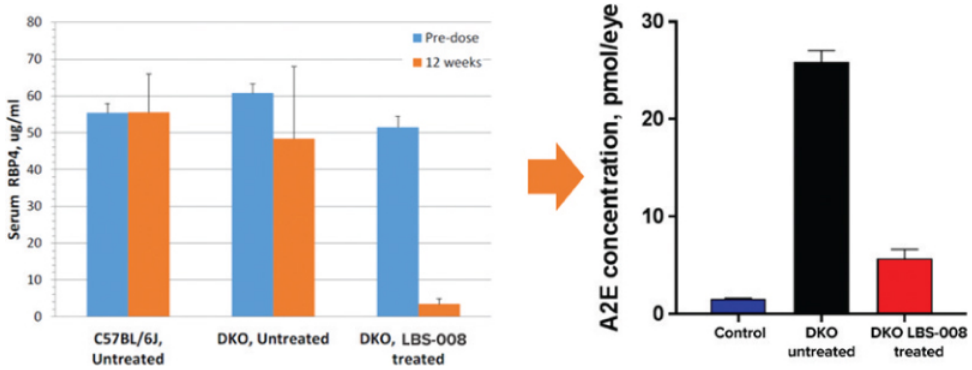


Source: https://makariwellness.com/stargardt-disease/

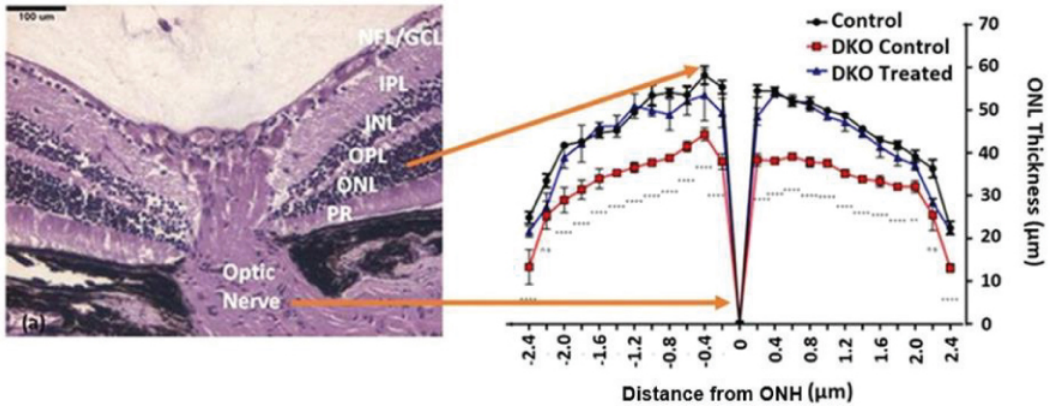
Preclinical Proof of Concept

Abca4−/− / Rdh8−/− STGD1 mouse model

In the Abca4−/− / Rdh8−/− double knockout STGD1 mouse model, daily dosing at approximately 25 mg/kg of LBS-008 was given for 12 weeks. A mean RBP4 reduction of approximately 90% in LBS-008 treated double knockout mice was achieved and led to an approximately 80% reduction of A2E, that are known to cause STGD1 and have been implicated in progression of dry AMD, compared to the untreated double knockout mice.



Importantly, Outer Nuclear Layer, or ONL, thickness was significantly decreased in untreated ABCA4-/-/RDH8-/- mice, compared to the double knockout mice treated with LBS-008. Macular degeneration in Dry AMD and STGD1 is associated with thinning of the ONL which indicates loss of photoreceptor cells, which is believed to be caused by excessive levels of bisretinoid toxins.



Clinical Development

As of the date of this prospectus, we have initiated our Phase 3 clinical trial in adolescent STGD1 patients, and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. We are also conducting our ongoing Phase 2 clinical trial of LBS-008 in adolescent STGD1 patients. Previously, we completed a Phase 1b clinical trial of LBS-008 in adolescent STGD1 patients in late-2021 and two Phase 1 clinical trials of LBS-008 in healthy adult subjects in mid-2020.

Phase 3 Clinical Trial in STGD1

As of the date of this prospectus, we have initiated a randomized, double-masked, placebo-controlled, global, multi-center Phase 3 clinical trial, to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients and received approval to commence patient enrollment in Taiwan, the U.K., Hong Kong and Switzerland. In addition, we are in the process of applying for the necessary approvals to conduct the same clinical trial in other relevant jurisdictions. This study consists of a screening period, a treatment period of 2 years, and a follow-up period of one month. Approximately 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). The Phase 3 clinical trial in STGD1 aims to evaluate the efficacy of LBS-008 by assessing any improvements or changes in visual function and morphological and biomarker changes as detected on specialized retinal imaging. Safety and tolerability will also be assessed during the clinical study period. This trial is expected to be conducted at multiple sites across Australia, Asia, Europe, and North America. See “Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us.”

Phase 1b/2 Clinical Trial in STGD1

We initiated an open-label, dose-finding Phase 1b/2 clinical trial in adolescent STGD1 patients in mid-2020 in Australia and Taiwan. The study design includes two portions: Phase 1b and Phase 2. We have completed the Phase 1b portion of this study in 11 adolescent STGD1 patients which has extended into a two-year, Phase 2 study with 13 adolescent STGD1 patients in Australia and Taiwan. The expected enrollment of this study was 10 patients. As of the date of this prospectus, data is available for the 11 patients who have completed the Phase 1b portion and for all 13 patients who have received at least 6 months of treatment and completed the scheduled assessments at the first 6 month interval.

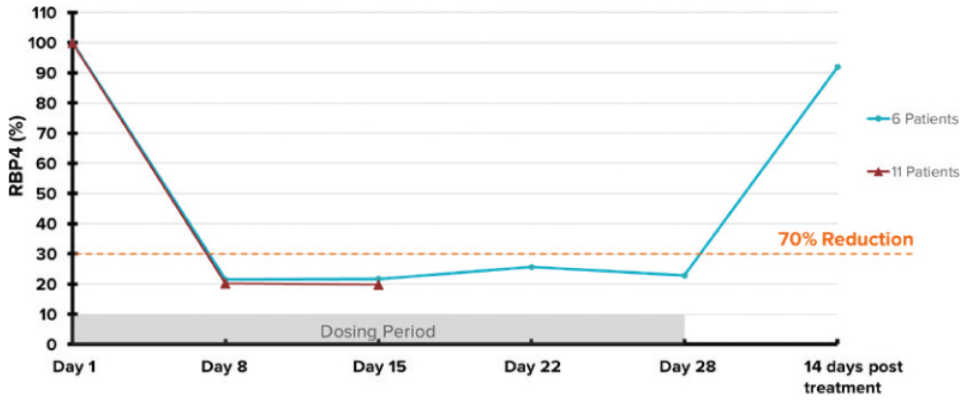
The Phase 1b portion is a dose-finding study designed to determine the optimal dose of LBS-008 and to evaluate safety, tolerability, PK and PD in adolescent STGD1 patients for a treatment period of 2 cycles of 14-day daily dosing of LBS-008 (28 days of daily treatment) and a 14-day follow-up period. The Phase 2 portion consists of a 2-year treatment period with a follow-up period of one month. In the Phase 2 portion of the study, in addition to monitoring the safety and tolerability, we aimed to monitor PK and PD

biomarkers (RBP4 and retinol) and the effects of treatment using various retinal imaging modalities (including DDAF, QDAF, SD-OCT, and microperimetry), change in BCVA, and the relationship between the change in RBP4 levels and rate of lesion growth. Furthermore, a Safety Review Committee, or SRC, and an independent Data and Safety Monitoring Board, or DSMB, were formed to monitor the Phase 1b portion of this study to evaluate all the safety, toxicity, and dose response data and provide recommendations for the appropriate dose to be used for Phase 2. The DSMB will continue to monitor the safety and efficacy trends throughout the Phase 2 study. Interim data read-outs will be captured at Months 12, 15, 18 and 21, and a final data read-out will be captured at Month 24.

Efficacy Results

For the Phase 1b portion, the PD profiles showed that the mean RBP4 level reached and maintained below 30% of the mean baseline value throughout the treatment period. Mean RBP4 level returned to close to baseline values following 14 days of drug cessation. LBS-008 plasma concentration and RBP4 suppression appeared to be correlated. Comparison of PD profiles observed in heathy adults and in adolescent STGD1 patients showed a similarity between the two populations.

Mean RBP4 level of Phase 1b



Note: After Day 15, data were collected from 6 subjects in Australian sites only as data could not be collected due to COVID-19 restrictions at the NTUH site in Taiwan. Mean change of RBP4 (%) for all 11 patients for Days 1 to 15 is presented as the 11-Patients line, and data for the 6 patients in Australian sites for the whole Phase 1b portion is presented as the 6-Patients line.

Upon completion of the Phase 1b portion, an optimal daily dose was identified and which was able to achieve a mean RBP4 reduction of > 70%, relative to baseline values.

We are currently conducting the Phase 2 portion of this study. A total of 13 adolescent STGD1 patients were enrolled in the Phase 2 portion of the Phase 1b/2 study. As of the date of this prospectus, all 13 patients have received at least 6 months of treatment and completed the scheduled assessments at the first 6 month interval. Change in BCVA (ETDRS letter score) and FAF imaging results at 6-months are compared to the baseline measurements at the start of Phase 2. The preliminary data shows that 8 of the 13 patients (or 61.5%) recorded a gain in BCVA (ETDRS letter score) in at least one eye, including 2 patients who recorded a gain in BCVA in both eyes. The average BCVA from the 13 patients was an average loss of 2.8 letters in the right eye, and an average gain of 1.9 letters in the left eye. On FAF retinal imaging, 8 of the 13 patients (or 61.5%) had a reduction or no change in their QDAF area size in at least one eye, including 5 patients who had a reduction or no change in QDAF area size in both eyes. There was an average gain in QDAF area in the right eye of 0.2 ± 0.09mm^2 (Mean ± SEM) and in the left eye of 0.1 ± 0.09mm^2 (Mean ± SEM). While 12 of the 13 patients had no DDAF lesion measured at the start of Phase 2 and at 6-months, 1 of the 13 patients had a DDAF lesion growth of 0.3mm^2 in both eyes during the 6-month period. On SD-OCT imaging, a gradual thinning with an average of approximately 7 to 10 microns (on total retinal thickness by ETDRS regions) was observed in both eyes. In the Ellipsoid Zone (EZ), an average increase in defect width of 0.26mm in the right eye and 0.61mm in the left eye were observed. However, 6 patients

had a reduction in EZ defect width in at least 1 eye (including 3 patients in both eyes). Additional interim data read-outs will be captured at Months 12, 15, 18 and 21, and a final data read-out will be captured at Month 24.

Phase 1b Safety Results

The preliminary safety results of the Phase 1b study shows that the only drug-related adverse events reported were DDA (i.e., a delay in the time required to adjust to a dimly lit environment), and xanthopsia/ chromatopsia (i.e., a transient color tint in the field of vision), both reported by 7 of the 11 patients (or 63.6%), and night vision impairment, reported by 1 of 11 patient (or 9.1%), and were all graded as mild. All of these adverse events were resolved with the cessation of treatment at the end of the Phase 1b study.

Reports of transient DDA, night vision impairment, and xanthopsia/chromatopsia were anticipated and are consistent with the mechanism of LBS-008 action. It is notable that the majority of DDA cases required confirmation by laboratory measure (dark adaptometry) as many subjects were asymptomatic. No deaths nor serious or severe adverse events were reported. In addition, there were no clinically significant findings related to vital signs, physical exams, or ECGs.

Adverse Events	Severity	Relationship to Drug	Frequency (#Patients)	% Recovered	% On-going
Xanthopsia/Chromatopsia	Mild	Definitely Related	7/11	7/7 (100%)	0/7
Delayed Dark Adaptation (DDA)	Mild	Definitely Related	7/11	7/7 (100%)	0/7
Night Vision Impairment	Mild	Definitely Related	1/11	1/1 (100%)	0/1

Phase 2 Safety Results

The preliminary safety results of the Phase 2 study shows that the only definitely and probably drug-related adverse events reported were DDA, reported by 8 of 13 patients (or 61.5%), xanthopsia/chromatopsia, reported by 6 of 13 patients (or 46.2%), night vision impairment, reported by 1 of 13 patients (or 7.7%), and increasing error score on FM100 test (a test of color vision and color perception), reported by 1 of 13 patients (or 7.7%), and were all graded as mild. No deaths nor serious or severe adverse events were reported. In addition, there were no clinically significant findings related to vital signs, physical exams, or ECGs.

Adverse Events	Severity	Relationship to Drug	Frequency (#Patients)	% Recovered	% On-going
Xanthopsia/Chromatopsia	Mild	Definitely Related	6/13	3/6 (50%)	3/6 (50%)
Delayed Dark Adaptation (DDA)	Mild	Definitely Related	8/13	1/8 (12.5%)	7/8 (87.5%)
Night Vision Impairment	Mild	Definitely Related	1/13	0/1	1/1 (100%)
Increasing error score on FM100	Mild	Probably Related	1/13	0/1	1/1 (100%)

Dry AMD

Background

Age-related macular degeneration, or AMD, is a common eye disorder among people over 50. It causes blurred or reduced central vision, due to thinning of the macula. The macula is the part of the retina responsible for clear vision in your direct line of sight.

Symptoms of Dry AMD

Source: https://www.ncbi.ie/supporting-you/everyday-living/eye-conditions/age-related-macular-degeneration-amd/

Based on the classification system established in the AREDS, AMD has four stages, all of which may occur in one or both eyes:

- Category 1 is designated as "No AMD," although there may be a few small (<63μm in diameter) yellowish subretinal deposits (i.e., drusen beneath the retina).
- Category 2 is designated as "Early AMD" and is characterized by multiple small drusen (<20μm in diameter), a few intermediate drusen (63-124μm in diameter), and abnormalities of the RPE, a monolayer of epithelial cells that lies beneath the retina and provides trophic and metabolic support to photoreceptor cells of the retina.
- Category 3 is designated as "Intermediate AMD," where there is extensive intermediate drusen, large drusen (>125μm in diameter), or GA (i.e., localized atrophy of the retina) and increased lipofuscin in the RPE.
- Category 4 is designated as "Advanced AMD" and is characterized by GA or neovascular maculopathy (i.e., 'wet' AMD).

The only approved therapies for AMD are for 'wet' AMD, which represents approximately 10% of all AMD cases. There are no approved therapies for the other stages of AMD, which are collectively referred to as dry AMD and represents approximately 90% of all AMD cases.

Clinical Development

Phase 2 or Phase 3 Clinical Trials in Dry AMD

We are currently evaluating our plan to initiate, in 2022, a randomized, double-masked, placebo-controlled, global, multi-center Phase 2 or Phase 3 trial to evaluate the safety and efficacy of LBS-008 in the treatment of dry AMD, which is expected to be conducted at multiple sites across the United States, Europe and Asia Pacific. See "Risk Factors — In the event that we elect to carry out clinical trials in China and/or expand our operations into China in the future, we will be subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us." Such trials would aim to evaluate the efficacy of LBS-008 by assessing any improvements or changes in visual function and morphological and biomarker changes as detected on specialized retinal imaging. Safety and tolerability will also be assessed during the clinical study period.

Patients are expected to be randomized to two treatment cohorts to receive a once-daily oral dose of LBS-008 or placebo.

Clinical Trials in Healthy Adult Subjects

Phase 1 Clinical Trials in Healthy Adult Subjects (Single and Multiple Ascending Dose Studies in Australia)

We have completed randomized, double-blind, placebo-controlled, single and multiple ascending dose Phase 1 trials of LBS-008 in 71 healthy adult subjects in July 2020 in Australia. 39 (including 10 placebo) and 32 (including 8 placebo) healthy adult subjects were enrolled in single ascending dose and multiple ascending dose, respectively. Sample sizes were selected based on clinical and practical considerations.

Our primary outcome was to evaluate the safety and toxicity (drug-related adverse events and their severity/frequency), PK, and PD biomarkers (RBP4 and retinol) on a range of single ascending dose levels (from 25-400 mg) and multiple ascending dose levels (from 5-25 mg) of LBS-008 in heathy adult subjects in fasted conditions.

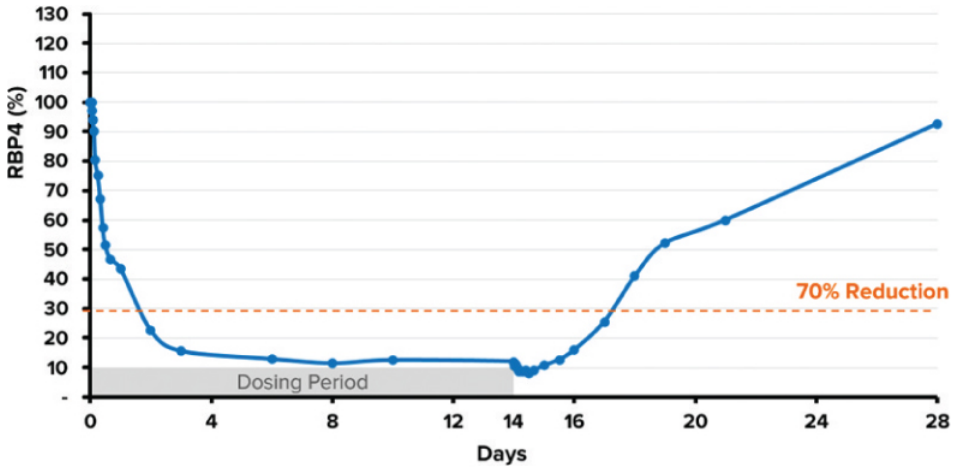
Furthermore, a SRC was formed to monitor and evaluate the safety data for the Phase 1 SAD and MAD studies.

Efficacy Results

In the SAD study, we found that single doses of 25 – 400 mg LBS-008 were well tolerated and reduced mean RBP4 level by > 70% from baseline. A direct correlation between the LBS-008 plasma concentration and RBP4 suppression was observed.

Similar results were observed at steady-state in the MAD portion of the study. We found that all dose levels were well tolerated and have identified an optimal daily dose to reduce serum RBP4 by > 70% from baseline.

Mean RBP4 level in optimal dose in Phase 1 MAD (excluding placebo)



Safety Results

All single ascending dose levels were well tolerated, including single ascending dose levels up to 400mg. One subject in the 100 mg cohort experienced a drug-related adverse event of mild transient xanthopsia. That event was resolved within 48 hours.

Drug-related adverse events in the SAD portion of the study

Adverse Events	Severity	Frequency (#Subjects)
Xanthopsia – yellow being more prominent in their color vision	Mild	1/29

All multiple ascending dose levels were also well tolerated. Most drug-related adverse events reported were mild in severity, and the most frequently reported drug-related adverse event was asymptomatic DDA, which did not show dose proportionality and reflects a reduction in vitamin A levels in the eye, which is the intended effect of LBS-008. No deaths, serious or severe adverse events were reported. The SRC approved dose escalations after reviewing the safety data profile at each dose level.

Drug-related adverse events in the MAD portion of the study

Adverse Events	Severity	Frequency (#Subjects)
Delayed Dark Adaptation (DDA)	Mild	16/24
Xanthopsia – yellow being more prominent in their colour vision	Mild	1/24
Photophobia – sensitivity to light	Mild	1/24
Ocular migraine	Mild	1/24
Intermittent dyspepsia (indigestion)	Mild	1/24
Migraine	Moderate	1/24

Phase 1 Clinical Trial in Healthy Adult Subjects (Single Ascending Dose Study in the United States)

We have completed a randomized, double-blind, placebo-controlled, single ascending dose Phase 1 trial of LBS-008 in 40 (including 10 placebo) healthy adult subjects in May 2020 in the United States. Our primary outcome was to evaluate the safety and toxicity (drug-related adverse events and their severity/frequency), PK, and PD biomarkers (RBP4 and retinol) on a range of single ascending dose levels, ranging from 10-50 mg, of LBS-008 in heathy adult subjects in fasted and fed conditions.

Efficacy Results

We found that single doses of 10–50 mg LBS-008 were well tolerated and reduced mean serum RBP4 level by around 70% from baseline. Following administration of a single oral dose of LBS-008, RBP4 level reached a minimum within 24-48 hours post-dose. Thereafter, RBP4 levels increased, returning to baseline levels generally by Day 12 post-dose compared with placebo subjects. The degree of lowering of RBP4 plasma concentrations increased with increasing LBS-008 dose. This study also compared doses of LBS-008 taken with and without food, which did not show a food effect with dosing.

Safety Results

All dose levels in this single ascending study were well tolerated. There were no reported drug-related adverse events in this Phase 1 study.

LBS-009 for NAFLD / NASH and T2D

LBS-009 is an anti-RBP4 oral therapy targeting liver disease, including NAFLD, NASH and T2D.

Currently, many compounds under investigation are focused on pathways associated with metabolism, inflammation, and fibrosis but they have demonstrated varied levels of efficacy often with conflicting results. NAFLD and NASH are a growing unmet need for which no FDA-approved treatments are currently available.

RBP4 is secreted by the liver and adipose tissue and has recently been identified as a pro-inflammatory cytokine in preclinical models of insulin resistance and liver disease. Therefore, RBP4 is currently being investigated as a clinical biomarker for human metabolic diseases. Clinical studies have found a significant association between elevated RBP4 levels in the circulation, impaired glucose tolerance, and NAFLD. Transgenic mice overexpressing RBP4 had a higher incidence of insulin resistance, a comorbid condition for NAFLD and NASH, and preclinical reports demonstrate that modulating RBP4 levels in the circulation will improve insulin resistance and reduce liver fat accumulation. LBS-009 is a small molecule designed to compete with retinol for binding to RBP4. When bound to LBS-009, RBP4 can no longer form a large molecular weight complex with transthyretin. Consequently, the RBP4/LBS-009 complex will be removed from circulation by renal filtration.

Preliminary PD studies with LBS-009 demonstrated the ability to reduce RBP4 levels in healthy rats by 85% following a single dose. Efficacy studies have been conducted in the ob/ob high-fat diet induced mouse model of metabolic disease. Treatment with LBS-009 significantly reduced RBP4 concentrations both in circulation and in adipose tissue, or fat tissue, resulting in improved insulin activity and glucose tolerance. Mice in these studies were dosed daily with LBS-009 for up to 16 weeks without any observed adverse effects. We believe that by therapeutically antagonizing RBP4 and reducing its concentration in the blood, we can mitigate local concentration of RBP4 in adipose tissue and reduce inflammation, thereby improving the metabolic phenotype. In preclinical studies, LBS-009 has shown the ability to ameliorate steatosis in transgenic mice, suggesting that antagonism of RBP4 with LBS-009 may serve as a potential pharmacotherapy for NASH.

Research and Development Governance

The research and development of drug products is a lengthy and expensive process. We have established research and development policies for all stages of our research and development activities, through our internal research project initiation processes and our preclinical and clinical development programs. Our research and development policies have enabled our senior management to continuously oversee and monitor

our Company's research and development activities for compliance with applicable laws, regulations, rules, guidelines and internal policies.

Our in-house discovery, research and development team focuses on identifying small-molecule compounds in our core therapeutic areas of macular degeneration and age-related metabolic diseases. The initiation of our research and development process begins with the identification and establishment of a research project. Upon conclusion of this initial process, an internal project report is produced by the research project team, which includes topics such as project background, significance, development history and research status, mechanism of action, pharmacokinetics, pharmacodynamics, clinical application, safety, drug interaction and market analysis, among other things.

We have relied on and plan to continue to rely on third-party CROs to monitor and manage data for some of our ongoing preclinical studies and clinical trials. We follow the highest industry standards to select the CROs that are going to conduct the services in order to meet FDA and other regulatory requirements.

Manufacturing and Supply

We currently rely on high-quality contract manufacturers to help produce preclinical and clinical supplies of our product candidate. Throughout our labs, we have assembled a seasoned internal team with deep experience in the field of chemistry to drive and help monitor our CMO processes and any external scale-up manufacturing. Our internal labs help monitor the manufacturing activities of research and development study material at our contract manufacturers to ensure compliance with local and international cGMP and applicable regulations.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain intellectual property and other proprietary protection for our product candidates, technologies, inventions, trade secrets and other know-how, as well as on our ability to defend and enforce our intellectual property or proprietary rights including any patent that we have or may issue from our owned, co-owned, or in-licensed patent applications, preserve the confidentiality of our trade secrets and operate without infringing, misappropriating or otherwise violating the valid and enforceable intellectual property and proprietary rights of other parties. We protect our proprietary and intellectual property position by, among other methods, licensing or filing in the United States and foreign jurisdictions, patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also seek to protect our trade secrets, know-how and continuing technological innovation through contractual obligations with third parties.

Patents

We have developed our lead product candidate, LBS-008, based on technology that we have exclusively licensed from the Trustees of Columbia University in the City of New York, or Columbia University, pursuant to a license agreement with Columbia University that was assigned to us from Lin Bioscience International Ltd., our principal shareholder. The license agreement has been amended five times, most recently as of February 4, 2022. As of April 20, 2022, the intellectual property in-licensed under our license agreement with Columbia University, including co-owned patents and patent applications, includes nine active patent families, which encompasses 18 issued U.S. patents and 4 pending U.S. patent applications, including original filings, continuations and divisional applications. The families also include numerous foreign counterparts, with claims granted or pending in Europe, China, Japan, South Korea, Australia and elsewhere. These licensed patent rights relate to methods of use, manufacture and compositions of matter and include issued patents with claims that recite a class of compounds directed to covering our lead compound, LBS-008, and specifically recite LBS-008. In terms of our key family of composition of matter patents, these include compounds of LBS-008 and LBS-009, and structurally similar derivatives, along with their methods of use in ophthalmic and metabolic indications. These issued patents covering LBS-008 and LBS-009 are expected to expire between 2034 and 2035, absent any patent term extensions.

In addition to the intellectual property licensed from Columbia University, as of April 20, 2022, we own and co-own six active patent families, which encompasses two issued U.S. patents and six pending U.S. patent applications, including provisional filings. These patent families also contain numerous foreign

counterparts, with claims granted or pending in Europe and elsewhere. These patent rights relate to methods of use, formulations, companion diagnostics, and methods for assessing visual function. Any patents issued from these patent applications are expected to expire between 2038 and 2043, absent any patent term adjustments or extensions.

In-licensed Patents and Patent Applications

Patent Family No.	Type of Patent	Issued Countries/ Regions and/or Application Type	Pending Countries/ Regions and/or Application Type	Termination Date (mm/dd/yyyy)	Subject to "March-in Rights" (Yes/ No)
1	Utility – Methods of Use	U.S Europe Japan	N.A	11/22/2031	Yes
2	Utility – Methods of Use	U.S	N.A	04/30/2033	Yes
3	Utility – Manufacture and Composition of Matter	U.S U.S Divisional #1 Europe Europe Divisional	U.S Divisional #2 Hong Kong	03/13/2034	Yes
4	Utility – Manufacture and Composition of Matter	U.S U.S Continuation #1 U.S Continuation #2 Europe	N.A	03/13/2034	Yes
5	Utility – Manufacture and Composition of Matter	U.S U.S Divisional	N.A	03/13/2034	Yes
6	Utility – Manufacture and Composition of Matter	U.S U.S Continuation	N.A	03/13/2034	Yes
7	Utility – Manufacture and Composition of Matter	U.S U.S Continuation #1 U.S Continuation #2 U.S Continuation #3 U.S Continuation #4 Europe Australia India Mexico Japan Philippines China Singapore Indonesia	U.S Continuation #5 Hong Kong South Korea Myanmar Thailand Canada China Divisional New Zealand Brazil Europe Divisional	04/29/2035	Yes
8	Utility – Methods of Use	N.A	U.S Europe Hong Kong China	08/01/2039	Yes

Co-owned Patents and Patent Applications

Patent Family No.	Type of Patent	Issued Countries/ Regions and/or Application Type	Pending Countries/ Regions and/or Application Type	Termination Date (mm/dd/yyyy)	Subject to "March-in Rights" (Yes/ No)
9	Utility – Methods of Use	U.S, U.S Divisional #1	U.S Divisional #2 Europe Taiwan Hong Kong	06/14/2038	No

Belite-owned Patents or Patent Applications

Patent Family No.	Type of Patent	Issued Countries/ Regions and/or Application Type	Pending Countries/ Regions and/or Application Type	Expected Termination Date (mm/dd/yyyy)	Subject to "March-in Rights" (Yes/ No)
10	Utility – Methods of Use	N.A	Europe Taiwan Hong Kong	06/14/2038	No
11	Utility – Formulations	N.A	U.S Europe Australia Canada China India Israel Japan South Korea Singapore Taiwan	07/06/2040	No
12	Utility – Companion Diagnostics	N.A	U.S Provisional	05/21/2042	No
13	Utility – Formulation	N.A	U.S Provisional	11/23/2042	No
14	Utility – Assessing Visual Function	N.A	U.S Provisional	04/14/2043	No

The term of individual issued patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. The life of a patent, and the protection it affords, is therefore limited and once the patent life of our issued patents have expired, we may face competition, including from other competing technologies. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug or biological product, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, we expect to apply for patent term extensions on certain issued patents covering our product candidates, depending upon the length of the clinical trials for each product candidate and other factors. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents. As a result, our owned, co-owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For more information, see the section entitled "Risk Factors — Risks Related to Our Intellectual Property".

We granted rights to use our intellectual property to manage our clinical trials for STGD1 in Australia to our wholly-owned subsidiary, RBP4 Pty Ltd.

Patent License Agreement with The Trustees of Columbia University in the City of New York

In September 2016, Lin BioScience, Inc., our ultimate controlling shareholder, entered into an agreement with Columbia University (as amended, the "**Columbia License Agreement**") for an exclusive worldwide license, under specified patent rights held by Columbia University, to develop and commercialize products covered by the licensed patent rights for all fields. The Columbia License Agreement was assigned to Lin Bioscience International Ltd. and subsequently assigned to us in 2018. We have the right to grant sublicenses under this license.

The patent rights licensed to us under the Columbia License Agreement include issued patents with claims that recite a class of compounds directed to covering our planned lead compound, LBS-008, and specifically recite LBS-008.

Under the Columbia License Agreement, we paid a one-time license fee of $2.5 million in connection with the execution thereof. We will be obligated to make minimum annual royalty payments to Columbia University of (i) $2.5 million on each of the second, third and fourth anniversaries of the first commercial sale of a licensed product and (ii) $5 million on each anniversary of the first commercial sale of a licensed product, commencing on the fifth anniversary of such sale. We will also be obligated to pay single-digit earned royalties to Columbia University based on net sales of each licensed product by us and our affiliates and sublicensees. The minimum royalty payments will be creditable against the earned royalties accrued during the same calendar year. The license agreement obligates us to use commercially reasonable efforts to research, discover, develop and market licensed products for commercial sale and distribution and achieve certain development and regulatory approval milestones within certain timeframes, if certain milestones are achieved. We are also obligated to periodically inform Columbia University of our progress in meeting such milestones. The failure to achieve any such milestone would constitute a breach of the Columbia License Agreement. If we pay Columbia University the required fee, we will be granted a 6-month extension. As of the date of this prospectus, we have complied with the development and regulatory approval milestones under the Columbia License Agreement and requested no extensions. In the event that, after completion of Phase I Trials, there are unforeseen changes in clinical or regulatory development that we believe would affect the timely achievement of any milestone, we may request an extension from Columbia University for such milestone, which will not be unreasonably withheld or delayed. In the event that Columbia University does not agree to extend the deadlines to meet the milestones, and we are in breach for failure to timely meet the milestones or to make milestone or royalty payments, Columbia University may elect to convert our license to a nonexclusive license without the right to sublicense or initiate legal proceedings against third party patent infringers or terminate our license. We are also obligated to make payments to Columbia University in an aggregate amount of up to $20 million based on achieving specified development and regulatory approval milestones and in an amount of up to $25 million based on achieving a specified cumulative sales milestone with respect to the first licensed product. In addition, we are obligated to pay Columbia University a specified portion of revenue (other than royalties) we receive from sublicensees and a percentage of revenue in the low double-digits received from any sale of a priority review voucher by us or a sublicensee. In the event that we or a sublicensee do not sell a priority review voucher within one year of receipt, the earned royalties that we would be obligated to pay to Columbia University based on net sales of licensed products would increase by 1%. From inception through December 31, 2021, we have made a payment of $1 million to Columbia University resulting from the Columbia License Agreement, which was triggered by the completion of our Phase 1 clinical trial. We believe we are in compliance with the terms of the license.

Our obligations under the Columbia License Agreement with respect to each licensed product in a particular country extends until the later of the expiration of the last-to-expire patent licensed from Columbia University covering the licensed product in such country, 20 years after the first commercial sale of the licensed product in such country or the expiration of any market exclusivity period granted by a regulatory agency. The last-to-expire patent licensed from Columbia University is anticipated to expire in 2039, absent any patent term adjustments or extensions.

Columbia University has the right to terminate the agreement if we breach the agreement and fail to cure our breach within specified cure periods or in the event of specified bankruptcy, insolvency and

liquidation events or if we initiate a proceeding challenging the validity or enforceability of any of the licensed patents. We have the right to terminate the agreement for our convenience at any time on 60 days' notice to Columbia University. In the event of termination, we have granted to Columbia University a royalty free, worldwide, non-exclusive license to make, use and sell products covered by claims of patents in-licensed by us, or derived from materials or technical information thereof, pursuant to the Columbia License Agreement and in connection with which we have filed patent applications or obtained patents.

Trade Secrets

In addition to patents, we may rely, in some circumstances, upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our scientific advisors, employees, consultants, collaborators, and other third parties, and invention assignment agreements with our consultants and employees.

Trademarks and domain names

As of the date of this prospectus, we had one registered trademark in the United States, one registered trademark in EU, two registered trademarks in China, one registered trademark in Hong Kong, and one registered trademark in Japan, and one trademark application pending in Canada. We did not have any trademark applications pending elsewhere around the world.

As of the date of this prospectus, we have registered the following domain names: tinlarebant.com, tinlarebant.net, tinlarebant.org, belitebio.com, and belitebio.com.tw.

Competition

Our industry is highly competitive, rapidly evolving and subject to significant change. Although we believe that our core competencies in the identification, research and development of innovative therapies and our management team's regulatory and commercialization expertise provide us with distinct competitive advantages, we face significant competition from companies of all sizes around the world, including major and specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions.

Many of our competitors have significantly greater resources, including greater access to capital, technical capabilities and human resources, as well as more experience in the development and regulatory approval process than we have. Mergers and acquisitions in our industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunities could be reduced or eliminated if our competitors develop or market novel therapies or other products that are more effective, safer or less costly than our current or future product candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates.

With respect to macular degeneration therapies, although there are currently no approved treatments available, our competitors for LBS-008 include several companies going through clinical development for their product candidates. Based on publicly available information, we understand that there is one Japan-based pharmaceutical company that has an asset in Phase 3 development for STGD1. There are also three U.S.-based companies advancing treatments for STGD1 and their assets are currently in Phase 2 and Phase 2b development, respectively, with the third company having recently completed their Phase 2a trial. In GA, there are three U.S.-based companies in late-stage clinical development. All three companies have assets in Phase 3 development.

Employees

As of the date of this prospectus, we have twelve employees and four of our employees are located in the United States. The following table sets forth the number of our employees by function as of the date of this prospectus:

Functions	Number of Employees	% of Total
Finance and Accounting	5	42%
Research and Development	7	58%
Total	**12**	**100%**

We believe that we maintain a good working relationship with our employees, and we have not experienced any material labor disputes in the past. None of our employees are represented by labor unions.

Facilities

Our facilities consist of office and lab space of approximately 350 square feet in San Diego, California under a lease that will expire on July 19, 2022, office space of approximately 88 square feet in Taiwan under a lease that expires on July 31, 2022, and office and lab space of approximately 86 square feet in Shanghai, China under a lease that is automatically renewed every three months. We believe our current facilities are sufficient to meet our near-term needs, and we do not foresee any difficulty in extending the lease terms of our facilities upon their respective expiration dates.

Legal Proceedings

We are currently not involved in any legal or administrative proceedings that may have a material adverse impact on our business, financial position or results of operations.

REGULATIONS

We are subject to a variety of U.S., European (including both laws applicable in the European Union and the U.K.) and PRC laws, rules and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of U.S., the European Union and PRC and that affect the dividends payment to our shareholders.

U.S. Regulation

Government Regulation and Product Approval

The U.S. Food and Drug Administration, or the FDA, and other regulatory authorities in the United States at federal, state and local levels extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of and for drug products. Along with third-party contractors, we are required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

The failure to comply with applicable statutory and regulatory requirements may subject a sponsor, applicant or marketer to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, "Warning Letters" (official messages from the FDA to a manufacturer or other organization providing notice that it has violated some rule in a federally regulated activity) or "Untitled Letters" (initial correspondences from the FDA that cite violations that do not meet the threshold of regulatory significance for a Warning Letter and request correction of the violation), product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice, or the DOJ, or other governmental entities.

Review and Approval for Licensing Drugs

The FDA regulates drugs primarily under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, and their associated implementing regulations. Our product candidates must be approved by the FDA through the new drug application, or 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 preclinical studies, including preclinical laboratory tests, preclinical animal studies and formulation studies all performed in compliance with applicable regulations, including the current good laboratory practice, or the cGLP, regulations;
- submission to the FDA of an investigational new drug application, or an IND, which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- manufacture, labeling and distribution of an investigational drug in compliance with current good manufacturing practices, or cGMP;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's current good clinical practices requirements, or cGCP, clinical trial registration, and other clinical trial

related regulations, to provide substantial evidence of effectiveness and evidence of safety for the drug product's proposed indication;

- preparation of and submission to the FDA of an NDA after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications;
- satisfactory completion of an FDA Advisory Committee review, where appropriate or if applicable, as may be requested by the FDA to assist with its review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities at which active pharmaceutical ingredient, or API, and finished drug product, or components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods, and proposed chemistry, manufacturing, and controls, or CMC, are adequate to preserve the drug's identity, safety, quality, purity, potency and efficacy;
- satisfactory completion of FDA audits of selected preclinical and/or clinical investigation sites to assure compliance with cGLP and cGCP requirements and the integrity of the preclinical and/or clinical data;
- payment of user fees under the Prescription Drug User Fee Act, or, as amended, the PDUFA, for the relevant year;
- obtaining FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States; and
- compliance with all post-approval requirements, including but not limited to, cGMP, CMC, post-market reporting and pharmacovigilance, registration and listing, advertising and promotional requirements, the potential requirement to implement risk evaluation and mitigations strategies, or REMS, and the potential requirement to conduct post-approval studies.

In addition to drug-specific requirements, combinations of differently regulated articles, such a drug and device (e.g., a drug delivery system or companion diagnostic) could also result in various addition requirements to consider, such as device and combination product requirements of the FDCA and its implementing regulations with respect to investigation, marketing, and post-market requirements.

Development of data and other information sufficient to support an NDA approval requires substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. From time to time, new legislation is enacted that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Preclinical Development

The data required to support an NDA is generated in two distinct development stages: preclinical and clinical. For new chemical entities, or NCEs, the preclinical 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 preclinical studies must comply with federal regulations, including cGLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of its IND. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND acts as an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment. Any subsequent protocol amendments must be submitted to the FDA as part of the IND, and the FDA must

allow these amendments to the IND to go into effect prior to their execution. Frequently, sponsors are also required to conduct additional animal studies after an IND is obtained and human clinical testing begins, and is often referred to as ‘preclinical’ or ‘nonclinical’ testing, even though it occurs in parallel with the clinical phase of development.

Clinical Development

Human clinical trials subject to the FDA’s jurisdiction may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

The FDA may also place a clinical hold or partial clinical hold on such study following commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor with a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Clinical studies involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an independent ethics committee and informed consent from subjects. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before the clinical trial begins at that site, and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or the DSMB. DSMBs provide authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if a DSMB determines that there is an unacceptable safety risk for subjects or based on other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and/or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

In addition, if conducting a clinical study in a non-U.S. population, acceptance of clinical trial results by the FDA will depend, among other things, on whether the non-U.S. population that enrolled in the study is sufficiently similar to the indicated U.S. population that the results of the trial would fairly represent expected results in the U.S. population. The same issue can also arise in multi-national trials where non-U.S. sites are enrolling subjects that will become part of the data submitted to the FDA.

For purposes of drug approval, clinical trials are typically conducted in the following sequential phases that may overlap or be combined:

- Phase 1: The investigational product is initially introduced into a small number of healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety,

dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These studies may also yield early evidence of effectiveness.

- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- Phase 3: The investigational product is administered to an expanded patient population generally at multiple geographically dispersed clinical trial sites to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval by the FDA and labeling of the drug product.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product, sometimes referred to as “Phase 4” studies. Such post-approval studies, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and the treatment of patients in the intended therapeutic indication.

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. In addition, IND safety reports must be submitted to the FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical trials, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure, which is a comprehensive document summarizing the body of information about an investigational product obtained during clinical and non-clinical trials.

Each of Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. 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 such IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, if a clinical trial is overseen by a Data Safety Monitoring Board, or DSMB, the DSMB will provide authorization for whether or not a study may move forward at designated check points based on access to certain data from the study.

During clinical development, the sponsor often refines the indication and endpoints on which the drug will be based. For endpoints based on patient-reported outcomes, or PRO, and observer-reported outcomes, or ORO, the process typically is an iterative one. The FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO and ORO instruments during the clinical development process, the FDA usually reserves final judgment until it reviews the drug.

Concurrent with clinical trials, companies must develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate, and cGMPs impose, among other things, 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 product candidate does not undergo unacceptable deterioration over its shelf life. Any changes to the drug product during development, and especially after Phase 2, can raise questions with respect to impact of changes on study results, and whether results may be extrapolated to support approval of a final finished dosage form for which approval is sought.

During the clinical development process, earlier phase drug results may be promising, but it cannot be assumed that subsequent phases of development will be successful. In fact, it is often the case that drugs with promising early phase data fail to ultimately show sufficient efficacy or safety to support approval in later phases of development.

NDA Submission and Review

Following study completion, study results and data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive preclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the FDA.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements thereto must contain data that is adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Under the PDUFA, each NDA must generally be accompanied by a significant application user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business which has fewer than 500 employees; in assessing whether an application qualifies as a ‘first application’ and calculating the number of employees, affiliates of the small business making the NDA submission are considered. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74th day after the FDA’s receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a “priority review” NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, 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, purity and efficacy. The FDA may refer applications for novel drugs or product candidates that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually follows such recommendations. The FDA may re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process.

Before approving an NDA, the FDA will also 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 also audit data from clinical trials to ensure compliance with cGCP 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. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The complete response letter may require additional clinical data and/or an additional pivotal clinical trials(s), and/or other significant, expensive and time-consuming requirements related to preclinical studies or clinical trials or manufacturing. If a complete response letter 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 limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS and the FDA will not approve the NDA without a REMS that the agency has determined is acceptable. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of a drug. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two or more adequate and well-controlled clinical trials, which must provide substantial evidence of effectiveness for, and demonstrate safety of, the proposed new product for a given indication (though, in certain cases, an NDA might be based on a single adequate and well-controlled clinical trial plus confirmatory evidence). These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes the FDA to approve an NDA based in part on prior FDA determinations as opposed to solely on safety and effectiveness data developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. However, the FDA may require applicants to perform additional studies or measurements to support the change(s) from the previously approved product. The FDA may then approve the new product candidate for all or some of

the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Pediatric Studies

With the enactment of the Food and Drug Administration Safety and Innovation Act in 2012, a sponsor who is planning to submit a marketing application (or supplement to an application) for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan, or a PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA, unless the drug is for an indication for which orphan designation has been granted. In the absence of an end-of-phase 2 meeting, the sponsor should submit the initial PSP as early as practicable but before the initiation of any phase 3 studies, or any combined phase 2 and phase 3 studies, of the drug that is the subject of the initial PSP. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, the FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but the product will be entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Those circumstances include instances in which another sponsor's application for the same drug product and indication is shown to be "clinically superior" to the previously approved drug. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved drug in terms of greater efficacy, greater safety or by providing a major contribution to patient care. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, the FDA incentivizes the development of drugs that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing

application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Also, the FDA may revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval. Congress has extended the PRV program through September 30, 2026, with the potential for PRVs to be granted through September 30, 2026.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to monitoring, recordkeeping, registration and listing, periodic reporting, reporting of certain deviations and adverse experiences, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA.

FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMP. We currently use contract manufacturing organizations, or CMOs, to manufacture the drugs used in our clinical trials and expect to rely on third parties for the production of commercial quantities of our products in accordance with cGMP regulations.NDA holders using CMOs, 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 their third-party contractors are required to register their establishments with the FDA and certain state agencies. These establishments are subject to routine and periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. Any interference with FDA inspection activities at our company or at CMOs can result in substantial penalties. The FDA has increasingly observed cGMP violations involving data integrity during site inspections and investigating compliance with data integrity requirements is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; requiring that activities are documented at the time of performance; audit trail functionality; requiring authorized access and limitations; validated computer systems; and the review of records for accuracy, completeness and compliance with established standards.

Post-approval changes to the manufacturing process, including changes of the site of manufacture, are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party CMOs that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance (*i.e.*, post-marketing safety reporting obligations) and other aspects of regulatory compliance.

The FDA may withdraw a product approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters, Untitled Letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products that it believes present safety problems by issuing an Import Alert;
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties;
- adverse publicity;
- voluntary or mandatory product recall; and
- recoupment of payment and damages for noncompliant drug products based on various legal theories, including a theory that reimbursement for noncompliant products violates federal and state false claims laws (e.g., the federal False Claims Act).

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, identity, strength, quality, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information in accordance with the FDA's good reprint practices or unsolicited request doctrine.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that such companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed. Among other legal theories, penalties may be sought based on a theory that off-label promotion causes submission of claims that for an unapproved use in violation of state and federal false claims laws.

Other 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. 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, require disclosure to the government and public of such interactions, and govern various matters regarding reimbursement of healthcare products. 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. Additionally, 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 prescription drugs and biologics are subject to the Drug Supply Chain Security Act, which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the Drug Supply Chain Security Act imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Hatch-Waxman Protections and Pediatric Exclusivity

Patent Term Restoration

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of an NDA if approval of the application is the first permitted commercial marketing or use of a drug containing the API under the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and NDA submission, and all of the review phase, which is the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which an NDA has not been submitted.

Patent Listing and the Orange Book

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each drug substance, drug product, and method-of-use patent whose claims cover the NDA drug product. Upon approval of the NDA, each of the patents listed in the application for the drug is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors as reference listed drugs, or RLD, in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA which relies upon the RLD's approval to support its own.

An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests (beyond, potentially, bioequivalence studies) to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug under various state laws. A 505(b)(2) NDA is generally used where there are one more difference from the RLD in terms of dosage form, labeling, or other properties, but where an applicant may nonetheless rely upon FDA's prior approval determinations with respect to the RLD to support safety and/or efficacy of the 505(b)(2) NDA drug product.

An ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the RLD in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. An ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain or carve out any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA or 505(b)(2) NDA will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The ANDA or 505(b)(2) NDA also will not be approved until any applicable non-patent market exclusivity listed in the Orange Book for the referenced product have expired.

Market Exclusivity

Upon NDA approval of a NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA or 505(b)(2) NDA seeking approval that uses the NDA as its RLD. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approval an ANDA or 505(b)(2) NDA seeking approval that uses the NDA as its RLD.

An ANDA or 505(b)(2) NDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA or 505(b)(2) may be filed before the expiration of the exclusivity period.

Pediatric Exclusivity

Another provision of the FDCA provides a potential opportunity for "pediatric exclusivity," which, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. In some instances, the same studies can satisfy both PREA and pediatric exclusivity requirements, and in other instances may request studies of new indications or other differences from initial NDA approval that is being sought or has been granted.

FDA Expedited Programs and Special Protocol Assessments

The FDA expedited programs and designations for serious conditions, like Fast Track, Breakthrough Therapy, Priority Review and Accelerated Approval, are intended to make certain drugs available as rapidly as possible.

Applicants must request Fast Track designation from the FDA, which provides access to a process to facilitate the development and expedite the review of a drug intended to treat serious conditions and fill an unmet need. The request can be initiated at any time during the drug development process. The FDA will review the request and make a decision within 60 days based on whether the drug fulfills an unmet medical need in a serious condition. A drug that receives Fast Track designation is eligible for some or all of the

following: (i) more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written correspondence from the FDA about things such as the design of the proposed clinical trial and the use of biomarkers; (iii) Accelerated Approval and Priority Review, if relevant criteria are met; and (iv) rolling review, under which the agency may initiate review of sections of a Fast Track product's NDA before the application is complete. Rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's PDUFA review period for a Fast Track application does not begin until the last section of the NDA is submitted.

Under the Breakthrough Therapy authority, a drug may be eligible for designation as a Breakthrough Therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. If a drug is designated a Breakthrough Therapy, the FDA will expedite the development and review of the drug. Every drug application submitted to the FDA is subject to consideration for Priority Review designation, even if the applicant does not request it. The FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original NDA. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary for approval. Priority Review does shorten the planned time period for review of an NDA (from six months compared with the ten-month standard review) by the FDA.

Fast Track, Breakthrough Therapy and Priority Review status may all be withdrawn by the FDA at any time if the agency finds that relevant criteria are no longer being met.

Under its Accelerated Approval authority, the FDA may approve a product for a serious disease or condition that fills an unmet need, including a Fast Track product, if it is found to have an effect on a surrogate endpoint in a marker that is thought to predict a clinical benefit. The FDA may also approve a product under Accelerated Approval authority if it is found to have an effect on an intermediate endpoint in a measure of therapeutic effect that is considered reasonably likely to predict a clinical benefit. The endpoint evidence to support Accelerated Approval may be epidemiological, pathophysiological, therapeutic, and pharmacologic or based on the use of biomarkers. Accelerated Approval can be withdrawn or the labeled indication of the drug changed if studies fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risk associated with the drug.

The Federal Food, Drug, and Cosmetic Act directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment, or an SPA. While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

An SPA request can be requested after a pre-Phase 3 meeting with the FDA. It allows the FDA and sponsor to agree on the study design for a Phase 3 study whose efficacy results will be the basis of an NDA. There is no guarantee that we will request or be able to receive and maintain Fast Track designation, Breakthrough Therapy designation, Priority Review designation, Accelerated Approval designation or a Special Protocol Assessment for any of our product candidates.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, clinical trial sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these clinical trials after completion if the

product candidate is ultimately approved, and disclosure of the results of these clinical trials will be delayed until such approval. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of in development programs.

U.S. Healthcare Regulation

Pharmaceutical Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Third-party payors establish the coverage and reimbursement policies for pharmaceutical products, and the marketability of any products for which we may receive regulatory approval for commercial sale depends on those payors' coverage policies and reimbursement rates. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our product candidates, if approved. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and health services, in addition to their cost-effectiveness, safety and efficacy. In addition, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement rates can vary significantly from payor to payor.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other U.S. Healthcare Laws and Compliance Requirements

Our business may be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which, among other things, prohibits executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- 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 federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; state and local laws regarding the manufacturing and distribution of drugs; 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 HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Healthcare Reform

In the United States there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, enacted in March 2010, has substantially changed healthcare financing and delivery by both governmental and private insurers. Among other things the Affordable Care Act included the following provisions:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, will be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; and
- a licensure framework for follow-on biological products.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Various portions of the Affordable Care Act are currently undergoing legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the Affordable Care Act. The implementation of the Affordable Care Act is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the Affordable Care Act are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2030 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The Consolidated Appropriations Act of 2021, extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021, has extended the suspension period to December 31, 2021. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the previous administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the previous administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the previous administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change, which was effective as of January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Biden administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the ongoing COVID-19 pandemic.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical study and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical studies and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. If we obtain approval to market a product candidate in the United States, any healthcare reforms adverse to drug manufacturers, including but not limited to, 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.

European Regulation

Government Regulation and Product Approval

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety

and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The process governing approval of biological medicinal products in the European Union generally follows the same principles as in the United States. Such products are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels.

Clinical Trial Approval

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain prior approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, or the CTR, but it will not become effective until January 31, 2022. The CTR will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the CTR, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new CTR provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of applications for authorization to conduct a clinical trial.

The CTR also establishes a Clinical Trials Information System database which will include various details of each clinical trial conducted in the EU, including the application for authorization to conduct a clinical trial and any review by a regulatory or ethics body. The CTR requires all information stored in the database to be publicly available, unless exempted under the Regulation to protect: (a) personal data; (b) commercially confidential information, in particular the marketing authorization status of the medicine, unless there is an overriding public interest; (c) confidential communication between Member States in the preparation of their assessment; or (d) supervision of clinical trials by Member States.

The CTR also clarifies the obligation to publish (a) summary results of the clinical trial within 1 year after the end of the trial (including a phase I trial); and (b) clinical study reports of the data generated in the course of the clinical trial within 30 days after the grant of the relevant marketing authorization.

The conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable laws until the CTR becomes applicable. A clinical trial commenced before January 31, 2022 can continue under the current legislative framework. The sponsor of a clinical trial commenced in 2022 can elect to conduct the trial under the old legislative framework or the CTR. Any clinical trial commenced after January 31, 2023 must do so under the CTR. If a clinical trial conducted under the old legislative framework continues for more than three years after January 31, 2025, the CTR will automatically begin to apply to that clinical trial.

PRIME Designation in the European Union

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage the development of medication in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized

procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Marketing Authorization

To obtain marketing authorization of a biological medicinal product under the European Union regulatory system, an applicant must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the European Union member states: the decentralized procedure, national procedure, or mutual recognition procedure. A marketing authorization may be granted only to an applicant established in the European Union.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of viral diseases and cancer. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where either the product contains a new active substance not yet authorized in the European Union, or where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of patients at a European Union level.

Under the centralized procedure, the CHMP is responsible for conducting an initial assessment of whether a product meets the required quality, safety and efficacy requirements, and whether a product has a positive benefit/risk profile. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

For products not falling within the mandatory scope of the centralized procedure, national marketing authorizations may be obtained, which are issued by the competent authorities of the European Union member states and only cover their respective territory. Where a product has already been authorized for marketing in an European Union member state, this national marketing authorization can be recognized in another European Union member state through the mutual recognition procedure. If the product has not received a national marketing authorization in any member state at the time of application, it can be approved simultaneously in various European Union member states through the decentralized procedure. As with the centralized procedure, the competent authorities of the European Union member states assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy before granting the marketing authorization.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The MAA for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Data and Marketing Exclusivity

The European Union also provides opportunities for market exclusivity. Upon receiving marketing authorization in the European Union, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents the regulatory authorities from accepting MAAs from generic or biosimilar applicants seeking to rely on the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union for a period of eight years from the date on which the reference product was first authorized in the European Union. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced and relied on, but no generic or biosimilar product can be marketed until the expiration of the additional two-year market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package including preclinical tests and clinical trials.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained, which is described in detail below. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority in a Member State with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on

justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the medicine on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements After Market Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of medicines to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of medicinal products and/or the general public, are strictly regulated in the European Union. It is prohibited to advertise prescription-only medicinal products to patients in the EU.

Orphan Designation and Exclusivity

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan medicine leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application for, or grant a marketing authorization for, a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

The criteria for designating an orphan medicine in the European Union are similar in principle to those in the United States. Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan medicine by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the medicine in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicine will be of significant benefit to those affected by that condition.

Orphan medicines are eligible for financial incentives such as reduction of fees or fee waivers made available by the European Union and its member states to support research into, and the development and availability of, orphan medicines. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Pediatric Exclusivity

If an applicant obtains a marketing authorization in all European Union member states, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for

the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the SPC.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The UK formally left the European Union on January 31, 2020. There was a transitional period, during which European Union laws continued to apply in the UK, which ended on December 31, 2020. The UK and European Union have signed an EU-UK Trade and Cooperation Agreement, which became provisionally applicable on January 1, 2021 and which will become formally applicable once ratified by both the UK and the European Union. This agreement provides details on how some aspects of the UK and European Union's relationship regarding medicinal products will operate, particularly in relation to Good Manufacturing Practice; however, there are still many uncertainties. Since the regulatory framework for medicinal products in the UK covering quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from European Union directives and regulations, the current regulatory framework in the UK is virtually identical to the framework in the European Union. The EU Clinical Trials Regulation (described in detail above), which is due to take effect on January 31, 2022, will not apply in Great Britain, but it will apply in Northern Ireland (as a result of the Northern Ireland Protocol).

However, post-Brexit, the UK Government is free to adopt laws that could diverge from the laws in the European Union. This could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. In the meantime, the Medicines and Healthcare products Regulatory Agency, the UK medicines and medical devices regulator, has published detailed guidance for industry and organizations to follow.

Pricing and Reimbursement Environment

Even if a medicinal product obtains a marketing authorization in the European Union, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Pricing and reimbursement of medicines is a matter reserved to individual Member States. Each Member State is free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of medicinal products for human use. Each Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements, caps and reference pricing mechanisms.

PRC Regulation

PRC Drug Regulation

The Drug Administration Law of the PRC, or the Drug Administration Law, promulgated by the Standing Committee of the NPC and the Implementing Measures of the Drug Administration Law, or the Implementing Measures of the Drug Administration law, promulgated by the State Council, have jointly established the legal framework for the administration of pharmaceutical products in China, including the research, development and manufacturing of new drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, and regulates and provides a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementing Measures of the Drug Administration Law, on the other hand, provides detailed implementation regulations for the Drug Administration Law.

The recent amendment to the Drug Administration Law, which became effective in December 2019, brought a series of changes to the drug supervision and administration system, including, but not limited to, the clarification of the drug marketing authorization holder system, pursuant to which each marketing authorization holder shall assume responsibilities for non-clinical trials, clinical trials, manufacturing and marketing, post-marketing studies, monitoring, reporting and handling of any adverse reactions of its drugs. The amendment also stipulates that the State supports the innovation of drugs with clinical value and specific or special effects on human diseases, encourages the development of drugs with new therapeutic mechanisms and that have multi-targeted, systematic regulatory and intervention functions on the human body and promotes the technological advancement of drugs. The NMPA has since promulgated two key implementing regulations for the amended Drug Administration Law: (i) the amended Administrative Measure for Drug Registration and (ii) the amended Measures on the Supervision and Administration of the Manufacture of Drugs. Both took effect on July 1, 2020. The NMPA also promulgated the Chemical Drug Registration Classification and Application Data Requirements in June 2020 as detailed implementing rules on drug classification.

We are required to follow the above-mentioned regulations in respect of our non-clinical research, clinical trials and production of new drugs.

Regulatory Authorities and Recent Government Reorganization

Pharmaceutical products and medical devices and equipment in China are monitored and supervised on a national scale by the NMPA (formerly known as China Food and Drug Administration, or the CFDA), while the local provincial medical products administrative authorities are responsible for the supervision and administration of drugs within their respective administrative regions. Pursuant to the Decision of the First Session of the Thirteenth National People's Congress on the State Council Institutional Reform Proposal made by the NPC in March 2018, the NMPA is no longer an independent agency and its duties shall be performed by the newly established State Administration for Market Regulation, or the SAMR, into which the various agencies responsible for, among other areas, consumer protection, advertising, anticorruption, pricing, fair competition and intellectual property, have been merged.

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

Formed on March 2018, the National Health Commission, or the NHC, (formerly known as the Ministry of Health, or the MOH, and the National Health and Family Planning Commission, or the NHFPC), is China's chief healthcare regulator. It is primarily responsible for overseeing the operation of medical institutions, which also serve as clinical trial sites, and regulating the licensure of hospitals and medical personnel.

Non-Clinical Research

In 2003, the NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, which was revised on in July 2017, to improve the quality of non-clinical research, and began conducting the Good Laboratories Practice certification program. Pursuant to the Circular on Administrative Measures for Certification of GLP for Non-clinical Laboratory issued by the NMPA in April 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities are in charge of the daily supervision of non-clinical research institutions. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A GLP Certification will be issued by the NMPA if all the relevant requirements are satisfied, and such certification will be published on the NMPA's website.

Preclinical Development

The NMPA requires supporting preclinical data for the registration applications for imported and domestic drugs. Preclinical work, including pharmacology and toxicology studies, must satisfy the requirements of the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. No approval is required from the NMPA to conduct preclinical studies.

Clinical Trials and Marketing Approval of New Drugs

Registration Categories

Pursuant to the Administrative Measures for Drug Registration in January 2020 and effective on July 1, 2020, which provides the standards and requirements for clinical trials and drug registration applications. Drug marketing registration applications are divided into three categories, namely traditional Chinese drugs, chemical drugs and biological products, and each type is further divided into several sub-types. For example, the registration applications of chemical drugs are further categorized by innovative chemical drugs, improved new chemical drugs, and generic chemical drugs, among others. As provided in the Administrative Measures for Drug Registration, the Drug Administration Law and Implementing Measures of the Drug Administration Law, upon completion of non-clinical research, clinical trials shall be conducted for the application of new drug registration, upon approval from NMPA or authorized institutions.

Prior to engaging with the NMPA on research and development approval, an applicant shall determine the registration category for its product candidate (subject to ultimate confirmation by the NMPA), which will determine the requirements for its clinical trial and marketing application. There are five categories for chemical drugs: Category 1, or innovative drugs, refers to drugs with NCEs that have not been marketed anywhere in the world; Category 2, or improved new drugs, refers to drugs with a new indication, dosage form, route of administration, combination or certain formulation changes not previously approved anywhere in the world; Categories 3 and 4 refer to generic drugs that reference an innovator drug (or certain well-known generic drugs) marketed either abroad or in China, respectively; and Category 5 refers to innovative or generic drugs that have already been marketed abroad but are not yet approved in China (*i.e.*, various imported drugs).

Priority Review Program under Current Reform Frame

The NMPA has adopted several expedited review and approval mechanisms since 2009 and created additional expedited programs in recent years that are intended to encourage innovation. Applications for these expedited programs can be submitted after the clinical trial application is admitted for review by the CDE. The newly amended Administrative Measures for Drug Registration, which became effective on July 1, 2020, set up several acceleration procedures for drug marketing registration including procedures for breakthrough therapy designation drugs, procedures for conditional approval, procedures for priority review and approval at the marketing authorization application stage and procedures for special approval in public health emergencies. In order to implement the amended Administrative Measures for Drug Registration, on July 7, 2020, the NMPA promulgated the specific working procedures for the evaluation of breakthrough therapy designation drugs, conditional approvals and priority review and approval at the marketing authorization application stage which replaced the previous priority evaluation and approval program. According to such working procedures, a priority review market authorization pathway may be available to the following drugs with distinctive clinical benefits: (i) drugs in short supply for urgent clinical need, innovative drugs and modified new drugs for the prevention and treatment of serious infectious diseases, rare diseases and other diseases; (ii) pediatric drugs of new varieties, dosage forms and specifications that meet the physiological characteristics of children; (iii) vaccines urgently needed for disease prevention and control and innovative vaccines; (iv) drugs included in the procedures for breakthrough therapy designation drugs; (v) drugs fulfilling the requirements for conditional approval; and (vi) other drugs for priority review and approval stipulated by the NMPA.

We believe that our current clinical stage product candidate could be classified as a drug under categories (i) and (ii) of the working procedures described above. Therefore, we may be entitled to the priority review market authorization pathway under the newly amended Administrative Measures for Drug Registration.

Clinical Trial Approval

All clinical trials conducted in China for the purpose of seeking marketing approval must be approved and conducted at a pharmaceutical clinical trial institution which shall be under filing administration.

In addition, the NMPA has adopted a notification system for clinical trials of new drugs. Pursuant to the *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices*, *or the Innovation Opinion*, the Announcement on Adjusting the Evaluation and Approval Procedure of Drug Clinical Trial and the newly amended Drug Administration Law, clinical trials may be commenced as long as the applicant has not received any objections from the CDE within 60 business days of application filing.

International Multi-center Clinical Trials Regulations

In January 2015, the NMPA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) to provide guidance on the regulation of the application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for its application to the NMPA for approval of an NDA, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in the Drug Administration Law and its implementation measures, the Administrative Measures for Drug Registration and other 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 drug under clinical trial, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing the Good Clinical Trial Practice, or GCTP, principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; and an ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the NMPA drug clinical trial information platform.

Pursuant to the Innovation Opinion, clinical trial data obtained from foreign centers may be used to apply for marketing application in China as long as such data meet the relevant requirements for the registration of drugs and medical devices in China. When using international multi-center clinical trial data to support marketing application in China, applicants shall provide the clinical trial data on racial difference, if any.

Trial Exemptions and Acceptance of Foreign Data

The NMPA may reduce its requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not as part of a global study), including early phase data, that meets its requirements. In July 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, or the Guidance Principles, as one of the implementing rules for the Innovation Opinion.

According to the Guidance Principles, the data of foreign clinical trials must meet certain authenticity, completeness, accuracy and traceability requirements, and such data must be obtained in consistency with the relevant requirements under the GCTP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Additionally, clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA permits 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 issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or 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 are required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

Drug Clinical Trial Registration

Pursuant to the Announcement on Drug Clinical Trial Information Platform released by the NMPA in September 2013, for all clinical trials approved by the NMPA and conducted in China, clinical trial registration must be completed and trial information must be published through the drug clinical trial information platform. In July 2020, the CDE released the Drug Clinical Trial Registration and Information Disclosure Practices (Trial). Under these measures, an applicant who has obtained the approval from the NMPA for a clinical trial and intends to conduct the clinical trial in China must complete trial pre-registration before starting the clinical trial and must also continue to update follow-up information according to the progress of clinical trial. If no subject has signed an informed consent within three years from the date of approval from the NMPA for the clinical trial, the approval will be automatically invalidated and the registration will not be granted.

Human Genetic Resources Approval

In 1998, the Ministry of Science and Technology and the MOH jointly established the rules for protecting and utilizing human genetic resources in China. In July 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that foreign-invested drug marketing authorization applicants (*i.e.*, sponsors) that sample and collect human genetic resources in clinical trials shall be required to make certain filings with the China Human Genetic Resources Management Office, or the HGRMO, through its online system. In October 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC.

In May 2019, the State Council of PRC issued the National Regulations on the Management of Human Genetic Resources, which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new notification system (as opposed to the advance approval approach originally in place) has been established for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China. Under the new system, a notification filing, specifying, among other things, the type, quantity and usage of the human genetic resource, with the HGRMO is required before conducting such clinical trials. The collection and use of China's human genetic resources in international collaboration on basic scientific research involving the export of such human genetic resources are still subject to the approval of the HGRMO.

Clinical Trial Process and Good Clinical Practices

Typically, drug clinical trials in China have four phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a product candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the pivotal study) refers to

clinical trials that further verify the product candidate's therapeutic efficacy and safety on patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug marketing application. Phase 4 refers to a new drug's post-marketing study, which may be required by NMPA at its sole discretion, to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc.

Pursuant to the NMPA, a clinical trial institution can be engaged by a sponsor to conduct a drug clinical trial after such institution has been duly recorded with the online platform designated by the NMPA. The newly amended Drug Administrative Law and the Regulations on the Administration of Drug Clinical Trial Institution jointly promulgated by the NMPA and the NHC specify the requirements for clinical trial institutions and recording procedures. Pursuant to these regulations, a clinical trial institution should comply with the requirements of cGCP and be capable of undertaking pharmaceutical clinical trials. It should evaluate or engage a third party to evaluate its clinical trial proficiency, facilities and expertise. According to the Implementing Regulations of the Drug Administration Law, a sponsor should only engage a duly recorded clinical trial institution to carry out a drug clinical trial.

The conduct of clinical trials must adhere to the cGCP and the protocols approved by the ethics committees of each study site. All applicants of pending drug registration submissions must conduct self-inspection and verification of their clinical trial data.

In April 2020, the NMPA and the NHC released the amended Good Clinical Practice for Pharmaceutical Product, or the Amended GCP, which took effect on July 1, 2020. Compared to the cGCP, 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. In addition, the Amended GCP requires that trial drugs shall be manufactured in compliance with pertinent requirements on good manufacturing of drugs for clinical trial and used in line with relevant trial protocols. The NMPA issued the consultation paper of Good Manufacturing Practice for Drugs Used in Clinical Trials in July 2018.

Communication with the CDE

Pursuant to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs promulgated by the NMPA on December 10, 2020, the applicants may propose to conduct communication meetings with the CDE during the research and development periods and in the registration applications of the innovative drugs. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development periods of drugs, mainly including meetings before the clinical trial application, meetings upon the completion of Phase 2 trials and before the commencement of Phase 3 trials, meetings before submitting a drug marketing application, and meetings for risk evaluation and control. Type III meetings refer to meetings that are not classified as Type I or Type II. According to the new Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs, the applicant who apply for conditional approval and/or the priority review and approval procedures shall communicate with the CDE and obtain confirmation before submitting the marketing application to NMPA. In addition, except for (i) clinical trial of new drugs with clear technical guidelines, mature research experience, and guaranteed quality of the application materials, or (ii) international multi-center clinical trials that are simultaneously developed internationally and have been approved to conduct clinical trials in countries and/or regions with sound regulatory systems, the applicant in principle shall apply for communication with the CDE before clinical trial application for new drugs. Furthermore, where the application for clinical trials of new drug has been approved, upon the completion of Phase 1 and 2 clinical trials and prior to Phase 3 clinical trial, or before submitting a drug marketing application, the applicant may submit the application for Communication Session to the CDE.

Drug Marketing Registration Application

Pursuant to the newly amended Administrative Measures for Drug Registration, the applicant may submit an application for drug marketing registration to the 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 a professional technical institution designated as competent by the NMPA. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by a professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the marketing authorization holders and the manufacturer.

Drug technology transfer regulations

In August 2009, the NMPA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs to standardize the registration process of drug technology transfers, which include application for, and evaluation, examination, approval and monitoring of, drug technology transfers. Drug technology transfers refer 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 new regulations. Drug technology transfers include new drug technology transfers and drug production technology transfers.

Manufacturing and Distribution

According to the newly amended Drug Administration Law, the Regulations of Implementation of the Drug Administration Law and the Measures on the Supervision and Administration of the Manufacture of Drugs, facilities that manufacture drugs in China must receive a drug manufacturing license from the local drug regulatory authority. Each drug manufacturing license issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a drug manufacturing license is subject to review by the relevant regulatory authorities on an annual basis. According to such regulations and measures, to the extent a marketing authorization holder manufactures its drugs internally and not through CMOs, such marketing authorization holder must apply for a drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

Similarly, to conduct sales, importation, shipping and storage, or collectively, the distribution activities, a company must obtain a Drug Distribution License from the local drug regulatory authority, subject to renewal every five years. A separate certification of compliance with the NMPA's drug good supply practice is also required.

China has implemented a "Two-Invoice System" to control the distribution of prescription drugs. The "Two-Invoice System" generally requires that no more than two invoices be issued throughout the distribution chain: one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly-owned or controlled distributors, or for imported drugs, to 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. Compliance with the Two-Invoice System is a prerequisite for pharmaceutical companies to participate in the procurement processes of public hospitals, which currently provide most of China's healthcare services. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

Administrative Observation Periods for New Drugs

According to the Implementing Measures of the Drug Administration Law, the NMPA may, for the purposes of protecting public health, set an administrative observation period of not more than five years for a new drug produced by a drug manufacturer. During the administrative observation period, no approval shall be given to any other manufacturer to produce or import the said drug.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

Packaging of Pharmaceutical Products

Pursuant to the Administration of Quality of Drug Clinical Practice, the applicant shall be responsible for proper packaging and labeling of drugs for clinical trials, and in double-blinded clinical trials, the test drug shall be consistent with the control drug or placebo in appearance, odor, packaging, labeling and certain other features. According to the Measures for the Administration of Pharmaceutical Packaging promulgated in February 1988, pharmaceutical packaging must comply with national and professional standards. If there is no national or professional standard available, an applicant may formulate and implement its own standards after obtaining the approval of the provincial administration or bureau of standards. The applicant must reapply if it needs to change its own packaging standards. Drugs that have not developed and received approval for packaging standards must not be sold or marketed in the PRC (except for drugs for the military).

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 in December 2019, 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 production registration certificate, filing certificate or production license. If no valid term is prescribed in the production registration certificate, filing certificate or production license, 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, the insert sheets and labels of drugs should be reviewed and approved by 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 and adverse reaction.

Regulatory Intellectual Property Protections

In January 2020, the United States and China signed the Economic and Trade Agreement Between the United States of America and the PRC (the "Trade Agreement"). Among other things, China agreed to provide for effective protection and enforcement of pharmaceutical-related intellectual property rights, including patents and undisclosed test or other data submitted as a condition of marketing approval, as further described below. These provisions of the Trade Agreement will need to be implemented in China. In October 2020, the Standing Committee of the NPC promulgated the amended PRC Patent Law, which became effective in June 2021. The newly amended PRC Patent Law sets up the framework and adds the provisions for patent linkage and patent term extension. However, the provisions for patent term extension and an early resolution mechanism are unclear and/or remain subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about their scope and implementation.

International Regulation

In addition to regulations in the United States, the European Union and the PRC, we will be subject to a variety of other regulations governing clinical trials and commercial sales and distribution of our products

to the extent we choose to develop or sell any products outside of the United States, Europe or the PRC. The approval and reimbursement process varies from country to country and the time may be longer or shorter than that required to obtain FDA, EMA or NMPA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

Anti-Corruption Laws

The FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, prohibit any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. This could become relevant in the conduct of international clinical trials where the sites for such studies may be a government-owned hospital. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

In the European Union, interactions between pharmaceutical companies and physicians are governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at the European Union level and in the individual European Union member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the European Union member states. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union member states also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information regarding our directors and executive officers as of the date of this prospectus.

Name	Age	Positions(s)
Yu-Hsin Lin	44	Chief Executive Officer, Chairman of the Board of Directors*
Hao-Yuan Chuang	38	Chief Financial Officer, Director*
Nathan L. Mata	56	Chief Scientific Officer
Ching-Chen Chiu	52	Vice President of Clinical Operations
Wan-Shan Chen	36	Director*
Hung-Wei Chen	40	Director*
John M. Longo	53	Independent Director Nominee#
Ita Lu	45	Independent Director Nominee#
Gary C. Biddle	70	Independent Director Nominee#

* This director was appointed by Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder.

\# Each of Dr. John M. Longo, Mr. Ita Lu and Prof. Gary C. Biddle has accepted appointment as a director, which will be immediately effective upon the declaration of effectiveness of our registration statement on Form F-1 by the SEC, of which this prospectus is a part.

The following is a biographical summary of the experience of our directors and executive officers.

Dr. Yu-Hsin Lin, aged 44, is our founder and has served as Director of our Company since we established the Company in March 2018 and the Chairman and the Chief Executive Officer of our Company since November 2021. Dr. Lin has also served as the chairman and the chief executive officer of Belite Bio Holdings Corp. (our wholly owned subsidiary incorporated in Delaware) since June 2016 and December 2017, respectively. From June 2016 to December 2017, Dr. Lin also served as the president of Belite Bio Holdings Corp. (our wholly owned subsidiary). Dr. Lin has served as director and chief executive officer of RBP4 Pty Ltd (our wholly owned subsidiary in Australia) since August 2018 and April 2021, respectively. Dr. Lin has served as director of Belite Bio (HK) Limited (our wholly owned subsidiary in Hong Kong) since June 2021, and the president of Belite Bio Holdings Corp. and Belite Bio, LLC (our wholly owned subsidiaries) since October 2021. Dr. Lin is primarily responsible for the overall management, strategic planning and corporate development of our Company. Dr. Lin is also the founder and has served as the director and the chairman and the chief executive officer of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder, since May 2016 and June 2016, respectively. From 2014 to 2016, Dr. Lin was the president and chief operating officer of CVie Therapeutics Limited. In 2014, Dr. Lin served as the general manager and medical director of ASLAN Pharmaceuticals (Nasdaq: ASLN). From 2010 to 2014, Dr. Lin served as the senior medical director of OBI Pharma, Inc. (TPEx: 4174). From 2008 to 2010, Dr. Lin worked as the medical instructor of Faculty of Medicine, University of Sydney. Dr. Lin received his master's degree in medicine from University of Sydney where he specialized in multidisciplinary medicine and surgery. Dr. Lin received his PhD in medicine from University of Sydney where he specialized in neurology & immunology. Dr. Lin also received a Specialist Certificate in Clinical Neuroscience from University of Melbourne and a Cancer Therapeutics & Research Certificate from Harvard Medical School. Dr. Lin further received his master's degree in business and administration from Columbia University, London Business School and HK University.

Mr. Hao-Yuan Chuang, aged 38, has served as the Chief Financial Officer of our Company since April 2020 and Director of our Company since November 2021. Mr. Chuang has also served as the director of Belite Bio (HK) Limited (our wholly owned subsidiary in Hong Kong) since June 2021 and as supervisor of Belite Bio (Shanghai) Limited (our wholly owned subsidiary in China) since August 2021. He is primarily responsible for leading our Company's finance, accounting, investor relations, and capital markets strategy and activities. Mr. Chuang is also the chief financial officer and a director of Lin BioScience, Inc. (Taiwan

OTC: 6696), our ultimate controlling shareholder, since August 2018 and September 2018, respectively. From December 2017 to August 2018, Mr. Chuang worked as the finance and accounting director of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder. From 2016 to 2017, Mr. Chuang served as the investment director of Suning International Limited. From 2015 to 2016, Mr. Chuang worked as the portfolio manager of The People's Insurance Company (Group) of China Limited (HKG: 1339). From 2013 to 2015, Mr. Chuang was the senior manager of Wanda Hotel Development Company Limited (HKG: 0169). From 2010 to 2013, Mr. Chuang was the manager of corporate finance of CITIC Securities International Company Limited. From 2006 to 2010, Mr. Chuang was the senior associate of Chii Ying Co., Ltd. Mr. Chuang received his bachelor's degree in economics and minor in business administration from National Taiwan University. He received his master's degree in business & administration from Columbia University, London Business School and HK University. Mr. Chuang is also a chartered financial analyst and financial risk manager.

Dr. Nathan L. Mata, aged 56, has served as the Chief Scientific Officer of our Company since November 2021. Dr. Mata has also served as the chief scientific officer of Belite Bio, LLC (our wholly owned subsidiary incorporated in Delaware) since August 2021. Dr. Mata is primarily responsible for overseeing our Company's scientific and clinical activities, including basic and applied research projects and clinical programs, as well as the development of new processes, technologies or products. From 2019 to 2021, Dr. Mata was the principal consultant of clinical development sector of Halloran Consulting Group. From 2018 to 2019, Dr. Mata was the clinical research & operations consultant of Kubota Vision Inc. (formerly Acucela Inc.). From 2015 to 2018, Dr. Mata worked for Trethera Corporation. He acted as the chief operating officer and director of R&D section from 2015 to 2017, and then worked as clinical research & operations consultant from 2017 to 2018. From 2012 to 2015, Dr. Mata was the principal clinical research scientist of Acucela Inc. From 2010 to 2012, Dr. Mata co-founded and served as the chief scientific officer of Revision Therapeutics. From 2006 to 2008, Dr. Mata served as the vice president of R&D of Sirion Therapeutics. He also served as the chief scientific officer and senior vice president of R&D sector in the same company from 2008 to 2010. From 2004 to 2006, Dr. Mata co-founded and served as a director of SYTERA, INC., which was the research and development unit of Sirion Therapeutics. Dr. Mata received his bachelor's degree in biology, master's degree in biochemistry and PhD in neurobiology from University of Texas at San Antonio.

Ms. Ching-Chen Chiu, aged 52, has served as the Vice President of Clinical Operations of our Company since November 2021 and as executive officer and legal representative of Belite Bio (Shanghai) Limited (our wholly owned subsidiary in China) since January 2022. She is primarily responsible for leading our global clinical operations. Prior to joining our Company, Ms. Chiu has over 15 years' experience leading global clinical CRO companies where she served as board and managing director of CMIC Asia Pacific and executive director of EPS International Co. Ltd. Ms. Chiu's extensive clinical operations and research experience includes managing over hundred clinical studies in multiple therapeutic areas for both CRO's and global pharmaceutical companies while she was at Pfizer and Bayer. Ms. Chiu received her bachelor's degree in science from Taipei Medical University, and master's degree in science (medical information) from University of Warwick, UK.

Ms. Wan-Shan Chen, aged 36, has served as a Director our Company since November 2021. She has also served as associate finance director of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder, since January 2019. From November 2017 to January 2019, Ms. Chen worked as the senior finance manager of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder. From June 2016 to October 2017, Ms. Chen worked as the finance manager of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder. From 2014 to 2016, Ms. Chen was finance manager of CVie Therapeutics Limited. From 2009 to 2014, Ms. Chen worked as assistant manager of audit department of Deloitte Taiwan. Ms. Chen received her master's degree in accounting from National Taipei University. Ms. Chen is also a certified public accountant in Taiwan.

Ms. Hung-Wei Chen, aged 40, has served as a Director of our Company since November 2021. She has also served as the director and the chief operating officer of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder, since July 2021 and August 2018, respectively. From July 2016 to August 2018, Ms. Chen worked as the clinical operations director of Lin BioScience, Inc. (Taiwan OTC: 6696), our ultimate controlling shareholder. From 2015 to 2016, Ms. Chen was associate clinical development

director of CVie Therapeutics Limited. From 2012 to 2014, Ms. Chen was senior clinical operations manager of OBI Pharma, Inc. (TPEx: 4174). From 2005 to 2012, Ms. Chen served as project manager, study manager, clinical operations manager, clinical quality manager and clinical research associate in Pfizer Taiwan. Ms. Chen received her master's degree in science (medicinal chemistry) from National Taiwan University. Ms. Chen is also a certified pharmacist.

Dr. John M. Longo, aged 53, has served as the independent Director of our Company since 2022. Dr. Longo has also served as a faculty member at Rutgers Business School on a full-time or part-time basis since June 1993, where he is currently professor of practice in its finance & economics department. Dr. Longo has also been a visiting professor of finance at Global EMBA -Asia, the joint EMBA program of Columbia Business School, London Business School, and the University of Hong Kong since 2016. Dr. Longo served as chief investment officer for two wealth management firms since October 2002, first with the MDE Group and then with Beacon Trust after its acquisition of the MDE Group in 2015. Dr. Longo has also served as the president of Cliff House Capital Management and its predecessor, Cyborg Capital Management, since March 2000. Cliff House Capital Management is primary used as a holding company for Dr. Longo's non-academic activities. Dr. Longo was previously a vice president in the management science group at Merrill Lynch & Co., Inc., having worked as a quantitative investment analyst for the firm from 1997 to 2000. Dr. Longo received his bachelor's degree in economics and computer science from Rutgers College in 1991. Dr. Longo further received his PhD and master of business administration in finance from Rutgers Business School in 1995. Dr. Longo has been a CFA Charter holder since 1998.

Mr. Ita Lu, aged 45, has served as the independent Director of our Company since 2022. Mr. Lu has also served as the managing partner of Taiwania Capital since May 2018. From 2017 to 2018, Mr. Lu served as the vice president of business development and investor relations of Etana Biotech. From 2009 to 2017, Mr. Lu served as the head of greater China healthcare of KGI Securities. From 2008 to 2009, Mr. Lu served as the equity research analyst of greater China healthcare of Yuanta Research. From 2006 to 2008, Mr. Lu served as the investment manager of China Investment Development Corp. (SEHK: 204). From 2001 to 2006, Mr. Lu served as the investment manager of China Development Industrial Bank. From 1999 to 2001, Mr. Lu served as the research associate of MedImmune, Inc. Mr. Lu received his bachelor's degree in cell structural biology from University of Illinois at Urbana-Champaign and further received his master's degree in biotechnology from Johns Hopkins University. Mr. Lu is also a certified senior securities specialist in Taiwan. Mr. Lu also passed Hong Kong Securities Institute Licensing Examination for Securities and Futures Intermediaries Paper 1.

Prof. Gary C. Biddle, aged 70, has served as the independent Director of our Company since 2022. He is professor of financial accounting at University of Melbourne and visiting professor at Columbia University Business School, University of Hong Kong (HKU), and London Business School. Professor Biddle earned his MBA and PhD degrees at University of Chicago. He previously served as professor at University of Chicago, University of Washington, Hong Kong University of Science and Technology (HKUST) and at HKU. In academic leadership, Professor Biddle served as Dean and Chair Professor at HKU, and as Academic Dean, Department Head, Council member, Court member, Senate member, and Chair Professor at HKUST. He co-created the EMBA-Global Asia program and taught the first class and decade of the Kellogg-HKUST EMBA program, both recently ranked #1 in the world by *Financial Times* and *QS*. Professionally, he is a member of the AICPA, Australian Institute of Company Directors, CPA Australia, and HKICPA. Professor Biddle has served as editor and editorial board member of premier academic journals and as American Accounting Association Executive Board member, Vice-President, and President-Elect nominee, on the Accounting Hall of Fame Selection Committee, Financial Reporting Review Panel of the Financial Reporting Council of Hong Kong, HKICPA Council, Accreditation and Financial Reporting Standards Committees of HKICPA, and Hong Kong Institute of Directors Training Committee. Professor Biddle is a leading expert in financial and management accounting (teaching both), value creation, economic forecasting, corporate governance, and performance metrics, including EVA®. His research appears in leading academic journals and in the financial press including *CNBC*, *CNN*, *SCMP*, *The Economist*, and *The Wall Street Journal*. He has nearly 9,400 Google Scholar citations has won 30 teaching honours. He also proudly serves as Non-Executive Director of Kingdee International Software, as Independent Non-Executive Director and Audit and Risk Committee Chair of Shui On Land Limited, as Independent Non-Executive Director and Audit and Finance Committee Chair of Real Pet Food Company

(New Hope Group), and he previously served as Remuneration Committee Chair of Chinachem Group. He also runs charity 10k races.

Board of Directors

Our board of directors will consist of seven (7) directors upon the SEC's declaration of effectiveness of our registration statement on Form F-1 of which this prospectus is a part. A director is not required to hold any shares in our company by way of qualification. A director who is in any way, whether directly or indirectly, interested in a contract or transaction or proposed contract or transaction with our company is required to declare the nature of his interest at a meeting of our directors. Subject to the Nasdaq Stock Market rules and disqualification by the chairman of the relevant board meeting, a director may vote in respect of any contract or transaction or proposed contract or transaction notwithstanding that he may be interested therein, and if he does so his vote shall be counted and he shall be counted in the quorum at any meeting of our directors at which any such contract or transaction or proposed contract or transaction is considered, provided (i) such director, if his or her interest in such contract or arrangement is material, has declared the nature of his or her interest at the earliest meeting of the board at which it is practicable for him or her to do so, either specifically or by way of a general notice and (ii) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee. Our directors may exercise all the powers of our company to raise or borrow money and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof, to issue debentures, debenture stock, bonds and other securities, whether outright or as collateral security for any debt, liability or obligation of our company or of any third party.

Committees of the Board of Directors

We will establish three committees under the board of directors immediately upon the effectiveness of our registration statement on Form F-1, of which this prospectus is a part: an audit committee, a compensation committee and a nominating and corporate governance committee. We will adopt a charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee. Our audit committee will consist of John M. Longo, Ita Lu and Gary C. Biddle. John M. Longo will be the chairman of our audit committee. We have determined that John M. Longo, Ita Lu and Gary C. Biddle satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market and Rule 10A-3 under the Exchange Act. We have determined that each of John M. Longo and Gary C. Biddle qualifies as an "audit committee financial expert." The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee will be responsible for, among other things:

- appointing the independent auditors and pre-approving all auditing and non-auditing services permitted to be performed by the independent auditors;
- reviewing with the independent auditors any audit problems or difficulties and management's response;
- discussing the annual audited financial statements with management and the independent auditors;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposures;
- reviewing and approving all proposed related party transactions;
- meeting separately and periodically with management and the independent auditors; and
- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Compensation Committee. Our compensation committee will consist of Hao-Yuan Chuang, Ita Lu and John M. Longo. Ita Lu will be the chairman of our compensation committee. We have determined that Ita Lu and John M. Longo satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and

executive officers. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated. The compensation committee will be responsible for, among other things:

- reviewing and approving, or recommending to the board for its approval, the compensation for our chief executive officer and other executive officers;
- reviewing and recommending to the board for determination with respect to the compensation of our non-employee directors;
- reviewing periodically and approving any incentive compensation or equity plans, programs or similar arrangements; and
- selecting compensation consultant, legal counsel or other adviser only after taking into consideration all factors relevant to that person's independence from management.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee will consist of Yu-Hsin Lin, John M. Longo and Gary C. Biddle. Gary C. Biddle will be the chairman of our nominating and corporate governance committee. John M. Longo and Gary C. Biddle satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nominating and corporate governance committee will be responsible for, among other things:

- selecting and recommending to the board nominees for election by the shareholders or appointment by the board;
- reviewing annually with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any remedial action to be taken.

Duties of Directors

Under Cayman Islands law, our directors owe fiduciary duties to our company, including a duty of loyalty, a duty to act honestly and a duty to act in what they consider in good faith to be in our best interests. Our directors must also exercise their powers only for a proper purpose. Our directors also owe to our company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth Courts have moved toward an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended and restated from time to time, and the class rights vested thereunder in the holders of the shares. In certain limited exceptional circumstances, a shareholder may have the right to seek damages in our name if a duty owed by our directors is breached.

Our board of directors has all the powers necessary for managing, and for directing and supervising, our business affairs. The functions and powers of our board of directors include, among others:

- convening shareholders' annual and extraordinary general meetings and reporting its work to shareholders at such meetings;
- declaring dividends and distributions;
- appointing officers and determining the term of office of the officers;
- exercising the borrowing powers of our company and mortgaging the property of our company; and

- approving the transfer of shares in our company, including the registration of such shares in our share register.

Terms of Directors and Officers

Our directors may be elected by an ordinary resolution of our shareholders. Alternatively, our board of directors may, by the affirmative vote of a simple majority of the directors present and voting at a board meeting appoint any person as a director to fill a casual vacancy on our board or as an addition to the existing board. Our directors are not automatically subject to a term of office and hold office until such time as they are removed from office by an ordinary resolution of our shareholders. In addition, a director will cease to be a director if he (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his office by notice in writing; (iv) is prohibited by any applicable Law or Nasdaq Stock Market rules from being a director; (v) without special leave of absence from our board, is absent from meetings of our board for three consecutive meetings and our board resolves that his office be vacated; or (vi) is removed from office pursuant to any other provision of our articles of association.

Our officers are appointed by and serve at the discretion of the board of directors, and may be removed by our board of directors.

Employment Agreements and Indemnification Agreements

We have entered into employment agreements with each of our executive officers. Under these agreements, the employment of our executive officers who are located at San Diego is governed by the laws of the State of California and is at-will and for no specific period of time. We may terminate employment for cause with 3-month notice, for certain acts of the executive officer, such as personal dishonesty, conviction of a crime, willful act which constitutes misconduct and is materially injurious to our Company, or continued violations of the executive officer's obligations to our Company. We may also terminate an executive officer's employment without cause and our executive officers may resign at any time, subject, in each case, to 3-month prior written notice. The employment of our executive officers who are located at Taiwan is governed by the laws of Taiwan and is for no specific period of time, which may be terminated at any time by mutual agreement or by either the executive officer or the Company pursuant to the applicable law.

Each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strictest confidence, and not to use, except for the benefit of our Company, or to disclose to any person, firm or corporation without written authorization of an officer of our Company, any confidential information, except under a non-disclosure agreement duly authorized and executed by our Company. The executive officers have also agreed to disclose in confidence to us all inventions, designs and trade secrets which they conceive, develop or reduce to practice during the executive officer's employment with us and to assign all right, title and interest in them to us, and assist us in obtaining and enforcing patents, copyrights and other legal rights for these inventions, designs and trade secrets.

In addition, each executive officer has agreed to be bound by non-competition and non-solicitation restrictions during the term of his or her employment and non-solicitation restrictions for one year following the last date of employment. Specifically, each executive officer has agreed not to (i) either directly or indirectly solicit, induce, recruit or encourage any of our employees to leave their employment, or attempt to solicit, induce, recruit, or encourage any of our employees to leave their employment; or (ii) directly or indirectly through any other person, use any of our trade secrets to influence or attempt to influence customers, vendors, suppliers, licensors, lessors, joint venturers, associates, consultants, agents, or partners of our Company to divert their business away from us.

We have also entered into indemnification agreements with each of our directors and executive officers. Under these agreements, 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 a director or officer of our company.

Compensation of Directors and Executive Officers

For the fiscal year ended December 31, 2021, we paid an aggregate of approximately US$0.17 million in cash to our directors and executive officers and did not grant any options to purchase our ordinary shares

to our directors and executive officers. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our directors and executive officers. Our PRC, U.S. and Australian subsidiaries are required by law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund. For share incentive grants to our directors and executive officers, see "— Share Incentive Plans."

Share Incentive Plans

2020 Share Incentive Plan

In December 2019, we adopted the Belite Bio, Inc Share Incentive Plan, or the 2019 Share Incentive Plan, which was later superseded and replaced by the Belite Bio, Inc Amended and Restated Share Incentive Plan, or the 2020 Share Incentive Plan, in December 2020. The terms of the 2019 Share Incentive Plan and the 2020 Share Incentive Plan are substantially the same other than the maximum aggregate number of shares we may issue under the respective plan.

The purpose of the 2020 Share Incentive Plan is to attract and retain the best available personnel, provide additional incentives to directors, employees and consultants, and promote the success of our business. The maximum aggregate number of ordinary shares that may be issued under the 2020 Share Incentive Plan is 4,165,310 ordinary shares. As of the date of this prospectus, options to purchase a total of 1,982,561 ordinary shares are outstanding under the 2020 Share Incentive Plan.

The following paragraphs summarize the principal terms of the 2020 Share Incentive Plan.

Type of Awards. The 2020 Share Incentive Plan permits the awards of options, share appreciation right, share bonuses, performance shares, share units, phantom shares, dividend equivalents, or similar rights to purchase or acquire ordinary shares or any similar securities with a value derived from the value of or related to the ordinary shares and/or returns thereon.

Plan Administration. The 2020 Share Incentive Plan shall be administrated by our board of directors or one or more committees appointed by the board of directors or another committee (within its delegated authority), the Plan Administrator.

Award Agreement. Each award under the 2020 Share Incentive Plan shall be evidenced by an award agreement in the form approved by the plan administrators. The terms of the award agreements will be determined by the plan administrators and consistent with the terms of the 2020 Share Incentive Plan.

Eligibility. The plan administrators may decide that an award under the 2020 Share Incentive Plan be granted to any employee, officer or director of the Company or its affiliates, or that it be granted to any consultant or adviser who provides services to the Company or its affiliates.

Vesting Schedule. In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

Exercise Price. The plan administrator determines the exercise price for each award, which is stated in the award agreement.

Term of the Awards. Options that are vested and exercisable will terminate if they are not exercised prior to the time as the plan administrator determines at the time of grant. However, the maximum exercisable term is ten years from the date of a grant.

Transfer Restrictions. With a few exceptions, no right of interest of a participant in any award may be subject in any manner to sale, transfer, anticipation, alienation, assignment, pledge, encumbrance or charge. This restriction does not apply to (i) transfers to our company, (ii) transfers by gift or domestic relations order to one or more family members, (iii) the designation of a beneficiary to receive benefits if a participant dies or transfers by will, (iv) permitted transfers or exercises on behalf of a participant by the participant's duly authorized legal representative if the participant has suffered a disability.

Termination and Amendment. The board of directors may, at any time, terminate or, from time to time, amend, modify or suspend the 2020 Share Incentive Plan, in whole or in part. No awards may be granted during any period that the board of directors suspends the 2020 Share Incentive Plan. To the extent

then required by applicable law or listing agency, any amendment to the 2020 Share Incentive Plan may be subject to shareholder approval. Unless earlier terminated by the board of directors, the 2020 Share Incentive Plan will terminate at the close of business on the day before the 10th anniversary of the date the board of directors approved the 2020 Share Incentive Plan.

2022 Performance Incentive Plan

In April 2022, we adopted our 2022 Performance Incentive Plan, which is conditional on and effective upon completion of this offering. The initial aggregate amount of ordinary shares that may be issued under the 2022 Performance Incentive Plan is 1,748,667, provided that the shares reserved under the 2022 Performance Incentive Plan shall automatically increase on the first trading day in January of each calendar year during the term of the 2022 Performance Incentive Plan, commencing in January 2023, by an amount equal to (i) four percent (4%) of the total number of ordinary shares issued and outstanding on December 31 of the immediately preceding calendar year or (ii) such lesser number of ordinary shares as may be established by our board of directors.

The following paragraphs describe the principal terms of our 2022 Performance Incentive Plan:

Plan Administration. Our 2022 Performance Incentive Plan will be administered by our board of directors or one or more committees (or subcommittees, as the case may be) appointed by our board of directors or another committee (within its delegated authority). Any such administrator is authorized and empowered to, subject to the express provisions of the 2022 Performance Incentive Plan, do all things necessary or desirable in connection with the authorization of awards and the administration of the 2022 Performance Incentive Plan.

Eligibility. The plan administrator may select among the following eligible individuals to whom an award may be granted: (i) our officers or employees, (ii) our directors; or (iii) consultants or advisers, who render bona fide services to us (except in connection with the offer or sale of securities in a capital-raising transaction or as a market maker or promoter of our securities).

Award agreements. Each award under the 2022 Performance Incentive Plan shall be evidenced by a written or electronic award agreement or notice in a form approved by the plan administrator.

Types of Awards. The types of awards that may be granted under our 2022 Performance Incentive Plan are:

- Share Options. A share option is the grant of a right to purchase a specified number of ordinary shares during a specified period as determined by the administrator. The maximum term of each option shall be ten years. The per share exercise price for each option granted to any eligible person subject to United States income tax shall be not less than the fair market value of an ordinary share on the date of grant of the option.
- Share Appreciation Rights. A share appreciation right, or SAR, is a right to receive a payment, in cash and/or ordinary shares, equal to the excess of the fair market value of a specified number of ordinary shares on the date the SAR is exercised over the “base price” of the award, which base price shall be set forth in the applicable award agreement and shall be not less than 100% of the fair market value of an ordinary share on the date of grant of the SAR. The maximum term of a SAR shall be ten years.
- Other Awards. The other types of awards that may be granted under the 2022 Performance Incentive Plan include: (a) share bonuses, restricted shares, performance shares, share units, restricted share units, deferred shares, phantom shares, or similar rights to purchase or acquire shares, whether at a fixed or variable price (or no price) or fixed or variable ratio related to the ordinary shares, and any of which may (but need not) be fully vested at grant or vest upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions, or any combination thereof; or (b) cash awards.

Vesting Schedule. In general, the plan administrator determines the vesting schedule, which is set forth in the award agreement.

Acceleration of Awards upon Certain Corporate Transactions. Upon the occurrence of any merger, combination, consolidation or other reorganization; any exchange of securities of our company; a sale of

all or substantially all of the business, shares or assets of our company; a dissolution of our company; or any other event in which our company does not survive (or does not survive as a public company in respect of our ordinary shares); or any change in control event defined in any applicable award agreement, the administrator of the 2022 Performance Incentive Plan may, in its discretion, provide for the accelerated vesting of any award or awards as and to the extent determined by the administrator in the circumstances.

Transfer Restrictions. Awards may not be transferred in any manner by the recipient other than by will or the laws of descent and distribution, except as otherwise provided by the plan administrator.

Amendment and Termination of Plan. No amendment, suspension or termination of the 2022 Performance Incentive Plan or amendment of any outstanding award agreement shall, without written consent of the participant, affect in any manner materially adverse to the participant any rights or benefits of the participant or obligations of our company under any award granted under the 2022 Performance Incentive Plan prior to the effective date of such change. Unless earlier terminated by our board of directors and subject to any extension that may be approved by shareholders, the 2022 Performance Incentive Plan shall terminate at the close of business on the day before the tenth anniversary of the effective date. After the termination of the 2022 Performance Incentive Plan either upon such stated expiration date or its earlier termination by our board of directors, no additional awards may be granted under the 2022 Performance Incentive Plan, but previously granted awards (and the authority of the administrator with respect thereto, including the authority to amend such awards) shall remain outstanding in accordance with their applicable terms and conditions and the terms and conditions of the 2022 Performance Incentive Plan.

The following table summarizes, as of the date of this prospectus, the number of ordinary shares underlying outstanding options that we granted to our directors and executive officers.

Name	Ordinary Shares Underlying Options	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Yu-Hsin Lin	827,814	$0.4386	December 23, 2020	December 22, 2030
	*	$ 6.00[(1)]	April 18, 2022[#]	[##]
Hao-Yuan Chuang	579,471	$0.4386	December 23, 2020	December 22, 2030
	*	$ 6.00[(1)]	April 18, 2022[#]	[##]
Nathan L. Mata	748,667	$ 6.00[(1)]	April 18, 2022[#]	[##]
Ching-Chen Chiu	350,000	$ 6.00[(1)]	April 18, 2022[#]	[##]
Wan-Shan Chen	*	$0.4386	December 23, 2020	December 22, 2030
Hung-Wei Chen	*	$0.4386	December 23, 2020	December 22, 2030
John M. Longo	*	$ 6.00[(1)]	April 18, 2022[#]	[##]
Gary C. Biddle	*	$ 6.00[(1)]	April 18, 2022[#]	[##]
All directors and executive officers as a group	2,853,442			

Note:

* Less than 1% of our total ordinary shares on an as-converted basis outstanding as of the date of this prospectus.

(1) The exercise price applies to all options granted on April 18, 2022, which is the final offer price of the offering.

[#] Our Board approved the option grant on April 18, 2022, which is conditional upon and becomes effective on the date on which this registration statement is declared effective by the United States Securities and Exchange Commission (‘‘Award Date’’).

[##] The expiration date of each such grant to be the day before the tenth anniversary of the Award Date.

As of the date of this prospectus, our award holders other than our directors and officers as a group held options to purchase 827,786 ordinary shares, with exercise prices ranging from US$0.1191 per share to US$6.00 per share.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares on an as-converted basis as of the date of this prospectus by:

- each of our directors and executive officers; and
- each person known to us to own beneficially more than 5% of our ordinary shares

The calculations in the table below are based on 18,095,317 ordinary shares on an as-converted basis outstanding as of the date of this prospectus, and 24,095,317 ordinary shares outstanding immediately after the completion of this offering. Each holder of ordinary shares is entitled to one vote per share on all matters submitted to them for a vote.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned Prior to This Offering		Ordinary Shares Beneficially Owned After This Offering		
	Ordinary Shares	% of Beneficial Ownership†	Ordinary Shares	% of Beneficial Ownership	% of aggregate voting power††
Directors and Executive Officers:**					
Yu-Hsin Lin[(1)]	2,463,015	13.61%	2,773,758	11.51%	11.51%
Hao-Yuan Chuang[(2)]	529,193	2.92%	532,241	2.21%	2.21%
Nathan L. Mata	—	—	—	—	—
Ching-Chen Chiu	*	*	*	*	*
Wan-Shan Chen[(3)]	*	*	*	*	*
Hung-Wei Chen[(4)]	193,526	1.07%	*	*	*
John M. Longo (independent director nominee).	—	—	—	—	—
Ita Lu (independent director nominee)[(5)].	—	—	—	—	—
Gary C. Biddle (independent director nominee)	—	—	—	—	—
Principal Shareholders:					
Lin Bioscience International Ltd[(6)].	13,928,597	76.97%	16,428,597	68.18%	68.18%

Notes:

* Less than 1% of our total ordinary shares on an as-converted basis outstanding as of the date of this prospectus.

** The business address of our directors and executive officers, except for Nathan L. Mata, John M. Longo and Ita Lu is Room 2972, 29F., No. 68, Sec. 5, Zhongsiao E. Rd., Xinyi Dist., Taipei City 110 , Taiwan; the business address of Nathan L. Mata is 5820 Oberlin Drive, Suite 101, San Diego, CA 92121; the business address of John M. Longo is 100 Rockefeller Road, Piscataway, NJ 08854; the business address of Ita Lu is 5F-7 No. 1 Xinyi Road Section 2, Taipei Taiwan; the business address of Gary C. Biddle is Level 8, 198 Berkeley Street, Carlton, VIC 3010, Australia.

† For each person and group included in this column, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the total number of shares outstanding and the number of shares such person or group has the right to acquire upon exercise of option, warrant or other right within 60 days after the date of this prospectus. The total number of ordinary shares outstanding as of the date of this prospectus on an as-converted basis is 18,095,317. The

total number of ordinary shares outstanding after the completion of this offering will be 24,095,317, including 6,000,000 ordinary shares sold by us in this offering in the form of ADSs, assuming that the underwriters do not exercise their option to purchase additional ADSs.

†† For each person and group included in this column, percentage of voting power is calculated by dividing the voting power beneficially owned by such person or group by the voting power of all of our ordinary shares as a single class. Our ordinary shares vote together as a single class on all matters submitted to a vote of our shareholders, except as may otherwise be required by law.

(1) Represents 731,728 ordinary shares directly held by Yu-Hsin Lin, and 1,731,287 shares indirectly held by Yu-Hsin Lin through Lin Bioscience International Ltd. The exercise price of the outstanding options granted to Yu-Hsin Lin is US$0.4386 per share.

(2) Represents 512,210 ordinary shares directly held by Hao-Yuan Chuang, and 16,983 shares indirectly held by Hao-Yuan Chuang through Lin Bioscience International Ltd. The exercise price of the outstanding options granted to Hao-Yuan Chuang is US$0.4386 per share.

(3) The exercise price of the outstanding options granted to Wan-Shan Chen is US$0.4386 per share.

(4) Represents 58,435 ordinary shares directly held by Hung-Wei Chen, and 135,091 shares indirectly held by Hung-Wei Chen through Lin Bioscience International Ltd. The exercise price of the outstanding options granted to Hung-Wei Chen is US$0.4386 per share.

(5) The renumeration for Mr. Lu's service as our director is comprised of cash payment and option grant. The cash portion of such remuneration will be deferred and will only be paid to Mr. Lu after his employment relationship with Taiwania Capital is terminated. In addition, the option portion of such remuneration will only be granted to Mr. Lu under our 2022 Performance Incentive Plan after his employment relationship with Taiwania Capital terminates.

(6) Represents 8,840,321 ordinary shares and 5,088,276 Series B Preferred Shares directly held by Lin Bioscience International Ltd.

As of the date of this prospectus, none of our ordinary shares are held by record holders in the United States. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

RELATED PARTY TRANSACTIONS

Private Placements

See "Description of Share Capital — History of Securities Issuances."

Shareholders Agreement

See "Description of Share Capital — Shareholders Agreement."

Employment Agreements and Indemnification Agreements

See "Management — Employment Agreements and Indemnification Agreements."

Share Incentive Plans

See "Management — Share Incentive Plans."

Other Transactions with Related Parties

LBS-007

2018 LBS-007 Co-Development Agreement. On February 27, 2018, Lin BioScience, Inc., our ultimate controlling shareholder, entered into a co-development agreement (the "**2018 LBS-007 Co-Development Agreement**") with Belite Bio Holdings Corp. (the direct subsidiary of Lin BioScience, Inc. at that time, and now our wholly owned subsidiary), pursuant to which (i) both parties agreed to jointly perform certain new drug development project(s) for the development of LBS-007 from February 27, 2018 to February 27, 2023; (ii) each party agreed to bear its own costs for the performance of such project; (iii) if the project becomes commercialized, 10% of the profit derived from such commercialization will be shared with Belite Bio Holdings Corp. provided that a written agreement is entered into by and between the parties and a third-party licensee; and (iv) Belite Bio Holdings Corp. acknowledged and agreed that Lin BioScience, Inc. was the sole and exclusive owner of all intellectual property rights that Belite Bio Holdings Corp. directly or indirectly managed, developed or assisted in the performance of such project. Lin BioScience, Inc. and Belite Bio Holdings Corp. entered into a deed of termination which terminated the 2018 LBS-007 Co-Development Agreement with effect from January 20, 2020 and the parties agreed to waive all obligations due under the agreement. We have not received any consideration owing to the above agreement.

LBS-021 and LBS-031

2018 LBS-021/031 R&D Services Agreement. On January 1, 2018, Lin BioScience, Inc., our ultimate controlling shareholder, entered into a research and development services agreement (the "**2018 LBS-021/031 R&D Agreement**") with our wholly owned subsidiaries, Belite Bio Holdings Corp. and Belite Bio, LLC (collectively, the "**Service Provider**"), pursuant to which the Service Provider agreed to (i) perform certain research and development services for Lin BioScience, Inc. for the development of LBS-021 and LBS-031 from January 1, 2018 to December 31, 2018, and (ii) assign the ownership of the deliverables to Lin BioScience, Inc and acknowledged and agreed that Lin BioScience, Inc. is the sole and exclusive owner of all intellectual property that the Service Provider directly or indirectly managed, developed or assisted in the performance of the services. The total consideration Belite Bio Holdings Corp. and Belite Bio, LLC received for such development services, assignment and licensing was nil and $85,821.17, respectively.

2019 LBS-021/031 R&D Services Agreement. On January 1, 2019, Lin BioScience, Inc., our ultimate controlling shareholder, entered into a research and development services agreement (the "**2019 LBS-021/031 R&D Agreement**") with our wholly owned subsidiaries, Belite Bio Holdings Corp. and Belite Bio, LLC (collectively, the "**Service Provider**"), pursuant to which the Service Provider agreed to (i) perform certain research and development services for Lin BioScience, Inc. for the development of LBS-021 and LBS-031 from January 1, 2019 to December 31, 2019, and (ii) assign the ownership of the deliverables to Lin BioScience, Inc. and acknowledged and agreed that Lin BioScience, Inc. is the sole and exclusive owner of all intellectual property that the Service Provider directly or indirectly managed, developed or assisted in the performance of the services. The total consideration Belite Bio Holdings Corp. and Belite Bio, LLC received for such development services, assignment and licensing was nil and $25,900.75, respectively.

LBS-009

2018 LBS-009 R&D Services Agreement. On July 1, 2018, we entered into a research and development services agreement (the "**2018 LBS-009 R&D Agreement**") with Lin BioScience, Inc., our ultimate controlling shareholder, and Belite Bio Holdings Corp. and Belite Bio, LLC, (our wholly owned subsidiaries) (collectively, the "**Service Provider**"), pursuant to which (i) the Service Provider agreed to provide certain new drug development services for pipeline LBS-009 to us from July 1, 2018 to June 30, 2019, including sample collection for RBP4 analysis and project management; (ii) the Service Provider acknowledged that we are the sole and exclusive owner of all intellectual property rights that they directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees to the Service Provider in an amount equal to 110% percent of actual costs for its performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. The total consideration we paid for such development services, assignment and licensing was nil to Lin BioScience, Inc., nil to Belite Bio Holdings Corp. and $39,408.87 to Belite Bio, LLC.

2019 LBS-009 R&D Services Agreement. On July 1, 2019, we entered into a research and development services agreement (the "**2019 LBS-009 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), Belite Bio Holdings Corp. and Belite Bio, LLC (our wholly owned subsidiaries) (collectively, the "**Service Provider**"), pursuant to which (i) the Service Provider agreed to provide certain new drug development services for pipeline LBS-009 to us from July 1, 2019 to June 30, 2020, including sample collection for RBP4 analysis and project management; (ii) the Service Provider acknowledged that we are the sole and exclusive owner of all intellectual property rights that they directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees to the Service Provider in an amount equal to 110% percent of actual costs for its performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. The total consideration we paid for such development services, assignment and licensing was nil to Lin BioScience, Inc., nil to Belite Bio Holdings Corp. and $3,280.02 to Belite Bio, LLC.

2020 LBS-009 R&D Services Agreement. On July 1, 2020, we entered into a research and development services agreement (the "**2020 LBS-009 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), Belite Bio Holdings Corp. and Belite Bio, LLC (our wholly owned subsidiaries) (collectively, the "**Service Provider**"), pursuant to which (i) the Service Provider agreed to provide preclinical studies for pipeline LBS-009 to us from July 1, 2020 to June 30, 2021; (ii) the Service Provider acknowledged and agreed that we are the sole and exclusive owner of all intellectual property rights that they directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees to the Service Provider in an amount equal to 110% percent of actual costs for its performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. The total consideration we paid for such development services was nil to Lin BioScience, Inc., nil to Belite Bio Holdings Corp. and nil to Belite Bio, LLC.

LBS-008

2018 LBS-008 R&D Services Agreement. On July 1, 2018, we entered into a research and development services agreement (the "**2018 LBS-008 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), pursuant to which (i) our ultimate controlling shareholder agreed to provide certain new drug development services for pipeline LBS-008 to us from July 1, 2018 to June 30, 2019; (ii) our ultimate controlling shareholder acknowledged and agreed that we are the sole and exclusive owner of all intellectual property rights that our ultimate controlling shareholder directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees equal to 110% percent of actual costs for our ultimate controlling shareholder's performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. For such development services, the total consideration paid by us was nil to Lin BioScience, Inc.

2019 LBS-008 R&D Services Agreement. On July 1, 2019, we entered into a research and development services agreement (the "**2019 LBS-008 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), pursuant to which (i) our ultimate controlling shareholder agreed to provide certain new drug development services for pipeline LBS-008 to us from July 1, 2019 to June 30, 2020; (ii) our ultimate controlling shareholder acknowledged and agreed that we are the sole and exclusive owner of all intellectual property rights that our ultimate controlling shareholder directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees equal to 110% percent of actual costs for our ultimate controlling shareholder's performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. On January 30, 2020, we entered into the first amendment to 2019 LBS-008 R&D Agreement with Lin BioScience, Inc., pursuant to which our ultimate controlling shareholder agreed to provide certain new drug development services and finance and accounting services. For such development and finance services, the total consideration paid by us was $56,747.86 to Lin BioScience, Inc.

2020 LBS-008 R&D Services Agreement. On July 1, 2020, we entered into a research and development services agreement (the "**2020 LBS-008 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), pursuant to which (i) our ultimate controlling shareholder agreed to provide certain new drug development services for pipeline LBS-008 to us from July 1, 2020 to June 30, 2021; (ii) our ultimate controlling shareholder acknowledged and agreed that we are the sole and exclusive owner of all intellectual property rights that our ultimate controlling shareholder directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees equal to 110% percent of actual costs for our ultimate controlling shareholder's performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. For such development services, the total consideration paid by us was $57,828.12 to Lin BioScience, Inc.

2021 LBS-008 R&D Services Agreement. On July 1, 2021, we entered into a research and development services agreement (the "**2021 LBS-008 R&D Agreement**") with Lin BioScience, Inc. (our ultimate controlling shareholder), pursuant to which (i) our ultimate controlling shareholder agreed to provide certain new drug development services for pipeline LBS-008 to us from July 1, 2021 to June 30, 2022; (ii) our ultimate controlling shareholder acknowledged and agreed that we are the sole and exclusive owner of all intellectual property rights that our ultimate controlling shareholder directly or indirectly managed, developed or assisted in the performance of the services; and (iii) we agreed to pay service fees equal to 110% percent of actual costs for our ultimate controlling shareholder's performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. On February 23, 2022, we entered into a first amendment to 2021 LBS-008 R&D Agreement with Lin BioScience, Inc., pursuant to which we granted our ultimate controlling shareholder a revocable, non-exclusive, non-transferable, royalty-free license (with the right to grant and authorize sublicenses) under RBP4 related patents in Taiwan to the extent necessary for our ultimate controlling shareholder to perform services stipulated under the 2021 LBS-008 R&D Agreement. For such development services, the total consideration paid by us was $124,785.59 to Lin BioScience, Inc. as of the date of this prospectus.

2019 Loan Agreements

2019 Loan Agreements between us and Lin Bioscience International Ltd. On July 12, 2019 and September 30, 2019, we entered into two intercompany loan agreements (the "**Cayman 2019 July Loan Agreement**" the "**Cayman 2019 September Loan Agreement**", respectively) with Lin Bioscience International Ltd. (our principal shareholder). Pursuant to the Cayman 2019 July Loan Agreement, Lin Bioscience International Ltd. agreed to provide an interest-free loan to us on request from time to time for a period of one year or any longer period as agreed by the parties commencing from July 12, 2019 with a facility limit of $80,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. Pursuant to the Cayman 2019 September Loan Agreement, Lin Bioscience International Ltd. agreed to provide an interest-free loan to us on request from time to time for a period of one year or any longer period as agreed by the parties commencing from September 30, 2019 with a facility limit of $800,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. On January 20, 2020, we entered into a first confirmation deed with Lin Bioscience International Ltd., which reduced the facility amount under the Cayman 2019 September Loan Agreement to $300,000, by converting $500,000 of the loan into equity via the issuance of 500,000 of our Ordinary Shares to Lin Bioscience International Ltd. On April 28, 2020, we entered into a second confirmation deed with Lin Bioscience International Ltd., which (i) reduced the facility limit under the Cayman 2019 September Loan Agreement to $165,000 by repaying $135,000 of the loan to Lin Bioscience International Ltd. no later than April 30, 2020; and (ii) terminated the Cayman 2019 July Loan Agreement subject to full repayment of the outstanding principal owed by us to Lin Bioscience International Ltd. no later than April 30, 2020. On August 14, 2020, we entered into a third confirmation deed with Lin Bioscience International Ltd., which terminated the Cayman 2019 September Loan Agreement, the first confirmation deed and the second confirmation deed subject to no facility amount under the Cayman 2019 September Loan Agreement, the first confirmation deed and the second confirmation deed draw down by us. As of the date of this prospectus, we have fully repaid the outstanding amount under the two loan agreements.

2019 Loan Agreements between RBP4 Pty Ltd and Lin BioScience Pty Ltd. On July 10, 2019 and on December 17, 2019, Lin BioScience Pty Ltd (the direct subsidiary of our ultimate controlling shareholder) entered into two intercompany loan agreements (the "**Australia 2019 July Loan Agreement**" and the "**Australia 2019 December Loan Agreement**", respectively) with RBP4 Pty Ltd (our wholly owned subsidiary). Pursuant to the Australia 2019 July Loan Agreement, Lin BioScience Pty Ltd agreed to provide an interest-free loan to us on request from time to time for a period of one year or any longer period as agreed by the parties commencing from July 10, 2019 with a facility limit of AUD450,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. Pursuant to the Australia 2019 December Loan Agreement, Lin BioScience Pty Ltd agreed to provide an interest-free loan to us on request from time to time for a period of one year or any longer period as agreed by the parties commencing from December 17, 2019 with a facility limit of AUD1,200,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. On January 20, 2020, Lin BioScience Pty Ltd and RBP4 Pty Ltd entered into a confirmation deed, which (i) confirmed that the aggregate outstanding principal amount under the two loan agreements was AUD650,000; and (ii) terminated the two loan agreements subject to full repayment of the outstanding principal and all other amounts owed by RBP4 Pty Ltd to Lin BioScience Pty Ltd no later than January 31, 2020. As of the date of this prospectus, RBP4 Pty Ltd has fully repaid the outstanding amount under the two loan agreements.

2019 Loan Agreements between us and Lin BioScience, Inc. On August 12, 2019, Lin BioScience, Inc. (our ultimate controlling shareholder) entered into an intercompany debt funding agreement (the "**Cayman 2019 August Loan Agreement**") with us. Pursuant to the Cayman 2019 August Loan Agreement, Lin BioScience, Inc. agreed to provide a loan to us on request from time to time for a period of one year or any longer period as agreed by the parties commencing from August 12, 2019 with a facility limit of $800,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. The loan bears an interest rate at the rate of 2.285% per annum. On April 28, 2020, we entered into a confirmation deed with

Lin BioScience, Inc., which (i) confirmed that the aggregate outstanding principal amount under the Cayman 2019 August Loan Agreement was $800,000; and (ii) reduced the facility limit to $450,000 by repaying $350,000 of the loan to Lin BioScience, Inc. no later than April 30, 2020. As of the date of this prospectus, we have fully repaid the outstanding amount under the Cayman 2019 August Loan Agreement.

2019 Loan Agreements between RBP4 Pty Ltd and Lin BioScience, Inc. On August 12, 2019, Lin BioScience, Inc. (our ultimate controlling shareholder) entered into an intercompany debt funding agreement (the "**Australia 2019 August Loan Agreement**") with RBP4 Pty Ltd (our wholly owned subsidiary). Pursuant to the Australia 2019 August Loan Agreement, Lin BioScience, Inc. agreed to provide a loan to our Australian subsidiary on request from time to time for a period of one year or any longer period as agreed by the parties commencing from August 12, 2019 with a facility limit of AUD1,000,000 to assist with the conduct and/or facilitation by us of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. The loan bears an interest rate at the rate of 2.285% per annum. On April 28, 2020, RBP4 Pty Ltd and Lin BioScience, Inc. entered into a confirmation deed, which (i) confirmed that the aggregate outstanding principal amount under the Australia 2019 August Loan Agreement was AUD1,000,000; (ii) reduced the facility limit to AUD700,000 by repaying AUD300,000 of the loan to Lin BioScience, Inc. no later than May 8, 2020, as well as the accrued interests. As of the date of this prospectus, we have fully repaid the outstanding amount under the Australia 2019 August Loan Agreement.

2020 Loan Agreements

2020 Loan Agreement between RBP4 Pty Ltd and Lin BioScience Pty Ltd. On January 20, 2020, Lin BioScience Pty Ltd (the direct subsidiary of our ultimate controlling shareholder) entered into an intercompany loan agreement (the "**2020 Lin Bio Loan Agreement**") with RBP4 Pty Ltd (our wholly owned subsidiary), pursuant to which Lin BioScience Pty Ltd agreed to provide an interest-free loan to our Australian subsidiary on request from time to time for a period of one year or any longer period as agreed by the parties commencing from January 20, 2020 with a facility limit of AUD190,000 to assist with the conduct and/or facilitation by our Australian subsidiary of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. On April 28, 2020, Lin BioScience Pty Ltd and RBP4 Pty Ltd entered into a first confirmation deed which reduced the facility limit to AUD185,000. On August 14, 2020, Lin BioScience Pty Ltd and RBP4 Pty Ltd entered into a second confirmation deed, which (i) confirmed that the outstanding principal amount was AUD185,000; and (ii) terminated the 2020 Lin Bio Loan Agreement and the first confirmation deed upon full repayment of the outstanding principal amount by RBP4 Pty Ltd no later than August 21, 2020. As of the date of this prospectus, RBP4 Pty Ltd has fully repaid the outstanding amount under the 2020 Lin Bio Loan Agreement.

2020 Loan Agreement between RBP4 Pty Ltd and Lin BioScience, Inc. On January 20, 2020, Lin BioScience, Inc. (our ultimate controlling shareholder) entered into an intercompany loan agreement (the "**2020 Lin BioScience Loan Agreement**") with RBP4 Pty Ltd (our wholly owned subsidiary), pursuant to which Lin BioScience, Inc. agreed to provide a loan to our Australian subsidiary on request from time to time for a period of one year or any longer period as agreed by the parties commencing from January 20, 2020 with a facility limit of AUD300,000 to assist with the conduct and/or facilitation by our Australian subsidiary of research and development in connection with clinical trials of LBS-008 or any other purpose approved by the lender in writing from time to time. The loan bears an interest rate at the lower of (i) the rate of 2.275% per annum; and (ii) the interest rate relating to "inbound loans" specified in PCG2017/2 issued by the Australian Taxation Office from time to time (being 2.33% per annum at the date of 2020 Lin BioScience Loan Agreement). On April 28, 2020, RBP4 Pty Ltd and Lin BioScience, Inc. entered into a confirmation deed, which terminated the 2020 Lin BioScience Loan Agreement subject to no facility amount draw down by RBP4 Pty Ltd. As of the date of this prospectus, RBP4 Pty Ltd has fully repaid the outstanding amount under the 2020 Lin BioScience Loan Agreement.

DESCRIPTION OF SHARE CAPITAL

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our memorandum and articles of association, the Companies Act (As Revised) of the Cayman Islands, which we refer to as the Companies Act below, and the common law of the Cayman Islands.

As of the date of this prospectus, our authorized share capital is US$50,000 divided into 500,000,000 shares, comprising of (i) 492,179,086 ordinary shares, par value US$0.0001 per share, and (ii) 2,377,642 shares of series A preferred shares of a par value of US$0.0001 each and (iii) 5,443,272 shares of series B preferred shares of a par value of US$0.0001 each. As of the date of this prospectus, 10,274,403 ordinary shares are issued and outstanding, 2,377,642 series A preferred shares are issued and outstanding and 5,443,272 series B preferred shares are issued and outstanding. All of our issued and outstanding ordinary and preferred shares are fully paid. All of our outstanding preferred shares will automatically convert into ordinary shares on a one-for-one basis upon the completion of this offering.

Immediately prior to the completion of this offering, our authorized share capital will be changed into US$50,000 divided into 500,000,000 shares comprising of (i) 400,000,000 ordinary shares of a par value of US$0.0001 each, and (ii) 100,000,000 undesignated shares of a par value of US$0.0001 each of such class or classes (however designated) as the board of directors may determine in accordance with our post-offering memorandum and articles of association. Immediately after the completion of this offering, we will have 24,095,317 ordinary shares issued and outstanding, assuming the underwriters do not exercise their option to purchase additional ADSs. All of our shares issued and outstanding prior to the completion of the offering are and will be fully paid, and all of our shares to be issued in the offering will be issued as fully paid.

Our Post-Offering Memorandum and Articles of Association

Our shareholders have conditionally adopted a third amended and restated memorandum and articles of association, which will become effective and replace our current second amended and restated memorandum and articles of association in its entirety immediately prior to the completion of this offering. The following are summaries of material provisions of the post-offering memorandum and articles of association and of the Companies Act, insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company. Under our post-offering memorandum and articles of association, the objects of our company are unrestricted, and we have the full power and authority to carry out any object not prohibited by the laws of the Cayman Islands.

Ordinary Shares. Holders of our ordinary shares will have the same rights except for voting and conversion rights. Our ordinary shares are issued in registered form and are issued when registered in our register of members. We may not issue shares to bearer. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends. Our directors may from time to time declare dividends (including interim dividends) and other distributions on our shares in issue and authorize payment of the same out of the funds of our company lawfully available therefor. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend may exceed the amount recommended by our directors. Our post-offering memorandum and articles of association provide that dividends may be declared and paid out of the funds of our Company lawfully available therefor. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or share premium account; and provided that in no circumstances may a dividend be paid if that would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid.

Voting Rights. Holders of our ordinary shares have the right to receive notice of, attend, speak and vote at general meetings of our company. Holders of ordinary shares shall, at all times, vote together as one class on all matters submitted to a vote by the members at any such general meeting. On all matters subject to a vote at general meetings of our company, (1) on a show of hands, each shareholder shall be entitled to one vote, whereas (2) on a poll, each shareholder shall be entitled to one vote per ordinary share. Our ordinary shares vote together as a single class on all matters submitted to a vote of our shareholders, except as may otherwise be required by law. Voting at any meeting of shareholders shall be decided by way of

a poll save that the chairman of the meeting may, in good faith, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands. Where a show of hands is allowed, before or on the declaration of the results of the show of hands, a poll may be demanded by the chairman of such meeting or any shareholder present in person or by proxy at the meeting.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes of the ordinary shares which are cast by those of our shareholders who attend and vote at the meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes of the ordinary shares which are cast by those of our shareholders who attend and vote at the meeting. Under the Companies Act, a special resolution will be required in order for our company to effect certain important matters as stipulated in the Companies Act, such as a change of name or making changes to our post-offering memorandum and articles of association. Our shareholders may, among other things, divide or combine their shares by ordinary resolution.

General Meetings of Shareholders. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our post-offering memorandum and articles of association provide that we may (but are not obliged to, unless as required by applicable law or the Nasdaq Stock Market rules) in each year hold a general meeting as our annual general meeting in which case we will specify the meeting as such in the notices calling it, and the annual general meeting will be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by the chairman of our board of directors or a majority of our directors (acting by a resolution of our board). Advance notice of at least seven calendar days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. A quorum required for any general meeting of shareholders consists of one or more of our shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third of all votes attaching to the issued and outstanding shares in our company entitled to vote at such general meeting.

The Companies Act provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our post-offering memorandum and articles of association provide that upon the requisition of any one or more of our shareholders holding shares which carry in aggregate not less than one-third of all votes attaching to all issued and outstanding shares of our company entitled to vote at general meetings, our board will be required to convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, our post-offering memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

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

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

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as Nasdaq Stock 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 must, within three calendar months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of the Nasdaq Stock Market, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine; provided, however, that the registration of transfers may not be suspended nor the register closed for more than 30 days in any year.

Liquidation. On the winding up of our company, if the assets available for distribution amongst our shareholders will be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus will be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay all of the paid-up capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

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

Redemption, Repurchase and Surrender of Shares. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by our shareholders by ordinary resolution. Our company may also redeem or repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Act, the redemption or repurchase of any share may be paid out of our Company's profits or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variation of Rights of Shares. Whenever the capital of our company is divided into different classes or series, the rights attached to any such class or series may, subject to any rights or restrictions for the time being attached to any class or series, only be materially adversely varied or abrogated with the consent in writing of the holders of not less than a majority of the issued shares of that class or with the sanction of an ordinary resolution passed at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued will not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied or abrogated by the creation, allotment, or issue of further shares ranking *pari passu* with or subsequent to such existing class of shares, or the redemption or purchase of any shares of any class by our company. The rights of the holders of shares shall not be deemed to be varied or abrogated by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

Issuance of Additional Shares. Our post-offering memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors may determine, to the extent of available authorized but unissued shares.

Our post-offering memorandum and articles of association also authorize 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;
- the rights and terms of redemption and liquidation preferences; and
- any other powers, preferences and relative, participating, optional and other special rights.

Our board of directors may issue 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.

Inspection of Books and Records. Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records (other than our memorandum and articles of association and our register of mortgages and charges). However, we intend to provide our shareholders with annual audited financial statements. See "Where You Can Find Additional Information."

Anti-Takeover Provisions. Some provisions of our post-offering 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; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our post-offering memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Changes in Capital. Our shareholders may from time to time by ordinary resolution:

- increase our share capital by such sum, to be divided into shares of such classes and amount, as the resolution shall prescribe;
- consolidate and divide all or any of our share capital into shares of a larger amount than our existing shares;
- sub-divide our existing shares, or any of them into shares of a smaller amount, provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; or
- cancel any shares which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of our share capital by the amount of the shares so canceled.

Our shareholders may by special resolution, subject to confirmation by the Grand Court of the Cayman Islands on an application by our company for an order confirming such reduction, reduce our share capital or any capital redemption reserve in any manner permitted by law.

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

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;

- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Differences in Corporate Law

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and, accordingly, there are significant differences between the Companies Act and the current Companies Act of England. In addition, the Companies Act differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements. The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (i) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (ii) a "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (a) a special resolution of the shareholders of each constituent company, and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose a company is a "parent" of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

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

Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) upon dissenting to a merger or consolidation, provide the dissenting shareholder complies strictly with the procedures set out in the Companies Act. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Act also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of

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

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

The Companies Act also contains a statutory power of compulsory acquisition which may facilitate the "squeeze out" of dissentient minority shareholder upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares within four months, the offeror may, within a two-month period commencing on the expiration of such four month period, require the holders of the remaining shares to transfer such shares to the offeror on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted in accordance with the foregoing statutory procedures, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' Suits. In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company, and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands court can be expected to follow and apply the common law principles (namely the rule in Foss v. Harbottle and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Indemnification of Directors and Executive Officers and Limitation of Liability. Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of directors and officers, 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 memorandum and articles of association provide that we shall indemnify our directors and officers, against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses,

losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our post-offering amended and restated memorandum and articles of association.

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

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

As a matter of Cayman Islands law, a director of a Cayman Islands exempted company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company — a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party, and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands exempted company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder Action by Written 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 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, and any such resolution in writing shall be as valid and effective as if the same had been passed at a general meeting of our company duly convened and 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 that it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Companies Act provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However,

these rights may be provided in a company's articles of association. Our post-offering memorandum and articles of association allow any one or more of our shareholders holding shares which carry in aggregate not less than one-third of the total number votes attaching to all issued and outstanding shares of our company as of the date of the deposit that are entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. Other than this right to requisition a shareholders' meeting, our post-offering memorandum and articles of association do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As a Cayman Islands exempted company, we are not obliged by law to call shareholders' annual general meetings.

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 shareholder's voting power with respect to electing such director.

There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands, but our post-offering 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 issued and outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our post-offering memorandum and articles of association, directors may be removed by an ordinary resolution of our shareholders. A director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his office by notice in writing; (iv) is prohibited by any applicable law or the Nasdaq Stock Market rules; (v) without special leave of absence from our board, is absent from meetings of our board for three consecutive meetings and our board resolves that his office be vacated; or (vi) is removed from office pursuant to any other provision of our post-offering memorandum and articles of association.

Transactions with Interested Shareholders. The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting shares 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 either an order of the courts of the Cayman Islands or by the board of directors.

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, or, if we are unable to pay our debts as they fall due, by an ordinary 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 our post-offering memorandum and articles of association, if our share capital is divided into more than one class of shares, the rights attached to any such class may only be materially adversely varied or abrogated with the consent in writing of the holders of not less than a majority of the issued shares of that class or with the sanction of an ordinary resolution passed at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the shares of that class, be deemed to be materially adversely varied or abrogated by the creation, allotment or issue of further shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any shares of any class by our company. The rights of the holders of shares shall not be deemed to be materially adversely varied or abrogated by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

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

Rights of Non-resident or Foreign Shareholders. There are no limitations imposed by our post-offering 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 memorandum and articles of association that require our company to disclose shareholder ownership above any particular ownership threshold.

History of Securities Issuances

The following is a summary of changes in our share capital in the past three years.

Ordinary shares

On March 27, 2018, we issued 1 ordinary share to Mapcal Limited, which was transferred to Lin Bioscience International Ltd. on March 27, 2018.

We issued to Lin Bioscience International Ltd. (i) 99 ordinary shares for consideration of $99.9999 on April 13, 2018; (ii) 5,340,221 ordinary shares for consideration of $900,000 plus assignment of the rights, title, interests and obligations of Lin Bioscience International Ltd. under the exclusive license agreement by and between Lin Bioscience International Ltd. and Columbia University and the transfer of 1,600 shares of Belite Bio Holdings Corp. (formerly known as Lin BioScience Holdings Corporation) on July 2, 2018; (iii) 2,500,000 ordinary shares for consideration of $2,500,000 on August 8, 2018; and (iv) 1,000,000 ordinary shares for consideration of $1,000,000 on January 20, 2020. Lin Bioscience International Ltd. is wholly owned by Lin BioScience, Inc., our ultimate controlling shareholder.

On December 31, 2020, we issued 727,676 ordinary shares to the optionees for the options exercised. Specifically, we issued: (i) 367,515 ordinary shares to Yu-Hsin Lin, our Founder, Chief Executive Officer and Chairman of the Board of Directors; (ii) 257,260 ordinary shares to Hao-Yuan Chuang, our Chief Financial Officer; (iii) 36,751 ordinary shares to Hung-Wei Chen; (iv) 22,050 ordinary shares to Wan-Shan

Chen; (v) 22,050 ordinary shares to Ming-Chiu Wu; and (vi) 22,050 ordinary shares to Yun-Ju Huang, in their exercise of options granted.

On December 31, 2021, we issued 706,406 ordinary shares to the optionees for the options exercised. Specifically, we issued: (i) 364,213 ordinary shares to Yu-Hsin Lin, our Founder, Chief Executive Officer and Chairman of the Board of Directors; (ii) 254,950 ordinary shares to Hao-Yuan Chuang, our Chief Financial Officer; (iii) 21,684 ordinary shares to Hung-Wei Chen; (iv) 23,463 ordinary shares to Wan-Shan Chen; (v) 20,243 ordinary shares to Ming-Chiu Wu; and (vi) 21,853 ordinary shares to Yun-Ju Huang, in their exercise of options granted.

Preferred shares

On January 31, 2020, we closed a private placement transaction pursuant to which we sold an aggregate of 1,296,963 Series A Preferred Shares for an aggregate consideration of $2,789,600 in cash and conversion of two convertible promissory notes in the principal amount of $1,000,000 each.

On February 14, 2020, we issued a total of 1,080,679 Series A Preferred Shares in connection with the second closing of the private placement transaction described above for an aggregate consideration of $4,002,400 in cash.

On December 24, 2020, we closed a private placement transaction pursuant to which we sold an aggregate of 5,443,272 Series B Preferred Shares for an aggregate consideration of $23,000,000 in cash.

Convertible Promissory Note

On October 22, 2019, we issued a convertible promissory note with the principal amount of US$1,000,000 with simple interest of 2.5% per annum to each of H&D Asset Management Co., Ltd. and Yun-Ju Huang. Pursuant to the note purchase agreement, the entire convertible promissory notes may be converted, at the option of the note holder, in to the type of equity securities issued in the next equity financing. On January 31, 2020, in conjunction with the first closing of Series A financing, the principal amount and the accrued but unpaid interests (in the total amount of US$13,835.62) under both convertible promissory notes were converted into Series A Preferred Shares.

Options

We have granted options to purchase our ordinary shares to certain of our officers (whether or not a director) or our employees or any of our Affiliates, any member of the Board, or any director of one of our Affiliates, or any eligible individual consultant or advisor. See “Management — Share Incentive Plans”.

Securities/Purchaser	Date of Issuance	Number of Securities	Exercise Price
Options			
Certain directors, officers and employees	December 17, 2019	Option to purchase up to 1,335,794 ordinary shares	$0.1191
Certain directors, officers and employees	December 23, 2020	Option to purchase up to 2,807,381 ordinary shares	$0.4386[1]
Certain key consultants	March 1, 2021	Option to purchase up to 41,736 ordinary shares	$4.2254
Certain directors, officers and employees	April 18, 2022	Option to purchase up to 1,698,667 ordinary shares	$ 6.00[2]

(1) This exercise price applies to all options granted on December 23, 2020 except for an option to purchase 6,267 ordinary shares granted to an employee in the US which has an exercise price of $2.69 per share.

(2) The exercise price applies to all options granted on April 18, 2022, which is the final offer price of the offering.

Amended and Restated Shareholders Agreement

In connection with our issuance of Series B Preferred Shares, we entered into an amended and restated shareholders agreement with the holders of our preferred shares and Lin Bioscience International Ltd. in December 2020.

The amended and restated shareholders agreement provides for certain special rights, including right of first refusal, co-sale rights, preemptive rights, registration rights and contains provisions governing the board of directors and other corporate governance matters. Unless specifically noted, below those special rights attached to our preferred shares, and shares of Lin Bioscience International Ltd. as well as the corporate governance provisions, will automatically terminate upon the completion of this offering. Each series of our preferred shares will be automatically converted to ordinary shares on a one-for-one basis immediately prior to the completion of this offering. For additional details on the effect of the automatic conversion and the related conversion ratio, see "Dilution," "Capitalization" and "Principal Shareholders."

Pursuant to our amended and restated shareholders agreement, we have granted certain registration rights to our shareholders that are signatory thereto on the ordinary shares owned by those shareholders or their transferees. Set forth below is a description of the registration rights granted under the agreement, which shall continue to apply following this offering.

Demand Registration Rights. At any time after six months following the effectiveness of a registration statement for the initial public offering of our securities, the holders of at least 25% of the voting power of the registrable securities then issued and outstanding may request in writing that we file a registration statement covering the registration of at least 10% of the registrable securities then outstanding on any internationally recognized exchange that is reasonably acceptable to such requesting holders; provided that the aggregate proceeds from the offering that is the subject of the registration exceeds US$50,000,000. Upon such a request, we shall, promptly give written notice of such request to all holders, and use our commercially reasonable efforts to cause the registration of all registrable securities that the holders request to be registered and included in such registration by written notice given by such holders to us within 15 days after our delivery of written notice to be registered and/or qualified for sale and distribution in such jurisdiction as the initiating holders may request. This demand registration right is subject to a customary exclusion right of underwriters. We are obligated to consummate no more than three (3) registrations that have been declared and ordered effective pursuant to such request.

Registration on Form F-3. If Form F-3 is available for an offering by holders, the holders of at least 10% of the voting power of the registrable securities then issued and outstanding may request in writing that we effect a registration on Form F-3; provided that the aggregate proceeds from the offering that is the subject of the registration exceeds US$50,000,000. We shall promptly give written notice of the proposed registration and as soon as practicable, use our commercially reasonable efforts to cause all or such portion of such holder's or holders' registrable securities as are specified in such request, together with all or such portion of the registrable securities of any other holder or holders joining in such request as are specified in a written request by such other holder or holders given within 15 days after our delivery of written notice to be registered and qualified for sale and distribution in such jurisdiction. We are obligated to consummate no more than two (2) registrations that have been declared and ordered effective within any twelve (12)-month period preceding the date of such request.

We have the right to defer filing of a registration statement on Form F-3 or a demand registration under certain circumstances. For example, we shall not be obligated to register or qualify registrable securities if in any jurisdiction in which we would be required to execute a general consent to service of process in effecting such registration or qualification, unless we are already subject to service of process in such jurisdiction. If in the good faith judgment of the Board, it would be materially detrimental to us or our members for a registration statement to be filed in the near future, then we shall have the right to defer such filing for a period during which such filing would be materially detrimental, provided, that we may not utilize this right for more than ninety (90) days on any one occasion or more than once during any twelve (12) month period; provided, further, that we may not register any other its securities during such period.

Piggyback Registration Rights. If we propose to register for a public offering of our securities (other than registration statements relating to any employee benefit plan or a corporate reorganization or certain

other exempted situations), we shall promptly give written notice of such registration to all holders of registrable securities and afford each such holder an opportunity to include in such registration all or any part of the registerable securities then held by such holder. If a holder decides not to include all of its registrable securities in any registration statement thereafter filed by us, such holder shall nevertheless continue to have the right to include any registrable securities in any applicable subsequent registration statement or registration statements as may be filed by us, subject to certain limitations. This piggyback registration right is subject to a customary exclusion right of underwriters.

Expenses of Registration. Subject to certain exceptions, we will bear all registration expenses. Each holder, however, shall bear its proportionate share of all of the underwriting discounts and selling commissions applicable to the sale of registrable securities or other amounts payable to underwriter(s) or brokers in connection with such offering by the holders.

Termination of Obligations. Our obligations to effect any demand, Form F-3 or piggyback registration shall terminate upon the earlier of (i) the date that is 5 years from the date of closing of a firm commitment underwritten public offering of our Ordinary Shares (or depositary receipts or depositary shares therefor) in the United States pursuant to an effective registration statement under the United States Securities Act of 1933, as amended, with an offering price (net of underwriting commissions and expenses) that implies a market capitalization of our Company immediately prior to such offering of not less than US$120,000,000 and that results in gross proceeds to our Company of at least US$30,000,000, or in a public offering of our Ordinary Shares (or depositary receipts or depositary shares therefor) in another jurisdiction which results in the Ordinary Shares trading publicly on a recognized international securities exchange approved by the holders of at least a majority of the voting power of the issued and outstanding Series A Preferred Shares and Series B Preferred Shares (voting together as a single class and on an as converted basis), so long as such offering satisfies the foregoing market capitalization and gross proceeds requirements, and (ii) with respect to any holder, the date on which such holder may sell all of such holder’s registrable securities under Rule 144 of the Securities Act in any ninety (90)-day period.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

Deutsche Bank Trust Company Americas, as depositary, will register and deliver the ADSs. Each ADS will represent ownership of 1 share, deposited with Deutsche Bank AG, Hong Kong Branch, as custodian for the depositary. Each ADS will also represent ownership of any other securities, cash or other property which may be held by the depositary. The depositary's corporate trust office at which the ADSs will be administered is located at 1 Columbus Circle, New York, NY 10019, USA. The principal executive office of the depositary is located at 1 Columbus Circle, New York, NY 10019, USA.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, or DTC, pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depositary to the ADS holders entitled thereto.

We will not treat ADS holders as our shareholders and accordingly, you, as an ADS holder, will not have shareholder rights. Cayman Islands law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your ADSs. As a holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and you, as an ADS holder, and the beneficial owners of ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. The laws of the State of New York govern the deposit agreement and the ADSs. See "— *Jurisdiction and Arbitration*."

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American Depositary Receipt. For directions on how to obtain copies of those documents, see "*Where You Can Find Additional Information*."

Holding the ADSs

How will you hold your ADSs?

You may hold ADSs either (1) directly (a) by having an American Depositary Receipt, or ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (b) by holding ADSs in DRS, or (2) indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADS holder. This description assumes you hold your ADSs directly. ADSs will be issued through DRS, unless you specifically request certificated ADRs. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent as of the record date (which will be as close as practicable to the record date for our ordinary shares) set by the depositary with respect to the ADSs.

- ***Cash.*** The depositary will convert or cause to be converted any cash dividend or other cash distribution we pay on the ordinary shares or any net proceeds from the sale of any ordinary shares, rights, securities or other entitlements under the terms of the deposit agreement into U.S. dollars if it can do so on a practicable basis, and can transfer the U.S. dollars to the United States and will distribute promptly the amount thus received. If the depositary shall determine in its judgment that such conversions or transfers are not practical or lawful or if any government approval or license is needed and cannot be obtained at a reasonable cost within a reasonable period or otherwise sought, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders

to whom it is possible to do so. It will hold or cause the custodian to hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid and such funds will be held for the respective accounts of the ADS holders. It will not invest the foreign currency and it will not be liable for any interest for the respective accounts of the ADS holders.

- Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary, that must be paid, will be deducted. See "*Taxation*." It will distribute only whole U.S. dollars and cents and will round down fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.*

- ***Shares.*** For any ordinary shares we distribute as a dividend or free distribution, either (1) the depositary will distribute additional ADSs representing such ordinary shares or (2) existing ADSs as of the applicable record date will represent rights and interests in the additional ordinary shares distributed, to the extent reasonably practicable and permissible under law, in either case, net of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary will only distribute whole ADSs. It will try to sell ordinary shares which would require it to deliver a fractional ADS and distribute the net proceeds in the same way as it does with cash. The depositary may sell a portion of the distributed ordinary shares sufficient to pay its fees and expenses, and any taxes and governmental charges, in connection with that distribution.

- ***Elective Distributions in Cash or Shares.*** If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, the depositary, after consultation with us and having received timely notice as described in the deposit agreement of such elective distribution by us, has discretion to determine to what extent such elective distribution will be made available to you as a holder of the ADSs. We must timely first instruct the depositary to make such elective distribution available to you and furnish it with satisfactory evidence that it is legal to do so. The depositary could decide it is not legal or reasonably practicable to make such elective distribution available to you. In such case, the depositary shall, on the basis of the same determination as is made in respect of the ordinary shares for which no election is made, distribute either cash in the same way as it does in a cash distribution, or additional ADSs representing ordinary shares in the same way as it does in a share distribution. The depositary is not obligated to make available to you a method to receive the elective dividend in shares rather than in ADSs. There can be no assurance that you will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

- ***Rights to Purchase Additional Shares.*** If we offer holders of our ordinary shares any rights to subscribe for additional shares, the depositary shall having received timely notice as described in the deposit agreement of such distribution by us, consult with us, and we must determine whether it is lawful and reasonably practicable to make these rights available to you. We must first instruct the depositary to make such rights available to you and furnish the depositary with satisfactory evidence that it is legal to do so. If the depositary decides it is not legal or reasonably practicable to make the rights available but that it is lawful and reasonably practicable to sell the rights, the depositary will endeavor to sell the rights and in a riskless principal capacity or otherwise, at such place and upon such terms (including public or private sale) as it may deem proper distribute the net proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them.

  If the depositary makes rights available to you, it will establish procedures to distribute such rights and enable you to exercise the rights upon your payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The Depositary shall not be obliged to make available to you a method to exercise such rights to subscribe for ordinary shares (rather than ADSs).

  U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

There can be no assurance that you will be given the opportunity to exercise rights on the same terms and conditions as the holders of ordinary shares or be able to exercise such rights.

- ***Other Distributions.*** Subject to receipt of timely notice, as described in the deposit agreement, from us with the request to make any such distribution available to you, and provided the depositary has determined such distribution is lawful and reasonably practicable and feasible and in accordance with the terms of the deposit agreement, the depositary will distribute to you anything else we distribute on deposited securities by any means it may deem practicable, upon your payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. If any of the conditions above are not met, the depositary will endeavor to sell, or cause to be sold, what we distributed and distribute the net proceeds in the same way as it does with cash; or, if it is unable to sell such property, the depositary may dispose of such property in any way it deems reasonably practicable under the circumstances for nominal or no consideration, such that you may have no rights to or arising from such property.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if we and/or the depositary determines that it is illegal or not practicable for us or the depositary to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons entitled thereto.

Except for ordinary shares deposited by us in connection with this offering, no shares will be accepted for deposit during a period of 180 days after the date of this prospectus. The 180 day lock up period is subject to adjustment under certain circumstances as described in the section entitled "*Shares Eligible for Future Sales — Lock-up Agreements*."

How do ADS holders cancel an American Depositary Share?

You may turn in your ADSs at the depositary's corporate trust office or by providing appropriate instructions to your broker. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to you or a person you designate at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, to the extent permitted by law.

How do ADS holders interchange between Certificated ADSs and Uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send you a statement confirming that you are the owner of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to you an ADR evidencing those ADSs.

Voting Rights

How do you vote?

You may instruct the depositary to vote the ordinary shares or other deposited securities underlying your ADSs at any meeting at which you are entitled to vote pursuant to any applicable law, the provisions of

our memorandum and articles of association, and the provisions of or governing the deposited securities. *Otherwise, you could exercise your right to vote directly if you withdraw the ordinary shares. However, you may not know about the meeting sufficiently enough in advance to withdraw the ordinary shares.*

If we ask for your instructions and upon timely notice from us by regular, ordinary mail delivery, or by electronic transmission, as described in the deposit agreement, the depositary will notify you of the upcoming meeting at which you are entitled to vote pursuant to any applicable law, the provisions of our memorandum and articles of association, and the provisions of or governing the deposited securities, and arrange to deliver our voting materials to you. The materials will include or reproduce (a) such notice of meeting or solicitation of consents or proxies; (b) a statement that the ADS holders at the close of business on the ADS record date will be entitled, subject to any applicable law, the provisions of our memorandum and articles of association, and the provisions of or governing the deposited securities, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the ordinary shares or other deposited securities represented by such holder's ADSs; and (c) a brief statement as to the manner in which such instructions may be given to the depositary or deemed given in accordance with the second to last sentence of this paragraph if no instruction is received by the depositary to give a discretionary proxy to a person designated by us. Voting instructions may be given only in respect of a number of ADSs representing an integral number of ordinary shares or other deposited securities. For instructions to be valid, the depositary must receive them in writing on or before the date specified. The depositary will try, as far as practical, subject to applicable law and the provisions of our memorandum and articles of association, to vote or to have its agents vote the ordinary shares or other deposited securities (in person or by proxy) as you instruct. The depositary will only vote or attempt to vote as you instruct. If we timely requested the depositary to solicit your instructions but no instructions are received by the depositary from an owner with respect to any of the deposited securities represented by the ADSs of that owner on or before the date established by the depositary for such purpose, the depositary shall deem that owner to have instructed the depositary to give a discretionary proxy to a person designated by us with respect to such deposited securities, and the depositary shall give a discretionary proxy to a person designated by us to vote such deposited securities. However, no such instruction shall be deemed given and no such discretionary proxy shall be given with respect to any matter if we inform the depositary we do not wish such proxy given, substantial opposition exists or the matter materially and adversely affects the rights of holders of the ordinary shares.

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. In addition, there can be no assurance that ADS holders and beneficial owners generally, or any holder or beneficial owner in particular, will be given the opportunity to vote or cause the custodian to vote on the same terms and conditions as the holders of our ordinary shares.

The depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and you may have no recourse if the ordinary shares underlying your ADSs are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we will give the depositary notice of any such meeting and details concerning the matters to be voted at least 30 business days in advance of the meeting date.

Compliance with Regulations

Information Requests

Each ADS holder and beneficial owner shall (a) provide such information as we or the depositary may request pursuant to law, including, without limitation, relevant Cayman Islands law, any applicable law of the United States of America, our memorandum and articles of association, any resolutions of our Board of Directors adopted pursuant to such memorandum and articles of association, the requirements of any markets or exchanges upon which the ordinary shares, ADSs or ADRs are listed or traded, or to any requirements of any electronic book-entry system by which the ADSs or ADRs may be transferred, regarding the capacity in which they own or owned ADRs, the identity of any other persons then or previously interested in such ADRs and the nature of such interest, and any other applicable matters, and (b) be bound

by and subject to applicable provisions of the laws of the Cayman Islands, our memorandum and articles of association, and the requirements of any markets or exchanges upon which the ADSs, ADRs or ordinary shares are listed or traded, or pursuant to any requirements of any electronic book-entry system by which the ADSs, ADRs or ordinary shares may be transferred, to the same extent as if such ADS holder or beneficial owner held ordinary shares directly, in each case irrespective of whether or not they are ADS holders or beneficial owners at the time such request is made.

Disclosure of Interests

Each ADS holder and beneficial owner shall comply with our requests pursuant to Cayman Islands law, the rules and requirements of the Nasdaq Stock Market and any other stock exchange on which the ordinary shares are, or will be, registered, traded or listed or our memorandum and articles of association, which requests are made to provide information, inter alia, as to the capacity in which such ADS holder or beneficial owner owns ADS and regarding the identity of any other person interested in such ADS and the nature of such interest and various other matters, whether or not they are ADS holders or beneficial owners at the time of such requests.

Fees and Expenses

As an ADS holder, you will be required to pay the following service fees to the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs):

Service	Fees
• To any person to which ADSs are issued or to any person to which a distribution is made in respect of ADS distributions pursuant to stock dividends or other free distributions of stock, bonus distributions, stock splits or other distributions (except where converted to cash)	Up to US$0.05 per ADS issued
• Cancellation of ADSs, including the case of termination of the deposit agreement	Up to US$0.05 per ADS cancelled
• Distribution of cash dividends	Up to US$0.05 per ADS held
• Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements	Up to US$0.05 per ADS held
• Distribution of ADSs pursuant to exercise of rights.	Up to US$0.05 per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs	Up to US$0.05 per ADS held
• Depositary services	Up to US$0.05 per ADS held on the applicable record date(s) established by the depositary bank

As an ADS holder, you will also be responsible for paying certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs) such as:

- Fees for the transfer and registration of ordinary shares charged by the registrar and transfer agent for the ordinary shares in the Cayman Islands (i.e., upon deposit and withdrawal of ordinary shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.
- Taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when ordinary shares are deposited or withdrawn from deposit).

- Fees and expenses incurred in connection with the delivery or servicing of ordinary shares on deposit.
- Fees and expenses incurred in connection with complying with exchange control regulations and other regulatory requirements applicable to ordinary shares, deposited securities, ADSs and ADRs.
- Any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (i.e., share dividends, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary 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 fees from any distribution to be made to the ADS holder.

The depositary may make payments to us or reimburse us for certain costs and expenses, by making available a portion of the ADS fees collected in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable, or which become payable, on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register or transfer your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any net proceeds, or send to you any property, remaining after it has paid the taxes. You agree to indemnify us, the depositary, the custodian and each of our and their respective agents, directors, employees and affiliates for, and hold each of them harmless from, any claims with respect to taxes (including applicable interest and penalties thereon) arising from any refund of taxes, reduced rate of withholding at source or other tax benefit obtained for you. Your obligations under this paragraph shall survive any transfer of ADRs, any surrender of ADRs and withdrawal of deposited securities or the termination of the deposit agreement.

Reclassifications, Recapitalizations and Mergers

If we:	Then:
Change the nominal or par value of our ordinary shares	The cash, shares or other securities received by the depositary will become deposited securities.
Reclassify, split up or consolidate any of the deposited securities	Each ADS will automatically represent its equal share of the new deposited securities.
Distribute securities on the ordinary shares that are not distributed to you, or Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action	The depositary may distribute some or all of the cash, shares or other securities it received. It may also deliver new ADSs or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the form of ADR without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, including expenses incurred in connection with foreign exchange control regulations and other charges specifically payable by ADS holders under the deposit agreement, or materially prejudices a substantial existing right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended*. If any new laws are adopted which would require the deposit agreement to be amended in order to comply therewith, we and the depositary may amend the deposit agreement in accordance with such laws and such amendment may become effective before notice thereof is given to ADS holders.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement if we ask it to do so, in which case the depositary will give notice to you at least 90 days prior to termination. The depositary may also terminate the deposit agreement if the depositary has told us that it would like to resign, or if we have removed the depositary, and in either case we have not appointed a new depositary within 90 days. In either such case, the depositary must notify you at least 30 days before termination.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property and deliver ordinary shares and other deposited securities upon cancellation of ADSs after payment of any fees, charges, taxes or other governmental charges. Six months or more after the date of termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. After such sale, the depositary's only obligations will be to account for the money and other cash. After termination, we shall be discharged from all obligations under the deposit agreement except for our obligations to the depositary thereunder.

Books of Depositary

The depositary 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 Company, the ADRs and the deposit agreement.

The depositary will maintain facilities in the Borough of Manhattan, The City of New York to record and process the issuance, cancellation, combination, split-up and transfer of ADRs.

These facilities may be closed at any time or from time to time when such action is deemed necessary or advisable by the depositary in connection with the performance of its duties under the deposit agreement or at our reasonable written request.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary and the Custodian; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary and the custodian. It also limits our liability and the liability of the depositary. The depositary and the custodian:

- are only obligated to take the actions specifically set forth in the deposit agreement without gross negligence or willful misconduct;
- are not liable if any of us or our respective controlling persons or agents are prevented or forbidden from, or subjected 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 and any ADR, by reason of any provision of any present or future law or regulation of the United States or any state thereof, the Cayman Islands or any other country, or of any other governmental authority or regulatory authority or stock exchange, or on account of the possible criminal or civil penalties or restraint, or by reason of any provision, present or future, of our memorandum and articles of association or any provision of or governing any deposited securities, or by reason of any act of God or war or other circumstances beyond its control (including, without limitation, nationalization, expropriation, currency restrictions, work stoppage, strikes, civil unrest, revolutions, rebellions, explosions and computer failure);
- are not liable by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our memorandum and articles of association or provisions of or governing deposited securities;
- are not liable for any action or inaction of the depositary, the custodian or us or their or our respective controlling persons or agents in reliance upon the advice of or information from legal counsel, any person presenting ordinary shares for deposit or any other person believed by it in good faith to be competent to give such advice or information;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement;
- are not liable for any special, consequential, indirect or punitive damages for any breach of the terms of the deposit agreement, or otherwise;
- may rely upon any documents we believe in good faith to be genuine and to have been signed or presented by the proper party;
- disclaim any liability for any action or inaction or inaction of any of us or our respective controlling persons or agents in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, holders and beneficial owners (or authorized representatives) of ADSs, or any person believed in good faith to be competent to give such advice or information; and
- disclaim any liability for inability of any holder to benefit from any distribution, offering, right or other benefit made available to holders of deposited securities but not made available to holders of ADS.

The depositary and any of its agents also disclaim any liability (i) for any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the deposit agreement, (ii) the failure or timeliness of any notice from us, the content of any information submitted to it by us for distribution to you or for any inaccuracy of any translation thereof, (iii) any investment risk associated with the acquisition of an interest in the deposited

securities, the validity or worth of the deposited securities, the credit-worthiness of any third party, (iv) for any tax consequences that may result from ownership of ADSs, ordinary shares or deposited securities, or (v) for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without gross negligence or willful misconduct while it acted as depositary.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Jurisdiction and Arbitration

The laws of the State of New York govern the deposit agreement and the ADSs and we have agreed with the depositary that the federal or state courts in the City of New York shall have exclusive jurisdiction to hear and determine any dispute arising from or in connection with the deposit agreement and that the depositary will have the right to refer any claim or dispute arising from the relationship created by the deposit agreement to arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The arbitration provisions of the deposit agreement do not preclude you from pursuing claims under the Securities Act or the Exchange Act in federal or state courts.

Jury Trial Waiver

The deposit agreement provides that each party to the deposit agreement (including each holder, beneficial owner and holder of interests in the ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any lawsuit or proceeding 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 law.

Requirements for Depositary Actions

Before the depositary will issue, deliver or register a transfer of an ADS, split-up, subdivide or combine ADSs, make a distribution on an ADS, or permit withdrawal of ordinary shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities and payment of the applicable fees, expenses and charges of the depositary;
- satisfactory proof of the identity and genuineness of any signature or any other matters contemplated in the deposit agreement; and
- compliance with (A) any laws or governmental regulations relating to the execution and delivery of ADRs or ADSs or to the withdrawal or delivery of deposited securities and (B) such reasonable regulations and procedures as the depositary may establish, from time to time, consistent with the deposit agreement and applicable laws, including presentation of transfer documents.

The depositary may refuse to issue and deliver ADSs or register transfers of ADSs generally when the register of the depositary or our transfer books are closed or at any time if the depositary or we determine that it is necessary or advisable to do so.

Your Right to Receive the Shares Underlying Your ADSs

You have the right to cancel your ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depositary has closed its transfer books or we have closed our transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting; or (3) we are paying a dividend on our ordinary shares;

- when you owe money to pay fees, taxes and similar charges;
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities, or other circumstances specifically contemplated by Section I.A.(l) of the General Instructions to Form F-6 (as such General Instructions may be amended from time to time); or
- for any other reason if the depositary or we determine, in good faith, that it is necessary or advisable to prohibit withdrawals.

The depositary shall not knowingly accept for deposit under the deposit agreement any ordinary shares or other deposited securities required to be registered under the provisions of the Securities Act, unless a registration statement is in effect as to such ordinary shares.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be evidenced by periodic statements issued by the depositary to the ADS holders entitled thereto. Profile is a required feature of DRS which allows a DTC participant, claiming to act on behalf of an ADS holder, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register such transfer.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have 6,000,000 ADSs outstanding, representing approximately 24.9% of our outstanding ordinary shares. All of the ADSs sold in this offering will be freely transferable by persons, other than by our "affiliates", without restriction or further registration under the Securities Act. Sales of substantial amounts of our ADSs in the public market could adversely affect prevailing market prices of our ADSs. Prior to this offering, there has been no public market for our ordinary shares or the ADSs. We have applied to list the ADSs on the Nasdaq Capital Market, but we cannot assure you that a regular trading market will develop in the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

Lock-up Agreements

We have agreed, for a period of 180 days after the date of this prospectus, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, lend or otherwise dispose of, except in this offering, any of our ordinary shares or ADSs or securities that are substantially similar to our ordinary shares or ADSs, including but not limited to any options or warrants to purchase our ordinary shares, ADSs or any securities that are convertible into or exchangeable for, or that represent the right to receive, our ordinary shares, ADSs or any such substantially similar securities (other than pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date such lock-up agreement was executed), or to file or cause to be filed any registration statement relating to the offering of any of our share capital, without the prior written consent of the representative of the underwriters.

Furthermore, each of our directors, executive officers and shareholders beneficially holding greater than 5% of our ordinary shares has also entered into a similar lock-up agreement for a period of 180 days from the date of this prospectus, subject to certain exceptions, with respect to our ordinary shares, ADSs and securities that are substantially similar to our ordinary shares or ADSs.

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 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 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 (together with any sales aggregated with them) 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 240,953 ordinary shares; or
- the average weekly trading volume of our ordinary shares of the same class, in the form of 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, each of our employees, consultants or advisors who purchases 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.

Registration Rights

Upon completion of this offering, certain holders of our ordinary shares or their transferees will have rights to require that we register their ordinary shares for resale under the Securities Act at any time following the six month anniversary of the completion of this offering.

TAXATION

The following summary of Cayman Islands and U.S. federal income tax considerations of an investment in the ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this registration statement, all of which are subject to change. This summary does not deal with all possible tax considerations relating to an investment in the ADSs or ordinary shares, such as the tax considerations under U.S. state and local tax laws or under the tax laws of jurisdictions other than the Cayman Islands and the United States. To the extent that the discussion relates to matters of Cayman Islands tax law, it represents the opinion of Maples and Calder (Hong Kong) LLP, our Cayman Islands legal counsel.

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 levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or 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.

Payments of dividends and capital in respect of our ordinary shares and ADSs will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of dividends or capital to any holder of our ordinary shares or ADSs, nor will gains derived from the disposal of our ordinary shares or ADSs be subject to Cayman Islands income or corporation tax.

United States Federal Income Tax Considerations

The following discussion is a general discussion of certain U.S. federal income tax considerations relating to the ownership and disposition of our ADSs or ordinary shares by U.S. Holders (as defined below) that acquire our ADSs in this offering and holds our ADSs as “capital assets” (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended (the “Code”). This discussion does not address any aspect of U.S. federal gift or estate tax, alternative minimum tax, the Medicare tax on net investment income, or the state, local or non-U.S. tax consequences of an investment in our ADSs or ordinary shares. This discussion is based on the Code, its legislative history, existing and proposed regulations promulgated thereunder, published rulings and court decisions, all as of the date of this prospectus. These laws are subject to change, possibly on a retroactive basis. No ruling has been obtained and no ruling will be requested from the U.S. Internal Revenue Service (the “IRS”), with respect to any of the U.S. federal income tax consequences described below, and as a result, there can be no assurance that the IRS will not disagree with or challenge any of the statements provided below.

This discussion is not a complete description of all tax considerations that may be relevant to particular investors in light of their individual circumstances or investors subject to special tax rules, such as:

- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of tax accounting for securities holdings;
- banks or certain financial institutions;
- insurance companies;
- tax-exempt organizations;
- partnerships or other entities treated as partnerships or other pass-through entities for U.S. federal income tax purposes or persons holding our ADSs or ordinary shares through any such entities;
- regulated investment companies or real estate investment trusts;
- persons that hold our ADSs or ordinary shares as part of a hedge, straddle, constructive sale, conversion transaction or other integrated investment;

- persons whose functional currency for tax purposes is not the U.S. dollar;
- U.S. expatriates; or
- persons that actually or constructively own 10% or more of (i) the total combined voting power of all classes of our voting stock or (ii) the total value of all classes of our stock (including our ADSs or ordinary shares).

Each prospective investor is urged to consult its tax advisor regarding the application of U.S. federal taxation to its particular circumstances, and the state, local, non-U.S. and other tax considerations of the ownership and disposition of our ADSs or ordinary shares.

General

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ADSs or ordinary shares that is:

- an individual citizen or resident of the United States for U.S. federal income tax purposes;
- a corporation, or other entity classified as a corporation for U.S. federal income tax purposes, that was created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (ii) the trust has a valid election in effect to be treated as a U.S. person.

For U.S. federal income tax purposes, income earned through an entity or arrangement classified as a partnership for U.S. federal income tax purposes is attributed to its owners. Accordingly, if a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our ADSs or ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding our ADSs or ordinary shares and their partners are urged to consult their tax advisors regarding an investment in our ADSs or ordinary shares.

For U.S. federal income tax purposes, it is generally expected that a U.S. Holder of ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. The remainder of this discussion assumes that a U.S. Holder of our ADSs will be treated in this manner. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Dividends

The following discussion is subject to the discussion under "Passive Foreign Investment Company" below. If we make cash distributions and you are a U.S. Holder, the gross amount of any distributions with respect to your ADSs or ordinary shares (including the amount of any taxes withheld therefrom) will be includible in your gross income on the day you actually or constructively receive such income as dividend income if the distributions are made from our current or accumulated earnings and profits, calculated according to U.S. federal income tax principles. We do not intend to calculate our earnings and profits according to U.S. federal income tax principles. Accordingly, you should expect that distributions on our ADSs or ordinary shares, if any, will generally be treated as dividend income for U.S. federal income tax purposes. Dividends received on our ADSs or ordinary shares will not be eligible for the dividends received deduction generally allowed to U.S. corporations. Dividends received by individuals and certain other non-corporate U.S. Holders may be subject to tax at the lower capital gain tax rate applicable to "qualified dividend income," provided that certain conditions are satisfied, including that (1) our ADSs or ordinary shares on which the dividends are paid are readily tradeable on an established securities market in the United States, (2) we are neither a PFIC nor treated as such with respect to such a U.S. Holder for the taxable year in which the dividend was paid and the preceding taxable year, and (3) certain holding period requirements are met. We expect our ADSs (but not our ordinary shares), which we have applied to list on

the Nasdaq Capital Market will be considered readily tradeable on an established securities market in the United States, although there can be no assurance in this regard. U.S. Holders should consult their own tax advisors regarding the potential availability of the reduced dividend tax rate in respect of our ADSs and ordinary shares.

Dividends paid on our ADSs or ordinary shares, if any, will generally be treated as income from foreign sources and will generally constitute passive category income for U.S. foreign tax credit purposes. Depending on the U.S. Holder's individual facts and circumstances, a U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit in respect of any nonrefundable non-U.S. withholding taxes imposed on dividends received on our ADSs or ordinary shares. A U.S. Holder who does not elect to claim a foreign tax credit for foreign taxes withheld may instead claim a deduction, for U.S. federal income tax purposes, in respect of such withholding, but only for a year in which such holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex and their outcome depends in large part on the U.S. Holder's individual facts and circumstances. Accordingly, U.S. Holders are urged to consult their tax advisors regarding the availability of the foreign tax credit under their particular circumstances.

Sale or Other Disposition

The following discussion is subject to the discussion under "Passive Foreign Investment Company" below. A U.S. Holder will generally recognize capital gain or loss upon the sale or other disposition of our ADSs or ordinary shares in an amount equal to the difference between the amount realized upon the disposition and the holder's adjusted tax basis in such ADSs or ordinary shares. The holder's adjusted tax basis will generally equal the amount the holder paid (including the offering price for the ADS or ordinary shares and trading fee, transaction levy and brokerage fee paid in connection with such purchase). Any gain or loss the U.S. Holder recognizes will generally be long-term capital gain or loss if the ADSs or ordinary shares have been held for more than one year and will generally be U.S.-source gain or loss for U.S. foreign tax credit purposes. Long-term capital gain of individuals and certain other non-corporate U.S. Holders will generally be eligible for a more favorable rate of taxation. The deductibility of a capital loss may be subject to limitations.

U.S. Holders are urged to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of our ADSs or ordinary shares, including the availability of the foreign tax credit under their particular circumstances.

Passive Foreign Investment Company

If we were classified as a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, the U.S. Holder would generally be subject to adverse U.S. tax consequences, in the form of increased tax liabilities (unless certain elections described below are timely made) and special U.S. tax reporting requirements.

A non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (after taking into account the income and assets of subsidiaries in which it owns at least a 25% interest by value), (i) at least 75% of its gross income is "passive" income, such as interest and income from financial investments (the "income test") or (ii) at least 50% of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce or are held to produce passive income (the "asset test"). For purposes of making a PFIC determination, the non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the gross income of any other corporation of which it is, directly or indirectly, a 25% or greater shareholder (by value). For purposes of the asset test, any cash and cash invested in short-term, interest bearing, debt instruments, or bank deposits that are readily convertible into cash will generally count as producing passive income or held for the production of passive income, and goodwill should be treated as an active asset to the extent that it is associated with activities that produce or are intended to produce active income.

Based on current estimate of our gross income and of the value of our gross assets (including goodwill) and the manner in which we conduct our business, we do not expect to be a PFIC for U.S. federal income tax purposes for the 2022 taxable year. Despite our expectation, there can be no assurance that we will not be

a PFIC for 2022 or any future taxable year as PFIC status is tested for each taxable year and will depend on the composition of our assets and income in such taxable year. We could be a PFIC for any taxable year if our market capitalization were to decrease significantly while we hold substantial cash and cash equivalents, or if the gross income that we and our subsidiaries earn from investing the portion of the cash raised in the offering is substantial in comparison with the gross income from our business operation. Furthermore, the application of the PFIC rules is subject to uncertainty in several respects, and there can be no assurance that the IRS will not challenge our application of the PFIC rules. *Our counsel expresses no opinion with respect to our expectations contained in this paragraph.*

If we were a PFIC for any taxable year during which you held our ADSs or ordinary shares, certain adverse U.S. federal income tax rules would apply. You would generally be subject to additional taxes and interest charges on certain "excess distributions" we make on any gain realized on the disposition or deemed disposition of your ADSs or ordinary shares, regardless of whether we continue to be a PFIC in the year in which you receive an "excess distribution" or dispose of or are deemed to have disposed of, your our ADSs or ordinary shares. Distributions in respect of our ADSs or ordinary shares during a taxable year in which we are a PFIC would generally constitute "excess distributions" if, in the aggregate, they exceed 125% of the average amount of distributions with respect to your ADSs or ordinary shares over the three preceding taxable years or, if shorter, the portion of your holding period before such taxable year.

To compute the tax on "excess distributions" or any gain, (i) the "excess distribution" or the gain would be allocated ratably to each day in your holding period, (ii) the amount allocated to the current year and any tax year prior to the first taxable year in which we were a PFIC would be taxed as ordinary income in the current year, (iii) the amount allocated to other taxable years would be taxable at the highest applicable marginal rate in effect for that year, and (iv) an interest charge at the rate for underpayment of taxes for any period described under (iii) above would be imposed on the resulting tax liability on the portion of the "excess distribution" or gain that is allocated to such period. In addition, if we were a PFIC (or treated as a PFIC with respect to you) for any taxable year in which we make a distribution or the preceding taxable year, such distribution would not qualify for taxation at the more favorable tax rate if we are deemed to be a PRC resident enterprise under PRC tax law, as discussed in the "Dividends" section above.

Under certain attribution rules, if we were a PFIC for any taxable year in which you hold our ADSs or ordinary shares, you would be deemed to own your proportionate share of lower-tier PFICs, and would be subject to U.S. federal income tax under the PFIC rules described in the preceding paragraphs on (i) a distribution on the shares of a lower-tier PFIC and (ii) a disposition of shares of a lower-tier PFIC, both as if such U.S. Holder directly held the shares of such lower-tier PFIC.

You might be able to make a "mark-to-market" election with respect to our ADSs, but not our ordinary shares, in order to elect out of the tax treatment discussed above. If you make a valid mark-to-market election, you will include in gross income for each taxable year that we are treated as a PFIC an amount equal to the excess, if any, of the fair market value of your ADSs as of the close of such taxable year over your adjusted basis in such ADSs. You will be permitted a deduction for the excess, if any, of the adjusted basis of your ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on any sale or other disposition of the ADSs, will be treated as ordinary income. Ordinary loss treatment also will apply to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on a sale or disposition of the ADSs, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ADSs. Your basis in your ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations that are not PFICs generally will apply to distributions by us, except that the favorable rate discussed in the "Dividends" section above that may apply if we are deemed to be a PRC resident enterprise under PRC tax law will not apply to any distribution if we are a PFIC (or treated as a PFIC with respect to you) in the taxable year of the distribution or the preceding taxable year. If a U.S. Holder makes a mark-to-market election in respect of our ADSs and we cease to be classified as a PFIC, the holder will not be required to take into account the gain or loss described above during any period that we are not classified as a PFIC.

The mark-to-market election is available only for "marketable stock," which is stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. For those purposes, we expect that our ADSs will each be treated as marketable stock upon their listing on the Nasdaq Stock Market, and we expect the exchange will be a qualified exchange for these purposes. We anticipate that our ADSs should qualify as being regularly traded. U.S. Holders of ordinary shares may be able to make a mark-to-market election but it is not certain, but no assurances may be given in this regard and such holders are advised to consult their own tax advisor regarding their eligibility to make such election. Because a mark-to-market election cannot technically be made for equity interests in lower-tier PFICs that we own, if we are a PFIC for any taxable year, a U.S. Holder generally will continue to be subject to the general PFIC rules with respect to the holder's indirect interest in any investments held by us that are treated as equity interest in a PFIC for U.S. federal income tax purposes. You should consult your tax advisor as to the availability and desirability of a mark-to-market election if we were a PFIC, as well as the impact of such election on interests in any lower-tier PFICs. The PFIC rules provide for a separate election, referred to as a qualified electing fund election, which, if available, results in a tax treatment different from (and generally less adverse than) the general PFIC tax treatment described above. That election, however, will not be available to you as we do not intend to provide the information you would need to make or maintain that election.

If you own our ADSs or ordinary shares during any taxable year that we are a PFIC, you will generally be required to file an annual report containing such information as the United States Treasury Department may require. You should consult your own tax advisor regarding the application of the PFIC rules to your investment in our ADSs or ordinary shares and the elections discussed above.

U.S. Information Reporting and Backup Withholding Rules

Dividend payments with respect to our ADSs or ordinary shares and the proceeds received on the sale or other disposition of our ADSs or ordinary shares may be subject to information reporting to the IRS and to backup withholding, unless you are an exempt recipient. Backup withholding will not apply, however, if you provide a taxpayer identification number, certifying that you are not subject to backup withholding or are otherwise exempt from backup withholding. Any amounts withheld under the backup withholding rules from a payment to you will be refunded or credited against your U.S. federal income tax liability, provided that the required information is timely provided to the IRS. Certain U.S. Holders who hold "specific foreign financial assets," including stock of a non-U.S. corporation that is not held in an account maintained by a U.S. "financial institution" may be required to attach to their tax returns for the year certain specified information. A U.S. Holder who fails to timely furnish the required information may be subject to a penalty. You are advised to consult with your own tax advisor regarding the application of the U.S. information reporting and backup withholding rules to your particular circumstances.

PROSPECTIVE INVESTORS IN OUR ADSS OR ORDINARY SHARES SHOULD CONSULT WITH THEIR OWN TAX ADVISOR REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES RESULTING FROM OWNING OR DISPOSING OUR ADSS OR ORDINARY SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF THE TAX LAWS OF ANY STATE, LOCAL OR NON-US JURISDICTION AND INCLUDING ESTATE, GIFT AND INHERITANCE LAWS.

UNDERWRITING

The Benchmark Company is acting as the representative of the underwriters and the book-running manager of the offering of the ADSs described in this prospectus. We have entered into an underwriting agreement with the representative of the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

Name	Number of ADSs
The Benchmark Company, LLC	6,000,000
Total	6,000,000

The underwriters are committed to purchase all the ADSs offered by us other than those covered by the option to purchase additional ADSs described below, if they purchase any ADSs. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

The underwriters are offering the ADSs, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at such price less a concession not in excess of US$0.24 per ADS. After the initial offering of the ADSs to the public, if all of the ADSs are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms.

Some of the underwriters are expected to make offers and sales both inside and outside the United States through their respective selling agents. All sales of ADSs in the United States will be made by broker-dealers registered with the SEC. Sales of any ADSs made outside of the United States may be made by affiliates of the underwriters.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect thereof.

Option to purchase additional ADSs

We have granted to the underwriters an option to purchase up to 900,000 additional ADSs from us at the public offering price per ADS, less underwriting discounts and commissions, for a period of 30 days from the date of this prospectus. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

Underwriting Discounts and Commissions

The following table shows the per ADS and total public offering price, underwriting discounts and commissions to be paid by us, and proceeds before expenses to us, assuming both no exercise and full exercise of the underwriters' option to purchase 900,000 additional ADSs.

		Total	
	Per ADS	No Exercise	Full exercise
Public offering price	US$6.00	US$36,000,000	US$41,400,000
Underwriting discounts and commissions[(1)]	US$0.45	US$ 2,700,000	US$ 3,105,000
Proceeds, before expenses, to us	US$5.55	US$33,300,000	US$38,295,000

(1) Underwriting discounts and commissions per ADS will be reduced to $0.225 on the 2,500,000 ADSs sold to Lin Bioscience International Ltd.

We have agreed to pay for the accountable out-of-pocket expenses of the underwriters, including road show expenses for the offering, prospectus tracking and compliance software for the offering, fees and disbursements of the underwriters' counsel up to an amount of $125,000, and the preparation of commemorative mememtos and lucite tombstones in connection with the offering, up to $150,000 in the aggregate, $25,000 of which has been paid prior to the date of this prospectus. We have also agreed to pay for background checks of our senior management up to an amount of $7,500. In the event that the offering is terminated, any advance expense deposits paid to the underwriters will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A). We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately US$2.1 million.

Representative's Warrants

Upon the closing of this offering, we have agreed to issue to the representative of the underwriters or its designees warrants to purchase a number of ADSs equal to 2.5% of the ADSs sold by us in this offering, including ADSs (if any) sold upon the exercise of the option to purchase additional ADSs (the "Representative's Warrants"). The Representative's Warrants will have an exercise price equal to $7.50 per ADS. The Representative's Warrants will be exercisable six months following issuance until the date that is five years after the date of commencement of sales in this offering in compliance with Financial Industry Regulatory Authority, or FINRA, Rule 5110. The Representative's Warrants are also exercisable on a cashless basis. The Representative's Warrants have been deemed compensation by FINRA and are subject to a 180-day lock-up pursuant to FINRA Rule 5110. Except as permitted by Rule 5110, the representative for the underwriters (or permitted assignees under Rule 5110) will not sell, transfer, assign, pledge, or hypothecate the Representative's Warrants or the securities underlying the Representative's Warrants, nor will any of them engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the option or the underlying securities for a period of 180 days from the commencement of sales under this prospectus. The exercise price and number of securities upon exercise of the Representative's Warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the Representative's Warrant exercise price or underlying ADSs will not be adjusted for issuances of ADSs at a price below the Representative's Warrant exercise price. The Representative's Warrants and the ordinary shares underlying the ADSs issuable upon exercise thereof are registered on the registration statement of which this prospectus forms a part.

Discretionary Accounts

The underwriters do not intend to confirm sales of the ADSs offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

We have agreed that, subject to certain exceptions, we will not, for a period of 180 days after the date of this prospectus, (i) offer, pledge, issue, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any of our ordinary shares or ADSs or securities convertible into or exercisable or exchangeable for any of our ordinary shares or ADSs, or publicly disclose the intention to undertake any of the foregoing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any ordinary shares, ADSs or any such other securities, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position in any ordinary shares, ADSs or any such other securities, or publicly disclose the intention to enter into any such agreement or transaction or (iii) file or cause to be filed any registration

statement relating to the offering of any of our share capital (regardless of whether any of the transactions described in (i) or (ii) above are to be settled by the delivery of ordinary shares, ADSs or such other securities, in cash or otherwise) or publicly disclose the intention to file any such registration statement, without the prior written consent of the representative of the underwriters.

Our directors, officers, and shareholders beneficially holding greater than 5% of our ordinary shares (collectively, the lock-up parties) have agreed that, without the prior written consent of the representative of the underwriters and subject to certain exceptions, they will not, for a period of 180 days after the date of this prospectus, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs, (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement would be settled by delivery of lock-up securities, in cash or otherwise.

The representative of the underwriters, in its sole discretion, may release the securities subject to any of the lock-up agreements described above, in whole or in part at any time.

We have further agreed to instruct Deutsche Bank Trust Company Americas, as depositary, not to accept any deposit of any ordinary shares or issue any ADSs for 180 days after the date of this prospectus (other than in connection with this offering), unless we instruct the depositary otherwise with the prior written consent of the representative of the underwriters. The foregoing does not affect the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares.

Right of First Refusal

We have granted the representative a right of first refusal, for a period of nine (9) months from the closing of this offering, to act as lead or joint-lead investment banker, lead or joint-lead book runner and/or lead or joint placement agent at the representative’s discretion, for each and every future public and private equity, equity-linked or debt offering, including all equity linked financings during such nine (9) month period, by us or our successor, or any subsidiary.

Electronic Offer, Sale and Distribution of ADSs

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representative of the underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

Listing

Our ADSs have been approved for listing on the Nasdaq Capital Market under the symbol “BLTE.”

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open

market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional ADSs referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising the option to purchase additional ADSs, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the option to purchase additional ADSs. 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 that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representative of the underwriters purchases ADSs in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those ADSs as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq, in the over-the-counter market or otherwise.

Pricing of the Offering

Prior to this offering, there has been no public market for our ADSs. The initial public offering price will be determined by negotiations between us and the representative of the underwriters. In determining the initial public offering price, we and the representative of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representative;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded securities of generally comparable companies; and
- other factors deemed relevant by the representative and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Other Relationships

Certain of the underwriters and their affiliates may provide from time to time certain commercial banking, financial advisory, investment banking and other services for us and our affiliates in the ordinary course of their business, for which they may receive customary fees and commissions. However, we have not yet had, and have no present arrangements with any of the underwriters for any further services.

Selling Restrictions

No action may be taken in any jurisdiction other than the United States that would permit a public offering of the ADSs or the possession, circulation or distribution of this prospectus in any jurisdiction

where action for that purpose is required. Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither the prospectus nor any other offering material or advertisements in connection with the ADSs may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any applicable laws, rules and regulations of any such country or 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.

Australia

This document:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or Exempt Investors.

The ADSs may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the ADSs may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any ADSs may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the ADSs, you represent and warrant to us that you are an Exempt Investor.

As any offer of ADSs under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the ADSs you undertake to us that you will not, for a period of 12 months from the date of issue of the ADSs, offer, transfer, assign or otherwise alienate those ADSs to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Canada

The ADSs may be sold 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 ADSs must be made in accordance with an exemption from, 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 for particulars 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.

Cayman Islands

This prospectus does not constitute an invitation or offer to the public in the Cayman Islands of the ADSs, whether by way of sale or subscription. The underwriters have not offered or sold, and will not offer or sell, directly or indirectly, any ADSs in the Cayman Islands.

Dubai International Finance Center, or DIFC

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

European Economic Area

In relation to each Member State of the European Economic Area and the United Kingdom, or each a Relevant State, no ADSs have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs 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 ADSs 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 underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any ADSs being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the representative of the underwriters has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to ADSs 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 ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Hong Kong

The ADSs have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus may be distributed only to, and is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds; provident funds; insurance companies; banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, each purchasing for their own account; venture capital funds; entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors. Qualified investors shall be required to submit written confirmation that they fall within the scope of the Addendum.

Japan

The ADSs have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the ADSs nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Kingdom of Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Korea

The ADSs have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the ADSs have been and will be offered in Korea as a private placement under the FSCMA. None of the ADSs may be

offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The ADSs have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the ADSs shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the ADSs. By the purchase of the ADSs, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the ADSs pursuant to the applicable laws and regulations of Korea.

Kuwait

Unless all necessary approvals from the Kuwait Capital Markets Authority pursuant to Law No. 7 of 2010 Concerning the Establishment of the Capital Markets Authority and Regulating of Securities Activities and the implementing regulations thereto (as amended), and the various resolutions, regulations, instructions and announcements issued from time to time pursuant thereto, or in connection therewith, have been given in relation to the marketing of, and sale of, the ADSs, the ADSs may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the ADSs has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the ADSs, as principal, if the offer is on terms that the ADSs may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the ADSs is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Mexico

None of the ADSs or the ordinary shares have been or will be registered with the National Securities Registry (Registro Nacional de Valores) maintained by the Mexican National Banking and Securities Commission (Comision Nacional Bancaria y de Valores), or CNBV, of Mexico and, as a result, may not be offered or sold publicly in Mexico. The ADSs and the ordinary shares may only be sold to Mexican institutional and qualified investors, pursuant to the private placement exemption set forth in the Mexican Securities Market Law (Ley del Mercado de Valores). As required under the Mexican Securities Market Law,

the company will give notice to the CNBV of the offering of the securities under the terms set forth herein. Such notice will be submitted to the CNBV to comply with the Mexican Securities Market Law, and for informational purposes only. The delivery to, and receipt by, the CNBV of such notice does not certify the solvency of the company, the investment quality of the securities, or that the information contained in this prospectus or in any prospectus supplement. The company has prepared this prospectus and is solely responsible for its content, and the CNBV has not reviewed or authorized such content.

People's Republic of China

This prospectus will not be circulated or distributed in the PRC and the ADSs will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the underwriters have not offered or sold any ADSs or caused the ADSs to be made the subject of an invitation for subscription or purchase and will not offer or sell any ADSs or cause the ADSs to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(b) 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

(c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) 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; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

State of Qatar

The ADSs described in this prospectus have not been, and will not be, offered, sold or delivered, at any time, directly or indirectly in the State of Qatar in a manner that would constitute a public offering. This prospectus has not been, and will not be, registered with or approved by the Qatar Financial Markets Authority or Qatar Central Bank and may not be publicly distributed. This prospectus is intended for the original recipient only and must not be provided to any other person. It is not for general circulation in the State of Qatar and may not be reproduced or used for any other purpose.

Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated 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 facility in Switzerland. 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, 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, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

Taiwan

The ADSs have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the ADSs in Taiwan.

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.

United Kingdom

The ADSs may not be made in the United Kingdom, except that an offer to the public of any ADSs may be made 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 representative for any such offer; or

(c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (as amended, the "FSMA").

provided that no such offer of ADSs shall result in the requirement for the publication by us of 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 any ADSs in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe for the ADSs, 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.

This prospectus is only being distributed to and is only directed at: (1) persons who are outside the United Kingdom; (2) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (3) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (ed) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The ADSs are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire the ADSs will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

EXPENSES RELATED TO THIS OFFERING

Set forth below is an itemization of the total expenses, excluding underwriting discounts and commissions, that we expect to incur in connection with this offering. With the exception of the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee, and the stock exchange market entry and listing fee, all amounts are estimates.

SEC Registration Fee	US$	4,000
FINRA Filing Fee		8,000
Stock Exchange Market Entry and Listing Fee		75,000
Printing and Engraving Expenses		126,000
Legal Fees and Expenses		1,697,000
Accounting Fees and Expenses		84,000
Miscellaneous		155,000
Total		**US$2,149,000**

LEGAL MATTERS

We are being represented by O'Melveny & Myers 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 Maples and Calder (Hong Kong) LLP. O'Melveny & Myers LLP may rely upon Maples and Calder (Hong Kong) LLP with respect to matters governed by Cayman Islands law and Commerce & Finance Law Offices with respect to matters governed by PRC law. The underwriters are being represented by Ellenoff Grossman & Schole LLP with respect to certain legal matters as to United States federal securities and New York State law.

EXPERTS

The consolidated financial statements of Belite Bio, Inc as of December 31, 2021 and 2020, and for each of the years in the two-year period ended December 31, 2021 have been included herein and in the registration statement in reliance upon the report of Friedman LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The office of Friedman LLP is located at One Liberty Plaza, 165 Broadway, 21st Floor, New York, NY 10006.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement, including relevant exhibits, with the SEC on Form F-1 under the Securities Act with respect to the underlying ordinary shares represented by the ADSs to be sold in this offering. We have also filed a related registration statement on Form F-6 with the SEC to register the ADSs. This prospectus, which constitutes a part of the registration statement on Form F-1, does not contain all of the information contained in the registration statement. You should read our registration statements and their exhibits and schedules for further information with respect to us and the ADSs.

Immediately upon the effectiveness of the registration statement on Form F-1 of which this prospectus forms a part, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC. All information filed with the SEC can be obtained over the internet at the SEC's website at *www.sec.gov*.

BELITE BIO, INC

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

FRIEDMAN LLP®

ACCOUNTANTS AND ADVISORS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Belite Bio, Inc

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Belite Bio, Inc (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, convertible preferred shares and shareholders' deficit, and cash flows for each of the years in the two year period ended December 31, 2021, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph — Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has an accumulated deficit, has incurred recurring losses from operations, has an expectation of continuing operating losses for the foreseeable future, and needs to raise capital to finance its future operation. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. These consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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/ Friedman LLP
Friedman LLP
We have served as the Company's auditor since 2021
New York, New York
March 15, 2022

BELITE BIO, INC

CONSOLIDATED BALANCE SHEETS
(in thousand US Dollars, except share and per share amounts)

	December 31	
	2020	**2021**
ASSETS		
Current Assets		
Cash	$ 25,618	$ 17,344
Prepayments and other current assets	50	87
Total current assets	25,668	17,431
Property and equipment, net	46	94
Prepayment for property and equipment	20	—
Deferred offering costs	—	815
Security deposits	7	8
TOTAL ASSETS	$ 25,741	$ 18,348
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIT		
Current liabilities		
Other payable due to related parties	$ 26	$ 71
Accrued expenses and other liabilities	946	1,564
Total current liabilities	972	1,635
TOTAL LIABILITIES	972	1,635
Commitments and contingencies		
Convertible preferred shares		
Series A convertible preferred shares, US$0.0001 par value, 2,377,642 shares authorized, issued and outstanding as of December 31, 2020 and 2021	8,806	8,806
Series B convertible preferred shares, US$0.0001 par value, 5,443,272 shares authorized, issued and outstanding as of December 31, 2020 and 2021	23,000	23,000
Total convertible preferred shares	31,806	31,806
Shareholders' deficit		
Ordinary shares, par value of US$0.0001 per share; 492,179,086 shares authorized; 9,567,997 and 10,274,403 shares issued and outstanding as of December 31, 2020 and 2021, respectively	1	1
Additional paid-in capital	10,563	12,325
Accumulated other comprehensive loss	(44)	(196)
Accumulated deficit	(17,557)	(27,223)
Total shareholders' deficit	(7,037)	(15,093)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIT	$ 25,741	$ 18,348

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

BELITE BIO, INC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousand US Dollars, except share and per share amounts)

	For the Years Ended December 31,	
	2020	2021
Expenses		
Research and development	3,688	7,419
General and administrative	2,055	2,378
Total operating expenses	5,743	9,797
Loss from operations	(5,743)	(9,797)
Other income (expense):		
Interest income	12	5
Interest expense	(21)	—
Other income	—	126
Total other (expense) income, net	(9)	131
Loss before income tax	(5,752)	(9,666)
Income tax expense	(1)	—
Net loss	(5,753)	(9,666)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	6	(152)
Total comprehensive loss	$ (5,747)	$ (9,818)
Weighted average number of ordinary shares used in per share calculation:		
− Basic and Diluted	8,790,397	9,569,932
Net loss per ordinary share		
− Basic and Diluted	$ (0.65)	$ (1.01)

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

BELITE BIO, INC

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIT
(In thousand US Dollars, except share)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated other Comprehensive loss	Accumulated deficit	Total Shareholders' deficit
	Shares	Amount	Shares	Amount				
Balance as of January 1, 2020	—	$ —	7,840,321	$ 1	$ 8,114	$ (50)	$ (11,804)	$ (3,739)
Issuance of ordinary shares	—	—	500,000	—	500	—	—	500
Issuance of ordinary shares upon conversion of other payable due to related parties	—	—	500,000	—	500	—	—	500
Issuance of Series A preferred shares	1,833,892	6,792	—	—	—	—	—	—
Issuance of Series A preferred shares upon conversion of convertible promissory notes	543,750	2,014	—	—	—	—	—	—
Issuance of Series B preferred shares	5,443,272	23,000	—	—	—	—	—	—
Exercise of share options	—	—	727,676	—	86	—	—	86
Share-based compensation expense	—	—	—	—	1,363	—	—	1,363
Net loss	—	—	—	—	—	—	(5,753)	(5,753)
Foreign currency translation adjustment	—	—	—	—	—	6	—	6
Balance as of December 31, 2020	**7,820,914**	**$31,806**	**9,567,997**	**$ 1**	**$ 10,563**	**$ (44)**	**$ (17,557)**	**$ (7,037)**
Exercise of share options	—	—	706,406	—	232	—	—	232
Share-based compensation expense	—	—	—	—	1,530	—	—	1,530
Net loss	—	—	—	—	—	—	(9,666)	(9,666)
Foreign currency translation adjustment	—	—	—	—	—	(152)	—	(152)
Balance as of December 31, 2021	**7,820,914**	**$31,806**	**10,274,403**	**$ 1**	**$ 12,325**	**$ (196)**	**$ (27,223)**	**$ (15,093)**

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

BELITE BIO, INC

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousand US Dollars)

	For the years ended December 31,	
	2020	**2021**
Cash flows from operating activities		
Net loss	$ (5,753)	$ (9,666)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	17	30
Share-based compensation expense	1,363	1,530
Gain on disposal of property and equipment	—	(8)
Changes in operating assets and liabilities:		
Other receivables due from related parties	4	—
Prepayments	192	(35)
Other payables due to related parties	(19)	45
Accrued expenses and other liabilities	(254)	632
Security deposits	8	(2)
Net cash used in operating activities	(4,442)	(7,474)
Cash flows from investing activities		
Acquisition of property and equipment	—	(74)
Prepayments for property and equipment	(20)	—
Proceeds from disposal of property and equipment	—	18
Net cash used in investing activities	(20)	(56)
Cash flows from financing activities		
Payments of deferred offering costs	—	(815)
Proceeds from related party loan	131	—
Repayment of related party loan	(2,450)	—
Proceeds from issuance of ordinary shares	500	—
Proceed from issuance of convertible preferred shares	29,792	—
Proceed from exercise of share options	86	232
Net cash used in financing activities	28,059	(583)
Effects of exchange rate on cash	4	(161)
NET (DECREASE) INCREASE IN CASH	23,601	(8,274)
CASH AT BEGINNING OF THE YEAR	2,017	25,618
CASH AT END OF THE PERIOD	$25,618	$17,344
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Interest paid	19	—
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING		
Conversion of convertible promissory notes and accrued interest into convertible preferred shares	2,014	—
Conversion of other payable due to related parties into ordinary shares	500	—

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

BELITE BIO INC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands except for number of shares and per share data, unless otherwise noted)

1. ORGANIZATION AND BASIS OF PRESENTATION

Belite Bio, Inc ("Belite" or the "Company") was incorporated under the laws of the Cayman Islands on March 27, 2018. The Company and its subsidiaries are engaged in research and development of first-in-class therapeutics targeting significant unmet needs.

In June 2016, the Company's ultimate controlling shareholder (i.e., the sole shareholder of Belite's principal shareholder, Lin Bioscience International Ltd.), Lin BioScience, Inc., a public company in Taiwan (stock code: 6696.TW), established Belite Bio Holdings Corp. (formerly known as Lin BioScience Holdings Corporation) and Belite Bio, LLC (formerly known as Lin BioScience, LLC), in Delaware. Belite Bio Holdings Corp. is established as an intermediate holding company and owns 100% equity interests in Belite Bio, LLC, which is mainly engaged in research and development of LBS-008 and LBS-009.

In March 2018, Lin BioScience, Inc., established the Company in the Cayman Islands, as a subsidiary to its wholly-owned subsidiary Lin Bioscience International Ltd., for reorganization purposes.

In June 2018, as part of the reorganization, the Company's principal shareholder, Lin Bioscience International Ltd., acquired the entire equity interest in Belite Bio Holdings Corp. from Lin BioScience, Inc. and then contributed the entire equity interest in Belite Bio Holdings Corp. to the Company in July 2018, together with other considerations in exchange for the Company's ordinary shares. Lin Bioscience International Ltd. transferred 1) cash of $900, 2) assignment of Lin BioScience, Inc.'s rights, title, interests and obligations under the exclusive license agreement by and between Lin BioScience, Inc. and Columbia University and 3) 1,600 shares of Belite Bio Holdings Corp. to the Company in exchange for its 5,340,221 ordinary shares. After above transaction, Belite Bio Holdings Corp. became Belite's wholly-owned subsidiary, which in turn owns 100% equity interests in Belite Bio, LLC.

Before and after the reorganization, the Company, together with its subsidiaries, is effectively controlled by the same shareholders, and therefore the reorganization is considered a recapitalization of entities under common control in accordance with Accounting Standards Codification ("ASC") 805-50-25. The consolidation of the Company and its subsidiaries have been accounted for at historical cost in the accompanying consolidated financial statements in accordance with ASC 805-50-45-5.

In August 2018, Belite Bio Holdings Corp. established RBP4 Pty Ltd in Australia as its wholly-owned subsidiary for carrying out clinical trials in Australia and tax refund purposes.

In January and February 2020, the Company closed two rounds of Series A Preferred Share financing and the relevant investors became shareholders of the Company. In December 2020, the Company closed a round of Series B Preferred Share financing and the relevant investors became shareholders of the Company. After the private placements, Lin Bioscience International Ltd. hold 80.10% of the Company's equity.

In June 2021, the Company established Belite Bio (HK) Limited in Hong Kong as a wholly-owned subsidiary which established Belite Bio (Shanghai) Limited in Shanghai, China in August 2021 for the purpose of carrying out clinical trials in China. As of December 31, 2021, the Company's principal subsidiaries are as follows:

Subsidiaries	Date of incorporation	Place of incorporation	Ownership	Principal activities
Belite Bio Holdings Corp. ("Belite Holding")	June 10, 2016	The United States of America	100% owned by Belite	Investment holding
Belite Bio, LLC ("Belite USA")	June 10, 2016	The United States of America	100% owned by Belite Holding	Research and development
RBP4 Pty Ltd ("RBP4")	August 13, 2018	Australia	100% owned by Belite Holding	Clinical trial activities
Belite Bio (HK) Limited ("Belite HK")	June 10, 2021	Hong Kong	100% owned by Belite	Investment holding
Belite Bio (Shanghai) Limited ("Belite Shanghai")	August 12, 2021	China	100% owned by Belite HK	Clinical trial activities

2. LIQUIDITY AND GOING CONCERN

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The Company has incurred recurring negative cash flows since inception and has funded its operations primarily from private placement of equity and debt securities. The Company had an accumulated deficit of approximately $17.6 million and $27.2 million as of December 31, 2020 and 2021, respectively. The Company had net losses of approximately $5.8 million and $9.7 million for the years ended December 31, 2020 and 2021. As of the issuance date of the consolidated financial statements, the remaining contractual costs expected to be incurred in future periods for the Company's clinical trials in STGD1 is approximately $10.0 million and the Company is also obligated to make payments to Columbia University in an aggregate amount of up to $20 million based on achieving specified development and regulatory approval milestones. The Company's ability to continue as a going concern is highly contingent on the ability to raise additional capital for ongoing research and development as the Company expects to continue incurring losses for the foreseeable future.

The Company intends to pursue a public offering of American Depositary Shares to fund future operations. If the Company is unable to complete a public offering for a sufficient amount in a timely manner, it would need to pursue other financing alternatives such as private financing of debt or equity or collaboration agreements. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to obtain sufficient funding, it could be required to delay its development efforts, limit activities and reduce research and development costs, which could adversely affect its business prospects.

Based on the Company's recurring losses and negative cash flows from operations since inception, expectation of continuing operating losses and negative cash flows from operations for the foreseeable future, the contractual costs expected to be incurred in future periods and the need to raise additional capital to finance its future operations, the Company's management concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year after the issuance date of the consolidated financial statements.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC").

Principle of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated on consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Significant accounting estimates reflected in the Company's consolidated financial statements include, but are not limited to, valuation of ordinary shares, share options, valuation allowance for deferred income tax assets, useful lives for property and equipment and share-based compensation. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Accordingly, actual results could differ from those estimates.

Risk and uncertainties

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's current and future product candidates will receive the necessary approvals or be commercially successful. If the approval is denied or delayed, it will have a material adverse impact on the business and consolidated financial statements of the Company.

Generally, the industry in which the Company operates subjects the Company to a number of other risks and uncertainties that can affect its operating results and financial condition. Such factors include, but are not limited to: the timing, costs and results of clinical trials and other development activities versus expectations; the ability to manufacture products successfully; competition from products sold or being developed by other companies; the price of, and demand for products once approved; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products.

Fair value measurements

The Company applies ASC 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements.

ASC 820 requires disclosures to be provided for fair value measurements. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Observable inputs such as quoted prices for identical instruments in active markets;

Level 2 — Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly;

Level 3 — Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach; and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities.

The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Company primarily include cash, accrued expenses and other liabilities, other payable due to related parties and convertible preferred shares. Convertible preferred shares were initially recorded at issue price net of issuance costs. The fair value of the other financial instruments closely approximates their fair value due to their short maturities.

Cash

Cash consists of demand deposits and time deposits placed with banks and have original maturities of less than three months. All cash is unrestricted as to withdrawal and use.

Deferred offering costs

Deferred offering costs consist of legal and other costs incurred through the balance sheet date that are directly related to the Company's initial public offering and that will be charged to shareholder's deficit upon the completion of the initial public offering. Should the initial public offering prove to be unsuccessful, the deferred offering costs, will be charged to operating expense in the consolidated statement of operations and comprehensive loss. During the years ended December 31, 2020 and 2021, the Company incurred nil and $815 of offering costs, respectively.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and impairment if applicable. Property and equipment consist of machinery and laboratory equipment. Depreciation is computed on a straight-line basis over estimated useful lives which are 5 years.

Repair and maintenance costs are charged to expense as incurred, whereas the costs of betterments that extend the useful life of property and equipment are capitalized as additions to the related assets.

Retirements, sale and disposals of assets are recorded by removing the cost and accumulated depreciation with any resulting gain or loss reflected in the consolidated statements of operations and comprehensive loss.

Long-lived asset impairment

The Company evaluates the recoverability of long-lived assets whenever events or changes in circumstances indicate the carrying value may not be fully recoverable. When these events occur, the Company evaluates the recoverability of long-lived assets by comparing the carrying amount of the assets to the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flows is less than the carrying amount of the assets, the Company recognizes an impairment loss based on the excess of the carrying amount of the assets over their fair value. Fair value is generally determined by discounting the cash flows expected to be generated by the assets, when the market prices are not readily available. The adjusted carrying amount of the assets become new cost basis and are depreciated over the assets' remaining useful lives. No impairment loss was recorded for the year ended December 31, 2020 and 2021.

Segment reporting

In accordance with ASC 280, Segment Reporting, the Company's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer. The Company's CODM reviews the consolidated results of operations when making decisions about allocating resources and assessing performance of the Company. The Company operates and manages it business as a single segment. The Company does not distinguish between markets for the purpose of making decisions about resources allocation and performance assessment. Hence, the Company has only one operating segment and one reportable segment. No geographical segments are presented as substantially all the Company's long-lived assets are located in Australia.

Research and development expenses

Research and development expenses primarily include (1) payroll, share-based compensation and other related costs of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Company, (3) costs related to preclinical testing of the Company's technologies and clinical trials such as payments to contract research organizations ("CRO") and contract manufacturing organizations ("CMO"), investigators and clinical trial sites that conduct the clinical studies; (4) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and

development expenses are charged to expense as incurred when these expenditures relate to the Company's research and development services and have no alternative future uses in accordance with ASC 730, Research and Development.

Accrued research and development expenses

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided under such contracts. The Company reflects research and development expenses in the consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities and determine accrual estimates through review of the underlying contracts along with discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, the Company adjusts its rate of expense recognition if actual results differ from its estimates. Estimates for accrued research and development expenses are classified as accrued expenses on the accompanying consolidated balance sheet.

As of December 31, 2021, the Company has several ongoing clinical studies in various clinical trial stages. The contracts with CRO and CMO are generally cancellable, with notice, at the Company's option. The Company did not record any accrued expenses related to cancellation of CRO or CMO contracts as of December 31, 2020 and 2021 as the Company did not have any plan to cancel the existing CRO or CMO contracts.

Leases

Leases are classified at the inception date as either a capital lease or an operating lease. The Company assesses a lease to be a capital lease if any of the following conditions exists: a) ownership is transferred to the lessee by the end of the lease term, b) there is a bargain purchase option, c) the lease term is at least 75% of the property's estimated remaining economic life or d) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception of the lease. The Company had no capital leases for the years presented.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over their respective lease terms. The lease term begins on the date of initial possession of the leased property for purpose of recognizing lease expense on straight-line basis over the term of the lease.

Income tax

The Company accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the tax income rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that some portion or all of a deferred income tax assets will not be realized in the foreseeable future.

The Company evaluates its uncertain tax positions using the provisions of ASC 740-10, Income Taxes, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Company recognizes in the financial statements the benefit of a tax position which is "more likely than not" to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is the Company's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

Convertible preferred shares

The preferred shares are redeemable by the holders upon a liquidation event, including a deemed liquidation event, which outside the sole control of the Company, and as such are presented as mezzanine equity. In accordance with ASC 480-10-S99, each issuance of the convertible preferred shares should be recognized at the issuance date fair value, net of issuance costs. The Company did not incur material issuance cost for any preferred shares issued. The non-cumulative undeclared dividends are not recorded in the consolidated balance sheet as the Company does not have the obligation to pay the cumulative dividend before it is declared by the board of directors.

The Company assesses whether an amendment to the terms of its convertible preferred shares is an extinguishment or a modification using the fair value model. When convertible preferred shares are extinguished, the difference between the fair value of the consideration transferred to the convertible preferred shareholders and the carrying amount of the convertible preferred shares (net of issuance costs) is treated as deemed dividends to the preferred shareholders.

Loss per share

Basic loss per ordinary share is computed by dividing net loss attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

The Company uses the two-class method whereby net loss is allocated between ordinary shares and other participating securities based on dividends declared (or accumulated) and participating rights in undistributed earnings as if all the earnings for the reporting period had been distributed. The Company's convertible preferred shares are participating securities as the preferred shares are entitled to receive dividends or distributions on an as converted basis. During periods of loss, the Company allocates no loss to participating securities because the holders of convertible preferred shares have no contractual obligation to share in the losses of the Company.

Diluted net loss per share is calculated by dividing net loss attributable to ordinary shareholders, as adjusted for the effect of dilutive ordinary equivalent shares, if any, by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares include ordinary shares issuable upon the conversion of the convertible preferred shares using the if-converted method, and ordinary shares issuable upon the exercise of share options, using the treasury stock method. Ordinary share equivalents are excluded from the computation of diluted earnings per share if their effects are anti-dilutive. For the periods presented herein, the computation of basic net loss per share using the two-class method is not applicable as the Company is in a net loss position and the participating securities do not have contractual rights and obligations to share in the losses of the Company.

Share-based compensation

Awards Granted to Employees

The Company grants share options to eligible employees, management and directors and accounts for these share-based awards in accordance with ASC 718 Compensation-Stock Compensation. Employees' share- based awards are measured at the grant date fair value of the awards and recognized as expenses a) immediately at grant date if no vesting conditions are required; or b) using graded vesting method over the requisite service period, which is the vesting period, on a straight-line basis; c) for share-based awards granted with performance condition, using graded vesting method over the period based on the expected milestone achievement dates. Share-based compensation expense is recorded in research and development and general and administrative expenses based on the classification of the work performed by the grantees.

The Company's determination of the fair value of share option on the date of grant utilized the Binominal Option Pricing Model with the assistance of an independent third-party valuation firm. Grant date fair value was impacted by Belite's ordinary share price as well as changes in assumptions regarding a number of subjective variables which included, but were not limited to, the expected term that options remained outstanding, the expected ordinary share price volatility over the term of the option awards, risk-free interest rates, and expected dividends.

To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed.

Awards Granted to Non-Employees

The Company has accounted for equity instruments issued to non-employees in accordance with ASU No. 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.

The Company recognizes share-based compensation cost for equity awards to non-employees with a performance condition at the fixed fair value on date of grant over the period based on the expected milestone achievement dates as the derived service period (usually the vesting period), on a straight-line basis. The Company considers the probable outcome of that performance condition when determines share-based compensation expenses and will recognize a cumulative true-up adjustment if the probability of the conditions has changed.

Translation of foreign currency financial statements

The functional currency is the local currency of the respective entities. The United States dollar ("$") is the functional currency of the Company's entities incorporated in the Cayman Islands, the United States and Hong Kong; the functional currency of the Company's Australia subsidiary and Shanghai subsidiary are Australian dollar ("AU$") and Renminbi ("RMB"), respectively.

The reporting currency of the Company is the United States dollar. Accordingly, the financial statements of the foreign subsidiaries are translated at the following exchange rates: assets and liabilities — current rate on balance sheet date; shareholders' equity — historical rate; income and expenses — weighted average rate during the year. The resulting translation adjustment is reflected in the accumulated other comprehensive loss.

Transactions denominated in other than the functional currencies are recorded at the rate of exchange in effect when the transaction occurs. Gains or losses, resulting from the application of different foreign exchange rates when cash in foreign currency is converted into the entities' functional currency, or when foreign currency receivable and payable are settled, are credited or charged to income in the period of conversion or settlement. At year-end, the balances of foreign currency monetary assets and liabilities are recorded based on prevailing exchange rates and any resulting gains or losses are included in the consolidated statements of comprehensive loss.

Comprehensive loss

Comprehensive loss represents net loss plus the results of certain changes in shareholders' deficit during a period from non-owner sources.

Comprehensive loss is defined as the changes in equity of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, Comprehensive Income, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the years presented, the Company's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

Concentration of risks

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses for the years ended December 31, 2020 and 2021:

Supplier	2020	2021
A	$ *	$2,385
B	*	1,213
C	776	765
D	1,187	*
E	448	*
F	442	*
G	423	*

* Represents less than 10% of research and development expenses for the years ended December 31, 2020 and 2021.

Concentration of credit risk

As of December 31, 2020 and 2021, the aggregate amount of cash of US$ 22,027 and US$ 9,973 respectively, were held at major financial institutions located in the Republic of China (“R.O.C.” or “Taiwan”), and US$ 3,591 and US$ 7,371, respectively, were deposited with major financial institutions located outside the R.O.C.. These financial institutions are of high credit quality and management continually monitors the credit worthiness of these financial institutions.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires lessees to recognize a right-of-use asset and lease liability on the balance sheet for all leases, including operating leases, with a term in excess of 12 months. The guidance also expands the quantitative and qualitative disclosure requirements. In July 2018, the FASB issued updates to the lease standard making transition requirements less burdensome. The update provides an option to apply the transition provisions of the new standard at its adoption date instead of at the earliest comparative period presented in the Company’s financial statements. The new guidance requires the lessee to record operating leases on the balance sheet with a right-of-use asset and corresponding liability for future payment obligations. FASB further issued ASU 2018-11 “Target Improvement” and ASU 2018-20 “Narrow-scope Improvements for Lessors.” In June 2020, the FASB issued ASU No. 2020-05, “Revenue from Contracts with Customers (Topic 606) and

Leases (Topic 842) Effective Dates for Certain Entities” (“ASU 2020-05”) in response to the ongoing impacts to businesses in response to the coronavirus (COVID-19) pandemic. ASU 2020-05 provides a limited deferral of the effective dates for implementing previously issued ASU 842 to give some relief to businesses and the difficulties they are facing during the pandemic. ASU 2020-05 affects entities in the “all other” category and public Not-For-Profit entities that have not gone into effect yet regarding ASU 2016-02, Leases

(Topic 842). Entities in the “all other” category may defer to fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The adoption of this amendment is not expected to have a material impact on the Company’s consolidated financial statements.

In December 2019, the FASB issued an accounting update which eliminated certain exceptions to the general principles in ASC 740, such as recognizing deferred taxes for equity investments, the incremental approach to performing intra-period tax allocation, and calculating income taxes in interim periods. The standard also simplified income tax accounting for franchise taxes that are partially based on income, transactions with a government that result in a step-up in the tax basis of goodwill, separate financial statements of legal entities that are not subject to tax, and enacted changes in tax laws in interim period.

This amendment is effective for fiscal years beginning after December 15, 2020. Early adoption is permitted. The adoption of this amendment is not expected to have a material impact on the Company's consolidated financial statements.

Except as mentioned above, the Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the Company's consolidated balance sheets, statements of operations and comprehensive loss and statements of cash flows.

4. PREPAYMENTS AND OTHER CURRENT ASSETS

Prepayments and other current assets consist of the following:

	As of December 31,	
	2020	2021
Prepayments		
− Prepayments for other services	$10	$64
Deductible value-added tax input	40	23
	$50	$87

5. PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following:

	As of December 31,	
	2020	2021
Laboratory equipment	$ 92	$141
Less: accumulated depreciation	(46)	(47)
Total	$ 46	$ 94

Depreciation expenses recognized during the years ended December 31, 2020 and 2021, were approximately $17 and $30, respectively.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2020	2021
Research and development	$488	$ 741
Legal and consulting	266	525
License royalties	187	147
Other	5	151
	$946	$1,564

7. CONVERTIBLE PREFERRED SHARES

In January and February 2020, the Company issued 2,377,642 shares of Series A convertible preferred shares ("Series A Preferred Shares") with a par value $0.0001 per share at $3.7036 per share for a total consideration of (i) cash $6,792 and (ii) notes principal plus unpaid interests $2,014 in convertible promissory notes issued in October, 2019.

In December 2020, the Company issued 5,443,272 shares of Series B convertible preferred shares ("Series B Preferred Shares") with a par value $0.0001 per share to a group of investors at $ 4.2254 per share for a cash consideration of $23,000. The shareholder agreement therefore was amended and restated to reflect the issuance of Series B in the liquidation preference. Other than above, the rights and obligations for shareholders of Series A Preferred Shares and Series B Preferred Shares are consistent.

Convertible preferred share consisted of the following as of December 31, 2020 and 2021 (in thousands, except share):

	December 31, 2020 and 2021				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A Preferred Shares	2,377,642	$2,377,642	$ 8,806	$ 8,806	2,377,642
Series B Preferred Shares	5,443,272	5,443,272	23,000	23,000	5,443,272
Total	7,820,914	7,820,914	31,806	31,806	7,820,914

Key terms of the Series A Preferred Shares and Series B Preferred Shares (collectively the "Preferred Shares") are summarized as follows:

Voting right

Each Preferred Share has voting rights equivalent to the number of ordinary shares to which it is convertible at the record date. The Preferred Shares shall vote separately as a class with respect to certain specified matters. Otherwise, the preferred shareholders and ordinary shareholders shall vote together as a single class.

Dividends right

Each holder of the Preferred Shares will be entitled to receive non-cumulative dividends when declared by the Board of Directors prior and in preference to ordinary shareholders. The dividend should be paid at the rate of 6% of the original issue price per share per annum on each Preferred Shares. After the preferential dividends relating to the Preferred Shares have been paid in full or declared and set apart in any fiscal year of the Company, any additional dividends out of funds or assets legally available therefore may be declared in that fiscal year for the Shares and, if such additional dividends are declared, the preferred shareholders shall be entitled to participate on an as converted-basis pro-rata in any dividends or distributions paid to the ordinary shareholders.

Conversion rights

Each holder of Preferred Shares shall have the right, at such holder's sole discretion, to convert all or any portion of the Preferred Shares into ordinary shares based on a one-for-one basis at any time. The initial conversion price is the issuance price of Preferred Shares, subject to adjustment in the event of stock splits, share combinations, share dividends and distribution, reorganization, mergers, consolidations, reclassifications, exchanges, substitutions, or dilutive issuance.

The Preferred Shares will be automatically converted into ordinary shares at the then-effective conversion price upon the earlier of (1) the closing of a Qualified Initial Public Offering, or (2) the date specified by written consent or agreement of majority holders of Preferred Shares.

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, or any deemed liquidation event as defined in the Company's articles of association, the holders of Preferred Shares are entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal to the original issue price, plus accrued but unpaid dividends (the "Preference Amount").

In the event insufficient funds are available to pay in full the Preference Amount in respect of each preferred shareholders, the sequence of liquidation right of all series of preferred shares was as follows:

(1) Series B Preferred Shares

(2) Series A Preferred Shares

After the Preference Amount has been paid, any remaining funds or assets legally available for distribution shall be distributed pro rata among the preferred shareholders together with ordinary shares.

8. SHARE-BASED COMPENSATION

On December 17, 2019, the Company adopted a share incentive plan ("2019 Plan"). Under the 2019 Plan, the Company's Board of Directors has approved that a maximum aggregate number of shares that may be issued pursuant to all awards granted shall be 1,960,080. On December 23, 2020, the Company replaced 2019 Plan with the amended and restated share incentive plan ("2020 Plan") and increased the maximum number of shares issuable to 4,165,310. The terms of the 2019 Plan and 2020 Plan are substantially the same other than the maximum aggregate number of shares the Company may issue under the respective plan.

Share options containing only service conditions granted to each grantee under the 2019 Plan and 2020 Plan will generally be exercisable upon the grantee renders service to the Company in accordance with a stipulated vesting schedule. Grantees are generally subject to a vesting schedule of no longer than three years, under which the grantee earns an entitlement to vest a certain percentage of his option grants at the end of each month or year of completed service. The share option awards shall expire no more than 10 years from their grant dates.

Share options containing both service conditions and performance conditions granted to each grantee under the 2019 Plan and 2020 Plan shall become eligible for vesting upon the occurrence of their applicable performance conditions (including but not limited to the completion of business and operational goals, etc.).

The fair value of options was determined using the Binomial Option Pricing Model, with the assistance from an independent third-party appraiser. The binomial model requires the input of highly subjective assumptions, including the expected volatility, the exercise multiple, the risk-free interest rate and the expected dividend yield. For expected volatility, the Company has made reference to historical volatility of several comparable companies in the same industry. The exercise multiple was estimated as the average ratio of the stock price to the exercise price of when employees would decide to voluntarily exercise their vested share options. As the Company did not have sufficient information of past employee exercise history, the exercise multiple was based on management's estimation. The risk-free rate for periods within the contractual life of the options is based on the market yield of U.S. Government Notes with a maturity life equal to the remaining maturity life of the options as of the valuation date. The expected dividend yield is based on our expected dividend policy over the contractual life of the options.

The assumptions used to estimate the fair value of the share options on the date of grant are as follows:

	As of December 17, 2019	As of December 23, 2020	As of March 1, 2021
Risk-free interest rate	1.72% – 1.74%	0.51%	0.87%
Expected volatility range	35.50% – 35.72%	36.59%	36.75%
Exercise multiple	2.8	2.8	2.8
Expected dividend yield	—	—	—

A summary of the Company's stock option activity under the plans for the years ended December 31, 2020 and 2021 is presented as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	1,335,794	$0.1191	$2.4720	9.96	3,301
Granted	2,807,381	$0.4386	$2.2574	—	—
Exercised	(727,676)	$0.1191	$2.4720	—	—
Forfeited or expired	(19,601)	$0.1191	$2.4733	—	—
Outstanding as of December 31, 2020	3,395,898	$0.3832	$2.2946	9.80	7,834
Granted	41,736	$4.2254	$0.4626	—	—
Exercised	(706,406)	$0.3289	$2.3311	—	—
Forfeited or expired	(748,667)	$0.4386	$2.2574	—	—
Outstanding Options, December 31, 2021	1,982,561	$0.4626	$2.2571	8.82	$4,480
Vested and Expected to Vest Options as of December 31, 2021	844,774	$0.3935	$2.3052	8.58	$1,969
Exercisable Options as of December 31, 2021	356,067	$0.2291	$2.4192	7.99	$ 891

	Years ended December 31,	
	2020	2021
Research and development	$ 77	$ 52
General and administrative	1,286	1,478
Total	$1,363	$1,530

Total unrecognized employee share-based compensation expense, may be adjusted for actual forfeitures occurring in the future, were $2,633 and $771 which are expected to be recognized over a weighted-average period of 1.68 years and 2.77 years as of December 31, 2020 and 2021, respectively.

9. INCOME TAX

The Company is not subject to income or other taxes in the Cayman Islands. However, subsidiaries are subject to taxes of the jurisdiction where they are located.

Cayman Islands

The Company is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

United States

Belite Bio Holdings Corp. and Belite Bio, LLC are subject to U.S. federal corporate income tax at a rate of 21% and state income tax in California at a rate of 8.84%.

Hong Kong

Belite Bio (HK) Limited is subject to Hong Kong profits tax on the taxable income as reported in the respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate in Hong Kong is 8.25% for assessable profits on the first HK$2 million and 16.5% for any assessable profits in excess.

Australia

RBP4 Pty Ltd is subject to Australia profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Australia tax laws. The applicable tax rate in Australia is 30%.

PRC

Provision for PRC corporate income tax is calculated based on the statutory income tax rate of 25% on the assessable income of Belite Shanghai during the year ended December 31, 2021 in accordance with relevant PRC enterprise income tax legislation, interpretations and practices.

No provision for PRC corporate income tax has been made for the year ended December 31, 2021 as Belite Shanghai had no such assessable profit for the year then ended.

The Company and its subsidiaries file separate income tax returns. The applicable statutory income tax rate in the Cayman Islands was zero for the Company for the years being reported. Reconciliation between the income tax expense computed by applying the statutory tax rate to loss before income tax and the actual provision for income tax is as follows:

	(In Thousands) Years ended December 31,	
	2020	2021
Federal statutory tax rate	21%	21%
State taxes	8.84%	8.84%
Withholding tax	0.02%	0.00%
Research and development credit	(0.03)%	(0.33)%
Non-deductible expenses	(0.27)%	(0.20)%
Changes in valuation allowances	(29.54)%	(29.31)%
Effective tax rate	$ 0.02%	$ 0.00%

The deferred income tax assets and liabilities as of December 31, 2020 and 2021 consisted of the following:

	As of December 31,	
	2020	2021
Deferred income tax assets		
Research and development credits	$ 59	$ 103
Net operating loss carryforwards	3,687	4,005
	3,746	4,108
Valuation allowance	(3,746)	(4,108)
Total net deferred income tax assets	$ —	$ —

Realization of the net deferred tax assets is dependent on factors including future reversals of existing taxable temporary differences and adequate future taxable income, exclusive of reversing deductible temporary differences and tax loss carry forwards. The Company evaluates the potential realization of deferred tax assets on an entity-by-entity basis. As of December 31, 2020 and 2021, the Company and all of its subsidiaries were in cumulative loss position, valuation allowances were provided against deferred tax assets in entities where it was determined it was more likely than not that the benefits of the deferred tax assets will not be realized.

As of December 31, 2020 and 2021, Belite Bio, LLC had U.S. federal and state research and development credit carryforwards of approximately $59 and $103, respectively. The U.S. federal research and development credit will expire from 2039 if not utilized, while the state research and development credit will never expire. Utilization of the research and development credits may be subject to significant annual limitation due to the ownership change limitations provided by the U.S. Internal Revenue Code of 1986 and similar provisions in the State of California's tax regulations. The annual limitation may result in the expiration of federal research and development credits before utilization.

As of December 31, 2020 and 2021, the Company's subsidiaries had U.S. net operating loss carryforwards for federal and state tax purposes of approximately $3,687 and $4,005, respectively. If not

utilized, the federal and state net operating loss carryforwards incurred before January 1, 2018 will begin to expire in 2036, and the remaining can be carried forward indefinitely but utilization is limited to 80% of the Company's taxable income in any given tax year based on current federal tax laws.

10. AUSTRALIA RESEARCH AND DEVELOPMENT TAX INCENTIVE

The Company's wholly owned subsidiary, RBP4 Pty Ltd, which conducts clinical development activities on behalf of the Company, is eligible under the Australian Research and Development Tax Incentive Program to receive a 43.5% refundable tax incentive from the Australian Taxation Office for qualified research and development expenditures. To be eligible, RBP4 Pty Ltd must have revenue of less than AU$20 million during the reimbursable period and cannot be controlled by income tax exempt entities. The tax incentive is recognized as a reduction to research and development expense when there is reasonable assurance that the tax incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. For the years ended December 31, 2020, and 2021, $779 and $339, respectively, were recorded in the consolidated statements of operations and comprehensive loss.

11. ORDINARY SHARES

As of December 31, 2020 and 2021 the Company was authorized to issue 492,179,086 shares of $0.0001 par value ordinary shares. Holders of the Company's ordinary shares are entitled to dividends, if and when, declared by the board of directors of the Company and after any convertible preferred share dividends are fully paid. The holder of each share of common stock is entitled to one vote. As of December 31, 2021, no dividends were declared.

12. NET LOSS PER SHARE

Basic and diluted net loss per share for the years ended December 31, 2020 and 2021 are calculated as follows:

	Years ended December 31,	
	2020	2021
Numerator:		
Net loss attributable to ordinary shareholders	$ (5,753)	$ (9,666)
Denominator:		
Weighted average number of ordinary shares outstanding – basic and diluted	8,790,397	9,569,932
Net loss per share – basic and diluted	$ (0.65)	$ (1.01)

For the years ended December 31, 2020 and 2021, the effects of all outstanding convertible preferred shares and share options have been excluded from the computation of diluted loss per share as their effects would be anti-dilutive.

The potentially dilutive securities that have not been included in the calculation of diluted net loss per share as their inclusion would be anti-dilutive are as follows:

	Years ended December 31,	
	2020	2021
Convertible preferred shares	7,820,914	7,820,914
Outstanding share options	3,395,898	1,982,561
Total	11,216,812	9,803,475

13. RELATED PARTY TRANSACTIONS

The table below sets forth the major related parties and their relationships with the Company as of December 31, 2020 and 2021:

Name of related parties	Relationship with the Company
Lin BioScience, Inc.	The ultimate shareholder of the Company
Lin Bioscience International Ltd.	The shareholder of the Company
Lin BioScience Pty Ltd	Controlled by the ultimate shareholder of the Company

The Company and its subsidiaries entered into several research and development services agreements with several related parties, including:

On July 1, 2020, Lin BioScience, Inc. and the Company entered into the LBS-009 R&D services agreement; whereby Lin BioScience, Inc. agreed to provide preclinical studies services for pipeline LBS-009 to the Company. The Company agreed to pay services fees in an amount equal to 110% percent of actual costs for its performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. The LBS-009 R&D services agreement terminated on June 30, 2021. For the year ended December 31 2020 and 2021, the Company did not receive any services connected to above agreement.

Lin BioScience, Inc. and the Company also entered into the LBS-008 R&D services agreements on July 1, 2020 and July 1, 2021, whereby Lin BioScience, Inc. agreed to provide certain new drug development services for pipeline LBS-008 to the Company. The Company agreed to pay services fees in an amount equal to 110% percent of actual costs for its performance of such development services and to reimburse the actual expenses for transportation, travel and lodging for the performance of such development services. For the year ended December 31 2020 and 2021, the Company recorded nil and $183 in research and development expenses, respectively.

In addition to above research and development agreements, the Company and its subsidiaries also entered into certain loan agreements with related parties since 2019, including:

Pursuant to the loan agreements entered into in 2019, Lin Bioscience International Ltd. agreed to provide an interest-free loan on request from time to time for a period of one year from July 2019. In July 2020, Belite Bio, Inc had fully repaid the outstanding amount under the loan agreements with Lin Bioscience International Ltd. For the year ended December 31, 2020, the proceeds received from and repayment made to Lin Bioscience International Ltd. were nil and $1,180, respectively.

In 2019 and 2020, RBP4 entered into several related party loan agreements with Lin BioScience Pty Ltd, whereby Lin BioScience Pty Ltd, agreed to provide interest-free loans on request from time to time for a period of one year commencing from July 2019. In January 2020, RBP4 had fully repaid the outstanding amount under the loan agreements with Lin BioScience Pty Ltd. For the year ended December 31, 2020, the proceeds received from and repayment made to Lin BioScience Pty Ltd. were $131 and $580, respectively.

In 2019 and 2020, Lin BioScience, Inc. entered into a related party funding agreement with RBP4 and the Company. Pursuant to the agreement, Lin BioScience, Inc. agreed to provide loans on request from time to time for a period of one year. In July 2020 the Company and RBP4 had fully repaid the outstanding amount under the loan agreements with Lin BioScience, Inc. For the year ended December 31, 2020, the proceeds received from and repayment made to Lin BioScience, Inc. were nil and $690, respectively.

(a) Related party balances

	As of December 31,	
	2020	2021
Due to related parties		
Lin BioScience, Inc.	$26	$71

(b) Related party transactions

During the years ended December 31, 2020 and 2021, related party transactions consisted of the following:

	Years ended December 31,	
	2020	2021
Lin BioScience, Inc.:		
Research and Development Expense	$—	$183
Professional Service Expense	$21	$ —
Interest Expense	$17	$ —

14. COMMITMENTS AND CONTINGENCIES

License Agreement with Columbia University

The Company is party to an exclusive license agreement with Columbia University (as amended, the "Columbia License Agreement"), which has been amended five times, most recently as of February 4, 2022, under which the Company licenses specified intellectual property from Columbia University. The patent rights licensed to the Company by Columbia University include issued patents with claims that recite a class of compounds directed to covering the Company's lead compound, LBS-008, and specifically recite LBS-008. The license agreement requires the Company to make minimum annual royalty payments to Columbia University of specified amounts on each anniversary of the first commercial sale of a licensed product, commencing on the second anniversary of such sale. The Company will also be obligated to pay single-digit earned royalties to Columbia University based on net sales of each licensed product by the Company and its affiliates and sublicensees. The minimum royalty payments will be creditable against the earned royalties accrued during the same calendar year. The license agreement obligates the Company to use commercially reasonable efforts to research, discover, develop and market licensed products for commercial sale and distribution and achieve certain development and regulatory approval milestones within certain timeframes, if certain milestones are achieved. The Company is also obligated to periodically inform Columbia University of its progress in meeting such milestones. The failure to achieve any such milestone would constitute a breach of the Columbia License Agreement. If the Company pays Columbia University the required fee, it will be granted a 6-month extension. As of the date of these financial statements, the Company has complied with the development and regulatory approval milestones under the Columbia License Agreement and requested no extensions. In the event that, after completion of Phase I Trials, there are unforeseen changes in clinical or regulatory development that the Company believes would affect the timely achievement of any milestone, it may request an extension from Columbia University for such milestone, which will not be unreasonably withheld or delayed. In the event that Columbia University does not agree to extend the deadlines to meet the milestones, and the Company is in breach for failure to timely meet the milestones or to make milestone or royalty payments, Columbia University may elect to convert the license to a nonexclusive license without the right to sublicense or initiate legal proceedings against third party patent infringers or terminate the license. The Company is also obligated to make payments to Columbia University in an aggregate amount of up to $20 million based on achieving specified development and regulatory approval milestones and in an amount of up to $25 million based on achieving a specified cumulative sales milestone with respect to the first licensed product. In addition, the Company is obligated to pay Columbia University a specified portion of revenue (other than royalties) it receives from sublicensees, and a percentage of revenue in the low double-digits received from any sale of a priority review voucher by us or a sublicensee. The Company cannot reasonably estimate whether, when and in what amount any of such payments shall be made, but believe it is in compliance with the terms of the license. From inception through December 31, 2021, the Company has made a payment of $1 million to Columbia University resulting from this license agreement, which was triggered by the completion of its Phase 1 clinical trial.

Clinical Research Organization (CRO)

In the course of normal business operations, the Company has agreements with contract service providers to assist in the performance of clinical trial activities. Such agreements are generally cancellable

upon reasonable notice and payment of costs incurred. As of the issuance date of the consolidated financial statements, the remaining contractual costs expected to be incurred in future periods for the Company's clinical trials in STGD1 is approximately $10.0 million.

Litigation

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not aware of any current pending legal matters or claims.

15. SUBSEQUENT EVENTS

The company evaluated subsequent events and transactions that occurred after the balance sheet date up to March 15, 2022, the date that the financial statements were issued. Based on the review, management did not identify any subsequent events that would have required adjustments or disclosure in the financial statements.

6,000,000 American Depositary Shares

Belite Bio, Inc

PROSPECTUS

Book-Running Manager

THE BENCHMARK COMPANY

Until May 24, 2022 (25 days after the date of this prospectus), all dealers that buy, sell or trade these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to its unsold allotments or subscriptions.

April 29, 2022