

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

**Form F-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**CONNECT BIOPHARMA HOLDINGS LIMITED**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

<p><b>Cayman Islands</b> (State or other Jurisdiction of Incorporation or Organization)</p>	<p><b>Not Applicable</b> (Translation of Registrant's Name into English)</p> <p style="text-align: center;"><b>2834</b> (Primary Standard Industrial Classification Code Number)</p> <p style="text-align: center;"><b>Science and Technology Park East R&amp;D Building, 3rd Floor 6 Beijing West Road, Taicang Jiangsu Province, China 215400</b> Tel: +86 512 5357 7866</p> <p>(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)</p>	<p><b>Not Applicable</b> (I.R.S. Employer Identification Number)</p>
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**Connect Biopharm LLC**  
**12707 High Bluff Drive, Suite 200**  
**San Diego, CA 92130**  
**Tel: +1 858 344 1036**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

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**Approximate date of commencement of proposed sale to the public:**  
**As soon as practicable after this Registration Statement becomes effective.**

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

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

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

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

**CALCULATION OF REGISTRATION FEE**

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (2)(3)	AMOUNT OF REGISTRATION FEE (4)
Ordinary shares, par value \$0.0001 per share (1)	\$	\$

(1) These ordinary shares are represented by American Depositary Shares, or ADSs, with each ADS representing \_\_\_\_\_ ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby are registered pursuant to a separate registration statement on Form F-6 (File No. 333-\_\_\_\_\_).

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.

(3) Includes the aggregate offering price of additional ordinary shares, represented by ADSs, which are issuable upon the exercise of the underwriters' option to purchase additional ADSs.

(4) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

**EXPLANATORY NOTE**

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting from this draft Registration Statement our interim consolidated financial statements as of and for the nine months ended September 30, 2019 and 2020 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time we first file this Registration Statement publicly. We intend to amend this Registration Statement on or prior to the date of such public filing to include all financial information required by Regulation S-X under the Securities Act of 1933, as amended, or the Securities Act.

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

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2021

PRELIMINARY PROSPECTUS

## American Depositary Shares



### Representing Ordinary Shares

This is an initial public offering of American Depositary Shares, or ADSs, of Connect Biopharma Holdings Limited.

We are selling \_\_\_\_\_ ADSs, representing \_\_\_\_\_ ordinary shares. Each ADS represents \_\_\_\_\_ ordinary shares, par value \$0.0001 per share.

Prior to this offering, there has been no market for our ADSs. It is currently estimated that the initial public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per ADS. We have applied to list our ADSs on the Nasdaq Global Market under the symbol "CNTB."

Investing in our ADSs involves risks. See "[Risk Factors](#)" beginning on page 14 of this prospectus.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and, as such, will be eligible for reduced public company disclosure requirements. Please see "Prospectus Summary—Implications of Being an Emerging Growth Company and a Foreign Private Issuer" for additional information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

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	PER ADS	TOTAL
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions (1)	\$ _____	\$ _____
Proceeds to Connect Biopharma Holdings Limited, before expenses	\$ _____	\$ _____

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(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted the underwriters an option to purchase up to an additional \_\_\_\_\_ ADSs within 30 days from the date of this prospectus at the initial public offering price, less the underwriting discounts and commissions.

At our request, the underwriters have reserved for sale, at the initial public offering price, up to \_\_\_\_\_ % of the ADSs offered hereby for our directors, officers, employees, business associates and related persons through a directed share program. See "Underwriting" for more information.

The underwriters expect to deliver the ADSs to the purchasers on or about \_\_\_\_\_, 2021.

**Jefferies**

**SVB Leerink**

**Piper Sandler**

**CICC**

Prospectus dated \_\_\_\_\_, 2021

TABLE OF CONTENTS

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<a href="#">EXPLANATORY NOTE</a>	1
<a href="#">ABOUT THIS PROSPECTUS</a>	iii
<a href="#">PRESENTATION OF FINANCIAL INFORMATION</a>	iv
<a href="#">PROSPECTUS SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	14
<a href="#">CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</a>	87
<a href="#">MARKET AND INDUSTRY DATA</a>	89
<a href="#">TRADEMARKS, SERVICE MARKS AND TRADENAMES</a>	90
<a href="#">USE OF PROCEEDS</a>	91
<a href="#">DIVIDEND POLICY</a>	93
<a href="#">CAPITALIZATION</a>	94
<a href="#">DILUTION</a>	96
<a href="#">OUR HISTORY AND CORPORATE STRUCTURE</a>	99
<a href="#">SELECTED CONSOLIDATED FINANCIAL DATA</a>	101
<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a>	103
<a href="#">BUSINESS</a>	115
<a href="#">MANAGEMENT</a>	170
<a href="#">PRINCIPAL SHAREHOLDERS</a>	185
<a href="#">RELATED PARTY TRANSACTIONS</a>	187
<a href="#">DESCRIPTION OF SHARE CAPITAL</a>	188
<a href="#">DESCRIPTION OF AMERICAN DEPOSITARY SHARES</a>	200
<a href="#">ORDINARY SHARES AND ADSs ELIGIBLE FOR FUTURE SALE</a>	210
<a href="#">TAXATION</a>	212
<a href="#">UNDERWRITING</a>	218
<a href="#">EXPENSES OF THE OFFERING</a>	230
<a href="#">LEGAL MATTERS</a>	231
<a href="#">EXPERTS</a>	232
<a href="#">ENFORCEMENT OF CIVIL LIABILITIES</a>	233
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	235
<a href="#">INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</a>	F-1

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**We are responsible for the information contained in this prospectus and any free-writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We are not, and the underwriters are not, making an offer to sell our ADSs in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or the sale of any ADSs.**

For investors outside the United States, neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our ADSs and the distribution of this prospectus outside the United States.

We are incorporated under the laws of Cayman Islands and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

**Until \_\_\_\_\_, 2021 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade ADSs, whether or not participating in the offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

**ABOUT THIS PROSPECTUS**

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms “Connect,” the “Company,” the “Group,” “we,” “us,” “our,” “our company” and “Connect Biopharma” refer to Connect Biopharma Holdings Limited, together with our direct and indirect wholly owned subsidiaries, Connect Biopharma Hong Kong Limited, Connect Biopharm LLC, Connect Biopharma Australia PTY LTD, Suzhou Connect Biopharma Co., Ltd., Connect Biopharma (Shanghai) Co., Ltd. and Connect Biopharma (Beijing) Co., Ltd.

## PRESENTATION OF FINANCIAL INFORMATION

Our consolidated financial statements included in this prospectus have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of our consolidated financial statements were prepared in accordance with U.S. GAAP. Our reporting currency is the renminbi. Unless otherwise indicated, all monetary amounts in this prospectus are in renminbi. All references in this prospectus to “\$,” “USD,” “U.S. dollars” and “dollars” mean U.S. dollars and all references to “¥” and “RMB” mean renminbi.

This prospectus contains translations of certain foreign currency amounts into U.S. dollars for the convenience of the reader. Unless otherwise stated, all translations from renminbi to U.S. dollars were made at RMB6.9762 to \$1.00, the exchange rate set forth in the China Foreign Exchange Trade System on December 31, 2019. We make no representation that the renminbi or U.S. dollar amounts referred to in this prospectus could have been or could be converted into U.S. dollars or renminbi, as the case may be, at any particular rate or at all. On February 1, 2021, the noon buying rate in New York for cable transfers payable in renminbi was RMB6.4669 to \$1.00.

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

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our ADSs. You should read this entire prospectus carefully, including "Risk Factors," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the notes thereto, before making an investment decision. In particular, we call your attention to the risk that we could be delisted from the Nasdaq Global Market pursuant to the Holding Foreign Companies Accountable Act enacted on December 18, 2020 if the Public Company Accounting Oversight Board continues to be unable to inspect our independent registered public accounting firm for three consecutive years.*

### Overview

We are a global clinical-stage biopharmaceutical company developing therapies for the treatment of T cell-driven inflammatory diseases. Our core expertise is in the use of functional cellular assays with T cells to screen and discover potent product candidates against immune targets. Our two most advanced clinical-stage programs include highly differentiated product candidates against validated targets. Our lead product candidate, CBP-201, is an antibody designed to target interleukin-4 receptor alpha, or IL-4Ra, which is a validated target for the treatment of inflammatory diseases such as atopic dermatitis, or AD, and asthma. The estimated global market for AD was approximately \$10.4 billion in 2020 and is expected to grow to \$19.3 billion by 2025, a compound annual growth rate, or CAGR, of 13.2%. Based on observed results in preliminary clinical studies, CBP-201 has the potential to be differentiated from dupilumab, an antibody that also targets IL-4Ra, which is now approved by the U.S. Food and Drug Administration, or FDA. We have initiated a Phase 2b trial of CBP-201 in the United States, Australia and New Zealand in AD patients with moderate-to-severe AD, and plan to initiate additional trials in asthma and chronic rhinosinusitis with nasal polyps, or CRSwNP, in the first half of 2021 and in AD patients in China in the second half of 2021. We anticipate reporting top-line results from our ongoing clinical trial in AD patients in the second half of 2021. Furthermore, we are developing CBP-307, a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1, or S1P1, for the treatment of inflammatory bowel disease, or IBD. Specifically, we are developing CBP-307 for two types of IBD, ulcerative colitis, or UC, and Crohn's disease, or CD. We anticipate reporting top-line results from a global Phase 2 trial in UC before the end of the first quarter of 2022 and also intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.

Our immune modulator product candidates originate from our approach to drug discovery based on using biologically relevant functional cellular assays to conduct primary drug screens instead of high-throughput biochemical assays. The clinical and preclinical results we have observed for our product candidates support the potential for this more physiologically relevant methodology, to yield highly differentiated solutions, in an efficient manner. Our approach is agnostic to drug modalities and has been used to identify both small molecule and antibody product candidates. We believe our approach leads to more rapid identification of relevant molecules and avoids the elimination of attractive molecules that could fail to advance through traditional screening assays. We apply our approach to develop product candidates against targets in T cell modulation related to inflammatory diseases with large unmet need. We believe we can successfully apply our expertise in T cell biology to discover and develop investigational product candidates to generate highly potent and specific T cell modulators, with a goal to produce first-in-class or best-in-class drugs for these target diseases.





- **CBP-307** is a small molecule modulator of S1P1, a regulator of T cell mobilization out of lymph nodes into the periphery. Inhibiting S1P1 leads to reduction in the levels of these T cells in circulation and a reduction in autoimmune-related inflammation. S1P1 is a validated therapeutic target with three drugs approved to treat multiple sclerosis: fingolimod, marketed as Gilenya® by Novartis, siponimod, marketed as Mayzent® by Novartis, and ozanimod, marketed as Zeposia®, by Bristol Myers Squibb. Evidence from third-party clinical trials suggests that the potential of S1P1 modulators is far broader than multiple sclerosis and includes highly prevalent diseases such as UC and CD. The estimated global market for UC was approximately \$5.4 billion in 2020, and the estimated global market for CD was approximately \$7.4 billion in 2019. We believe that CBP-307 is well-positioned to address these diseases due to its potency, specificity and pharmacokinetics observed in our preclinical studies and early clinical trials. We are conducting a global Phase 2 trial in UC and anticipate reporting top-line results before the end of the first quarter of 2022. In addition, we intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.
- **CBP-174** is a peripherally acting, small molecule histamine receptor 3, or H3R, antagonist, for oral administration to treat chronic itch associated with skin inflammation. We have exclusively licensed global rights to CBP-174 from Arena Pharmaceuticals, Inc., or Arena, to complement our CBP-201 program in AD. We believe that the ability to quickly alleviate itch in the setting of AD has the potential to complement the anti-pruritic effect of disease-modifying IL-4Ra antagonists such as our CBP-201 product candidate or dupilumab. In clinical trials, these IL-4Ra targeted products required weeks of treatment for many AD patients to obtain significant relief of itching. Our preclinical models have indicated that CBP-174 led to reductions in scratching within the first 30 minutes of dosing, which could potentially translate to rapid reduction in pruritus in the clinic. We intend to initiate a Phase 1 dose escalation study with CBP-174 in healthy adults in the first half of 2021 and anticipate reporting top-line results in the second half of 2021.

### Our Strategy

Our goal is to become a global biopharmaceutical company developing and commercializing therapies for patients suffering from inflammatory diseases. Our strategy to achieve this goal is as follows:

- **Discover and develop product candidates targeting inflammatory diseases with significant unmet medical need.** We specialize in designing and developing product candidates that modulate the immune system, with a particular focus on T cells. By leveraging our internal expertise and unique insights in therapeutic targeting of the immune system, our goal is to identify highly differentiated, potentially best-in-class product candidates against validated targets as well as potential first-in-class molecules against novel targets. We will continue to focus on the discovery and development of product candidates targeting inflammatory diseases with significant unmet medical need and affecting millions of patients worldwide.
- **Continue development of our three most advanced product candidates.** We believe CBP-201, CBP-307 and CBP-174 each can provide significant therapeutic benefit to patients suffering from inflammatory disorders, such as AD, IBD, asthma and CRSwNP, and pruritus associated with inflammatory skin diseases. We plan to advance these product candidates into and through clinical trials in the indications currently being investigated. In addition, we plan to expand the development of our product candidates into other indications.
- **Advance our earlier stage programs and continue to invest in R&D to expand and enhance our pipeline.** We are continuing to expand our pipeline of product candidates by applying our expertise in immunology to select targets, design assays, and execute preclinical drug discovery programs. We plan to continue to advance our discovery programs, including CBP-233, a humanized antibody against interleukin-33, into clinical studies for the treatment of allergic inflammation.
- **Leverage our core strengths in China and the United States and expand our operations globally.** We are currently headquartered in China with operations in the United States and Australia and clinical

development activities in those geographies as well as Europe. With respect to our operations in China, we leverage our relationships with clinical research organizations, large patient population and local infrastructure in ways that we believe provide us with a competitive advantage. In addition to our core capabilities in China, we plan to leverage our expertise and relationships regarding drug development outside of China. We currently intend to retain significant commercial rights to our product candidates globally and will consider high-value commercial partnerships in select territories.

#### **Our Team**

We were founded by a team with broad knowledge of the drug discovery industry and domain expertise in targeting immunological pathways. Zheng Wei, Ph.D., our Chief Executive Officer, has over 25 years of experience at drug discovery organizations including Arena and was a scientist and program leader at ChemoCentryx. Wubin (Bill) Pan, Ph.D., our President and Chairman, was a co-founder, China President, and Chief Operation Officer of Crown Bioscience. We believe that our experience and professional networks in both the drug discovery and contract research industry provide us with critical insights on best practices to optimally build a highly efficient and cost-effective discovery and development organization. Our physical presence in China and the United States enables us to take advantage of high-quality local talent while facilitating access to other global resources. We have raised approximately \$220 million to date and are supported by top tier investors including RA Capital Management, BlackRock, Lilly Asia Ventures, Boxer Capital, HBM Healthcare, Qiming Venture Partners, Northern Light Venture Capital and Cowin Venture.

#### **History and Corporate Structure**

In May 2012, Suzhou Connect Biopharma Co., Ltd., or Connect SZ, was incorporated as a limited liability under the laws of the PRC. At such time, Connect SZ held 100% of the equity interests of Connect Biopharm LLC, or Connect US, a single member LLC incorporated under the laws of the State of California. Connect US commenced its operations in January 2012.

In July 2014, Connect Biopharma Australia PTY LTD, or Connect AU, was formed as a limited liability company incorporated under the laws of Australia.

In October 2015, Connect Biopharma (Shanghai) Co., Ltd., or Connect SH, was formed as a limited liability company incorporated under the laws of the PRC.

In November 2015, Connect Biopharma Holdings Limited was formed as a Cayman Islands exempted company with limited liability, and in December 2015, Connect Biopharma Hong Kong Limited, or Connect HK, was formed as a limited liability company under the laws of Hong Kong. Connect Biopharma Holdings Limited and Connect HK were formed for the purpose of effecting the reorganization described below as holding companies for the majority shareholders of Connect SZ.

In January 2016, the Company and its subsidiaries underwent a reorganization, or the Reorganization, pursuant to which Connect Biopharma Holdings Limited issued ordinary shares to Dr. Wei and Dr. Pan, each of whom were founders of the company group, in exchange for their equity interests held in Connect SZ. As a result of issuance of the ordinary shares, Dr. Wei and Dr. Pan held 100% of the equity interests in the Company and Connect HK and retained joint control over the Company and its subsidiaries.

Following the issuance of equity interests in the Company to Dr. Wei and Dr. Pan, the remaining 30% of the equity interests in Connect SZ were held by an existing investor. These interests are referred to as the Non-Controlling Interests.

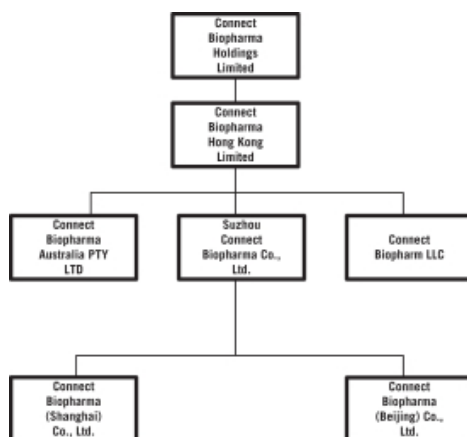
In October 2018, we underwent a restructuring, pursuant to which we transferred 100% of the outstanding shares of our subsidiaries Connect US and Connect AU (which were then held by Connect SZ) to Connect HK. Following such transfer, Connect US and Connect AU become wholly owned subsidiaries of Connect HK. Also in October 2018, we issued ordinary shares of Connect Biopharma Holdings Limited to the holders of

Non-Controlling Interests in Connect SZ in exchange for such Non-Controlling Interests and Connect Biopharma Holdings Limited issued Series Pre-A convertible preferred shares, par value \$0.0001 per share, or the Series Pre-A Preferred Shares, and Series A convertible preferred shares, par value \$0.0001 per share, or the Series A Preferred Shares, to the preferred holders of Connect SZ as consideration for the same equity interests they held in Connect SZ, respectively. Following these transactions, the shareholders of Connect SZ became shareholders of our company and Connect SZ became a wholly owned subsidiary of Connect HK. We refer to the 2018 events described above as the Restructuring.

Connect SZ continues to hold 100% of the equity interest in Connect SH and Connect Biopharma (Beijing) Co., Ltd., or Connect BJ, which was formed subsequent to the Restructuring in July 2019 as a limited liability company incorporated under the laws of the PRC.

Following the Reorganization and the Restructuring, each as described above, Connect Biopharma Holdings Limited became the ultimate parent of the Company and all its subsidiaries.

The following diagram illustrates our corporate structure as of the date of this prospectus:



### Corporate Information

We are a Cayman Islands exempted company incorporated with limited liability and were incorporated in November 2015. Prior to this, the business was conducted by Connect SZ which was incorporated in May 2012 in Suzhou in the PRC. Our registered office in the Cayman Islands is at the offices of Maples Corporate Services Limited at PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. Our principal executive offices are located at Science and Technology Park, East R&D Building, 3rd Floor, 6 Beijing West Road, Taicang, Jiangsu, China 215400, and our telephone number is +86 512 5357 7866. Our website address is [www.connectbiopharm.com](http://www.connectbiopharm.com). The information contained on, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

### Summary of Risk Factors

An investment in our ADSs is subject to a number of risks, including risks related to our limited operating history, financial position and capital requirements, risks related to the discovery, development and regulatory approval of our product candidates, risks related to our reliance on third parties, risks related to commercialization of our product candidates, risks related to our business operations and industry, risks related to intellectual property, risks related to doing business in the PRC and risks related to the ADSs and this offering. You should carefully consider all of the information in this prospectus before making an

investment in the ADSs. The following list summarizes some, but not all, of these risks. Please read the information in the section entitled "Risk Factors" for a more thorough description of these and other risks.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- Even if this offering is successful, we will require substantial additional financing to achieve our goals.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur unforeseen costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We depend on enrollment of patients in our clinical trials for our product candidates and may experience delays or difficulties enrolling patients in our clinical trials.
- Our product candidates may be associated with serious adverse events or undesirable side effects or have other properties that could delay or halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- We have conducted and may continue to conduct clinical trials for our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.
- We are early in our development efforts. If we are unable to successfully develop product candidates or experience significant delays in doing so, our business will be materially harmed.
- Our approach to the discovery and development of product candidates based on potent T cell modulation activity is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our approach obsolete.
- As an organization, we are in the process of conducting our first Phase 2 clinical trials for CBP-201 and CBP-307, have never conducted later-stage clinical trials or submitted a New Drug Application, or NDA, or Biologics License Application, or BLA, and may be unable to do so for any of our product candidates.
- The regulatory approval processes of the FDA, the PRC National Medical Products Administration, or NMPA, and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, to conduct certain aspects of our preclinical studies and clinical trials.
- We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately, in certain jurisdictions, for commercialization.
- The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies.
- The COVID-19 pandemic has and could continue to materially and adversely impact our business, including our clinical trials, supply chain and business development activities.
- We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.
- Our success depends on our ability to obtain, maintain, protect and enforce our intellectual property and our proprietary technologies.

- Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.
- There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.
- The approval of the China Securities Regulatory Commission, or the CSRC, may be required in connection with this offering under a PRC regulation. The regulation also establishes more complex procedures for acquisitions conducted by foreign investors that could make it more difficult for us to grow through acquisitions.
- The audit report included in this prospectus was prepared by an auditor who is not inspected by the PCAOB and, as such, our investors are deprived of the benefits of such inspection. In addition, the adoption of any rules, legislations or other efforts to increase U.S. regulatory access to audit information could cause uncertainty, and we could be delisted or prohibited from being traded “over-the-counter” if we are unable to meet the PCAOB inspection requirement in time. This could have a material and adverse impact on the value of your investment.
- An active, liquid and orderly market for the ADSs may not develop, and you may not be able to resell your ADSs at or above the public offering price.
- The trading price of the ADSs could be highly volatile, and purchasers of the ADSs could incur substantial losses.
- As a foreign private issuer, we are not subject to certain U.S. securities law disclosure requirements that apply to a domestic U.S. issuer, which may limit the information publicly available to our shareholders.
- Holders of ADSs have fewer rights than shareholders and must act through the depository to exercise their rights.
- We have identified material weaknesses in our internal control over financial reporting.

### **Implications of Being an Emerging Growth Company and a Foreign Private Issuer**

#### ***Emerging Growth Company***

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- the option to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply 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 (i.e., an auditor discussion and analysis);
- not being required to submit certain executive compensation matters to shareholder advisory votes, such as “say-on-pay,” “say-on-frequency” and “say-on-golden parachutes;” and
- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

As a result, we do not know if some investors will find our ADSs less attractive. The result may be a less active trading market for our ADSs, and the price of our ADSs may become more volatile.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised

accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to irrevocably opt out of this extended transition period and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Under federal securities laws, our decision to opt out of the extended transition period is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion; (ii) the last day of the fiscal year following the fifth anniversary of the completion of this offering; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1 billion in non-convertible debt securities during any three-year period.

***Foreign Private Issuer***

Upon the completion of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. 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 specific information, or current reports on Form 8-K, upon the occurrence of specified significant events.

In addition, we will not be required to file annual reports and consolidated financial statements with the SEC as promptly as U.S. domestic companies whose securities are registered under the Exchange Act, and we will not be required to comply with Regulation FD, which restricts the selective disclosure of material information.

Both foreign private issuers and emerging growth companies also are exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

**THE OFFERING**

ADSs offered by us	ADSs
ADSs to be outstanding immediately after this offering	ADSs (or ADSs if the underwriters exercise in full their option to purchase additional ADSs)
Ordinary shares to be outstanding immediately after this offering	ordinary shares (or ordinary shares if the underwriters exercise in full their option to purchase additional ADSs)
Option to purchase additional ADSs	We have granted the underwriters an option to purchase up to an additional ADSs from us within 30 days of the date of this prospectus.
American Depositary Shares	<p>Each ADS represents ordinary shares, par value \$0.0001 per share.</p> <p>The depositary will hold ordinary shares underlying your ADSs. As an ADS holder, you will not be treated as one of our shareholders and you will not have direct shareholder rights. You will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time.</p> <p>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.</p> <p>You may surrender your ADSs to the depositary in exchange for ordinary shares. The depositary will charge you fees for any exchange.</p> <p>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.</p> <p>To better understand the terms of our ADSs, see “Description of American Depositary Shares.” We also encourage you to read the deposit agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.</p>
Depository	
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase additional ADSs), assuming an initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting



	discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund the research and development of our product candidates, including CBP-201, CBP-307 and CBP-174, to fund the research and preclinical and clinical development of our other development programs, including CBP-233, and to fund other current and future research and development activities and for working capital and other general corporate purposes, which may include capital projects. See “Use of Proceeds.”
Risk factors	See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our ADSs.
Directed share program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to % of the ADSs offered hereby for our directors, officers, employees, business associates and related persons through a directed share program. ADSs purchased through the directed share program will not be subject to a lock-up restriction, except in the case of ADSs purchased by any of our directors or officers. We do not know if any of these potential investors will choose to purchase all or any portion of the allocated shares, but the number of ADSs available for sale to the general public will be reduced to the extent these individuals or entities purchase such reserved ADSs. Any ADSs that are not so purchased will be offered by the underwriters to the general public on the same basis as the other ADSs offered by this prospectus. See “Underwriting” for more information.
Proposed Nasdaq Global Market symbol	“CNTB”
	The number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering is based on 77,254,917 ordinary shares outstanding as of September 30, 2020, inclusive of the 4,473,305 ordinary shares issued to Connect Union, Inc., or Connect Union, as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company pursuant to the 2019 Stock Incentive Plan, or the 2019 Plan (including the 166,468 additional ordinary shares issued to Connect Union in December 2020), and after giving effect to the automatic conversion of all our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares (including the conversion of 4,744,341 shares of our Series C redeemable convertible preferred shares, or the Series C Preferred Shares, issued in December 2020 into 4,744,341 ordinary shares) immediately prior to the completion of this offering. The number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering excludes (i) ordinary shares we have agreed to issue to our founders upon the completion of this offering pursuant to the Second Amended and Restated Shareholders Agreement, or Shareholders Agreement, by and among us and certain of our shareholders, and (ii) ordinary shares to be reserved for future issuance under our 2021 Incentive Award Plan, or the 2021 Plan, which have not previously been issued to Connect Union, and ordinary shares to be reserved for future issuance under our 2021 Employee Share Purchase Plan, or the 2021 ESPP, both of which will become effective in connection with the completion of this offering.
	To implement the 2019 Plan, the 4,473,305 ordinary shares to be issued pursuant to awards under our 2019 Plan were issued to Connect Union as nominee for purposes of the implementation of awards issued or to be

issued to employees, directors and consultants of our company under the 2019 Plan. The 4,473,305 ordinary shares issuable under our 2019 Plan includes (i) 822,149 shares issuable upon the exercise of share options outstanding as of September 30, 2020, with a weighted-average exercise price of \$0.55 per ordinary share; (ii) 12,705 ordinary shares issued pursuant to share options exercised prior to September 30, 2020 and (iii) 1,977,488 shares issuable upon the exercise of share options granted after September 30, 2020, with an exercise price of \$4.69 per ordinary share. See “Management—2019 Stock Incentive Plan” for additional information regarding the 2019 Plan and the settlement of share options described above.

Unless otherwise indicated, all information contained in this prospectus assumes:

- the filing and effectiveness of our amended and restated memorandum and articles of association, which will occur immediately prior to the completion of this offering;
- the issuance of 4,744,341 shares of our Series C Preferred Shares in December 2020;
- the conversion of all our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares (including the conversion of 4,744,341 shares of our Series C Preferred Shares issued in December 2020 into 4,744,341 ordinary shares), which will occur immediately prior to the completion of this offering;
- no exercise of the outstanding share options described above;
- a one-for- reverse share split of our ordinary shares to be effected before the completion of this offering; and
- no exercise by the underwriters of their option to purchase additional ADSs in this offering.

**SUMMARY CONSOLIDATED FINANCIAL DATA**

The following tables present the summary consolidated financial data as of the dates and for the periods indicated for our business. We have derived actual historical amounts included in the following summary of consolidated financial data as of and for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements appearing elsewhere in this prospectus. The historical results presented are not necessarily indicative of our future results. The summary consolidated financial data set forth below should be read together with our audited consolidated financial statements for the years ended December 31, 2018 and 2019 and the related notes to those statements, as well as the sections "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB.

	YEAR ENDED DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 <sup>(1)</sup>
<b>Consolidated Statements of Loss Data:</b>			
Research and development expenses (2)	(59,275)	(106,414)	(15,254)
Administrative expenses(2)	(7,175)	(9,713)	(1,392)
Other income	433	2,836	407
Other gains—net	3,802	3,050	437
<b>Operating loss</b>	<b>(62,215)</b>	<b>(110,241)</b>	<b>(15,802)</b>
Finance income	1,255	1,066	153
Finance cost	(9,905)	(53)	(8)
Finance (cost)/income—net	(8,650)	1,013	145
Fair value loss of financial instruments with preferred rights	(23,012)	(59,397)	(8,514)
<b>Loss before income tax</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
Income tax expense	—	—	—
<b>Loss for the year</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss attributable to:</b>			
Owners of the Company	(76,965)	(168,625)	(24,171)
Non-controlling interests	(16,912)	—	—
	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss per share:</b>			
Basic and diluted	RMB (3.58)	RMB (5.74)	USD (0.82)

(1) USD1.00 = RMB6.9762.

(2) Included share-based compensation as follows:

	AS OF DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 <sup>(1)</sup>
Research and development expenses	584	3,635	521
Administrative expenses	—	240	34
<b>Total</b>	<b>584</b>	<b>3,875</b>	<b>555</b>

(1) USD1.00 = RMB6.9762.

	AS OF DECEMBER 31, 2019					
	ACTUAL		PRO FORMA <sup>(1)</sup>		PRO FORMA AS ADJUSTED <sup>(2)</sup>	
	RMB'000	USD'000 <sup>(3)</sup>	RMB'000	USD'000	RMB'000	USD'000
<b>Consolidated Balance Sheet Data:</b>						
Cash and cash equivalents	308,972	44,289				
Financial assets at fair value through profit or loss	30,632	4,391				
Working capital <sup>(4)</sup>	335,415	48,079				
Total assets	372,588	53,410				
Financial instruments with preferred rights <sup>(5)</sup>	643,008	92,172				
Total liabilities	670,875	96,167				
Total shareholders' deficit	(298,287)	(42,757)				

(1) Gives effect to (i) the receipt of approximately \$135.0 million of gross proceeds from the sale of 21,349,537 shares of our Series C Preferred Shares, (ii) the automatic conversion of all of our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares and the resultant reclassification of the carrying value of the convertible preferred shares to permanent equity, and (iii) the filing and effectiveness of our amended and restated memorandum and articles of association; items (ii)-(iii) of which will occur immediately prior to the completion of this offering.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of ADSs in this offering at an assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total shareholders' deficit by \$ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1,000,000 in the number of ADSs offered by us in this offering, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total shareholders' deficit by \$ million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the assumed initial public offering price remains the same. The pro forma and pro forma as adjusted information discussed above is illustrative only and will depend on the actual public offering price, the actual number of ADSs offered by us and other terms of this offering determined at pricing.

(3) USD1.00 = RMB6.9762.

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

(5) Financial instruments with preferred rights will be settled at the completion of this offering through the issuance of ordinary shares.

## RISK FACTORS

*You should carefully consider the risks and uncertainties described below and the other information in this prospectus, including our consolidated financial statements and related notes appearing elsewhere in this prospectus and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our ADSs. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.*

### **Risks Related to Our Limited Operating History, Financial Position and Capital Requirements**

***We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.***

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2012, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, performing research and development activities, establishing our intellectual property portfolio, discovering potential product candidates and conducting preclinical studies and clinical trials. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. CBP-201 and CBP-307 are in clinical development, while our other development programs remain in the preclinical or discovery stage. We have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses were RMB93.9 million and RMB168.6 million (USD24.2 million) for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of RMB292.1 million (USD41.9 million). Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our current or future product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve

profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***Even if this offering is successful, we will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.***

The development of biopharmaceutical product candidates is capital-intensive. Since our inception, we have used substantial amounts of cash to fund our operations and we expect our expenses to increase in connection with our ongoing activities during the next few years, particularly as we conduct our ongoing and planned clinical trials of CBP-201, CBP-307 and CBP-174, continue research and development for and initiate clinical trials of our other development programs, including CBP-233, and seek regulatory approval for our current product candidates and any future product candidates we may develop. In addition, as our product candidates progress through development and toward commercialization, we will need to make royalty payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates, including Arena, from whom we have licensed certain patents and know-how relating to H3R antagonists. For more information regarding our license agreement with Arena, see “Business—Licensing Agreements.” Furthermore, if and to the extent we seek to acquire or in-license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, licensing payments, royalty payments and/or other types of payments. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash and cash equivalents and the net proceeds from this offering will be sufficient to meet our anticipated cash and capital expenditure requirements for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. The impact of the COVID-19 pandemic on the capital markets may affect the availability, amount and type of financing available to us in the future. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials and preclinical studies of our product candidates which we are pursuing or may choose to pursue in the future;
- safety concerns related to the use of our product candidates;
- adverse findings regarding the efficacy of our product candidates as additional information is acquired;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining, enforcing and defending our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;

- the costs associated with hiring additional personnel and consultants as our clinical activities increase;
- the timing and amount of the royalty or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any product candidates, products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

***Raising additional capital may cause dilution to our shareholders, including purchasers of the ADSs in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar 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 funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our ADSs.

#### **Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates**

***Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur unforeseen costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

All jurisdictions in which we intend to conduct our clinical drug development activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of the PRC and the United States. We currently conduct clinical trials in the United States, the PRC, Australia and New Zealand and must comply with the numerous and varying regulatory requirements of each jurisdiction. Before obtaining marketing approval from the FDA, the NMPA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the efficacy and safety of our product candidates. Clinical testing is expensive, time-consuming and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. 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 marketing approval of their drugs.

## [Table of Contents](#)

To date, we have not completed any pivotal clinical trials for any of our product candidates. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA, the NMPA or another regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments in trials conducted by competitors for related technology that raises FDA, NMPA or foreign regulatory authority concerns about risk to patients of the technology broadly, or findings by the FDA, the NMPA or a foreign regulatory authority that an investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling suitable patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's, the NMPA's or any other regulatory authority's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trials of the same class of agents conducted by other companies;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;



- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing processes; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical and clinical trials. For example, enrollment of our Phase 2 clinical trial of CBP-307 in patients with CD in the PRC was prematurely terminated due to challenges in recruitment caused by the COVID-19 pandemic. Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

Clinical trials must be conducted in accordance with the FDA, the NMPA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, the NMPA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the NMPA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, which we are doing for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services, languages or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, the NMPA or comparable foreign regulatory authorities. The FDA, the NMPA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, the NMPA or a comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, the NMPA or a comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. 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 our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

***We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling patients in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as 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. In addition, there may be limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment also depends on many other factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential risks and advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner, or may require us to abandon one or more clinical trials altogether. For example, enrollment of our Phase 2 clinical trial of CBP-307 in patients with CD in the PRC was prematurely terminated due to challenges in recruitment caused by the COVID-19 pandemic. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some 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 our product candidates.

***Our product candidates may be associated with serious adverse events or undesirable side effects or have other properties that could delay or halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the NMPA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more

extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. In the single-dose regimen of our Phase 1 trial of CBP-307, one healthy adult treated with 2.5mg of CBP-307 experienced bradycardia associated with transient asystole, which was deemed a treatment-related serious adverse event. The healthy adult was treated with high-flow oxygen and fully recovered.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to cease selling any product candidates or products for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

***We have conducted and may continue to conduct clinical trials for our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.***

We have conducted, and may in the future choose to conduct, clinical trials outside the United States for our product candidates. Although the FDA may accept data from clinical trials conducted outside the United States not conducted under IND, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted in accordance with Good Clinical Practices, or GCPs, and the FDA must also be able to validate the data from the study through an on-site inspection if necessary. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for which we intend to seek approval for the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. Many foreign regulatory bodies, such as the NMPA, 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, NMPA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, NMPA or any similar foreign regulatory authority does not accept the data from our clinical trials of our product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

**Interim, “top-line” and 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.**

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line 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, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our ADSs or ordinary shares after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

**We may attempt to secure approval from the FDA, the NMPA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, the NMPA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, the NMPA or such comparable foreign regulatory authority may seek to withdraw accelerated approval.**

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program in the United States, for example, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA or the NMPA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA or the NMPA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA or NMPA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, the NMPA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type.

Further, there have been recent regulatory initiatives in the PRC in relation to clinical trial approvals, the evaluation and approval of certain drugs and medical devices and the simplification and acceleration of the clinical trial process. As a result, the regulatory process in the PRC is evolving and subject to change.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for one of our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***We are early in our development efforts and have only two product candidates, CBP-201 and CBP-307, in clinical development. All of our other development programs are still in the preclinical or discovery stage. If we are unable to successfully develop product candidates or experience significant delays in doing so, our business will be materially harmed.***

We are in the early stages of our development efforts and have only two product candidates, CBP-201 and CBP-307, in clinical development. One of our lead product candidates, CBP-201, entered into a Phase 2b clinical trial in June 2020 for atopic dermatitis, and our other lead product candidate, CBP-307, entered into a Phase 2 clinical trial in October 2018 for ulcerative colitis. All of our other development programs, including CBP-174 and CBP-233, are still in the preclinical or drug discovery stage and will need to progress through IND-enabling studies prior to clinical development. We have invested substantially all of our efforts and financial resources into developing our current product candidates, identifying potential product candidates and conducting preclinical studies and clinical trials. As a result, we have limited infrastructure and experience in conducting clinical trials as a company and in engaging in regulatory interactions, and cannot be certain that our ongoing or planned clinical trials will be initiated or completed on time, if at all, that our planned development programs would be acceptable to the FDA, the NMPA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Because of the early stage of our development and clinical programs, the success of our product candidates will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- submission of and authorization to proceed with clinical trials under INDs by the FDA or similar regulatory filing by the NMPA or comparable foreign regulatory authorities for the conduct of clinical trials of our preclinical product candidates and our proposed design of future clinical trials;
- demonstrating safety, purity, potency and/or efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including NDAs or BLAs from the FDA or similar regulatory filings from the NMPA, and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

- establishment, maintenance, enforcement and defense of patent, trade secret and other intellectual property and proprietary protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our products following approval, if any;
- the impact of the COVID-19 pandemic on our current or future clinical trials, including any enrollment delays; and
- maintaining and growing an organization of people who can develop our products and technology.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy or safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety or efficacy of any of our product candidates sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

***Our approach to the discovery and development of product candidates based on potent T cell modulation activity is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our approach obsolete.***

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on the rapid identification of molecules with potent T cell modulation activity, which is a novel and unproven approach. Our drug screening approach is designed to enable us to identify and develop product candidates targeting multiple allergic and autoimmune diseases.

While we believe our preclinical results and Phase 1 results for each of CBP-201 and CBP-307 were supportive of further clinical development, we have not yet succeeded and may never succeed in demonstrating the safety and efficacy of any of our product candidates in later stage clinical trials or in obtaining marketing approval thereafter. Our two clinical-stage product candidates, CBP-201 and CBP-307, are in Phase 2b and Phase 2 clinical trials, respectively. Our other development programs are in preclinical development, and we have not yet completed any later stage clinical trials for any other product candidates.

Our approach to targeting molecules that we believe have potent T cell modulation activity may be unsuccessful in identifying additional product candidates, and any product candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the product candidates unmarketable or unlikely to receive marketing approval. Further, because all of our development programs are based on our drug screening approach, adverse developments with respect to either of our CBP-201 and CBP-307 programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our T cell modulating activity approach. If we fail to stay at the forefront of technological change in utilizing this technology and approach to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches (including, for example, using different targeting approaches from ours), potentially eliminating the advantages that we believe we derive from our targeting of molecules with potent T cell modulation activity. By contrast, adverse developments with respect to other companies that attempt to use a similar T cell modulation approach to ours may adversely impact the actual or perceived value of and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

***As an organization, we are in the process of conducting our first Phase 2 clinical trials for CBP-201 and CBP-307, have never conducted later-stage clinical trials or submitted an NDA or BLA, and may be unable to do so for any of our product candidates.***

We are early in our development efforts for our product candidates, and we will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA, NMPA or comparable foreign regulatory approval to market any of our current or future product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA or BLA is a complicated process. We have not previously conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an IND or an NDA or BLA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert the attention of management. In addition, we have had limited interactions with the FDA and the NMPA and cannot be certain how many additional clinical trials of CBP-201, CBP-307, CBP-174 or any other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that will support regulatory submissions and lead to approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs or BLAs for and commercializing our product candidates.

***The regulatory approval processes of the FDA, the NMPA and comparable foreign authorities are lengthy, time consuming and unpredictable, 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 approval by the FDA, the NMPA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate in the United States, the PRC or any other jurisdiction, and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or any other jurisdiction until we receive regulatory approval of an NDA or BLA from the FDA or the comparable foreign regulatory submission from a foreign regulatory authority.

Prior to obtaining approval to commercialize a product candidate in the United States, the PRC or elsewhere, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, the NMPA or foreign regulatory agencies, that such product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, the NMPA or other regulatory authorities. The FDA or the NMPA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA, the NMPA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates, or require us to conduct additional nonclinical or clinical testing or abandon a program for many other reasons, including the following:

- the FDA, the NMPA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the NMPA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required for approval by the FDA, the NMPA or comparable foreign regulatory authorities;

## Table of Contents

- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the NMPA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or NDA or other submission or to obtain regulatory approval in the United States, the PRC or elsewhere;
- the FDA, the NMPA or applicable foreign regulatory authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- our clinical sites, investigators or other participants in our clinical trials may deviate from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- the FDA, the NMPA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of ours or third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the NMPA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, the NMPA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical trials and receive approval of an NDA, BLA or foreign marketing application for our product candidates, the FDA, the NMPA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA, the NMPA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

***Disruptions at the FDA, the NMPA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and the NMPA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the regulatory authority's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the regulatory authority's ability to perform routine functions. Average review times at the FDA and the NMPA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, the NMPA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on



July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections only to resumption of all regulatory activities. 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, or if global health concerns continue to prevent the FDA, the NMPA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA, the NMPA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

**Risks Related to Our Reliance on Third Parties**

***We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements 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 upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for 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 and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the NMPA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the NMPA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under Current Good Manufacturing Practice, or cGMP, regulations. Our

failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. 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 or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately, in certain jurisdictions, for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We are planning to construct manufacturing facilities in Jiangsu, China, which we expect to be completed by the end of 2023, to be used to develop and manufacture preclinical and clinical material for future clinical trials for certain product candidates and to build commercial supply in certain jurisdictions, including the PRC. However, we rely, and even after our manufacturing facilities are completed, validated and qualified, we expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials, particularly in the U.S. and other non-PRC jurisdictions. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. The expected construction of our manufacturing facilities may also result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. If construction or regulatory approval of our manufacturing facilities is delayed, we may not be able to manufacture sufficient quantities of our product candidates, which would limit our development activities and our opportunities for growth.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We are continuously evaluating multiple vendors both in the PRC and abroad to ensure that we have a continuous supply of product candidates for global studies and trials. However, we may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the NMPA or other comparable foreign regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the NMPA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we currently rely on other third parties to manufacture our product candidates and to perform quality testing and other services, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements are intended to limit the rights of the third parties to use or disclose our confidential information, but such agreements could be

breached, and we might not enter into such agreements with all applicable parties. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, the discovery by a competitor or other third party of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships.***

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidates or manufacturing constraints. For example, we have in-licensed from Arena certain patents and know-how relating to H3R antagonists. We may not be successful in our efforts to establish other such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

***If the custodians or authorized users of our controlling non-tangible assets, including chops and seals, fail to fulfill their responsibilities, or misappropriate or misuse these assets, our business and operations may be materially and adversely affected.***

Under PRC law, legal documents for corporate transactions are executed using the chop or seal of the signing entity or with the signature of a legal representative whose designation is registered and filed with the relevant local branch of the State Administration for Market Regulation, or the SAMR. We generally execute legal documents by affixing chops or seals, rather than having the designated legal representatives sign the documents. The chops of our subsidiaries are generally held by the relevant entities so that documents can be executed locally. Although we usually utilize chops to execute contracts, the registered legal representatives of our subsidiaries have the apparent authority to enter into contracts on behalf of such entities without chops, unless such contracts set forth otherwise.

In order to maintain the physical security of our chops, we generally have them stored in secured locations accessible only to the designated key employees of our legal, administrative or finance departments. Our designated legal representatives generally do not have access to the chops. Although we have approval procedures in place and monitor our key employees, including the designated legal representatives of our subsidiaries, the procedures may not be sufficient to prevent all instances of abuse or negligence. There is a risk that our key employees or designated legal representatives could abuse their authority, for example, by binding our subsidiaries with contracts against our interests, as we would be obligated to honor these contracts if the other contracting party acts in good faith in

reliance on the apparent authority of our chops or signatures of our legal representatives. If any designated legal representative obtains control of the chop in an effort to obtain control over the relevant entity, we would need to have a shareholder or board resolution to designate a new legal representative and to take legal action to seek the return of the chop, apply for a new chop with the relevant authorities, or otherwise seek legal remedies for the legal representative's misconduct. If any of the designated legal representatives obtains and misuses or misappropriates our chops and seals or other controlling intangible assets for whatever reason, we could experience disruption to our normal business operations. We may have to take corporate or legal action, which could involve significant time and resources to resolve while distracting management from our operations, and our business and operations may be materially and adversely affected.

#### **Risks Related to Commercialization of Our Product Candidates**

***Even if our product candidates receive regulatory approval, they will be subject to ongoing regulatory review and significant post-marketing regulatory requirements and oversight.***

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, the NMPA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, the NMPA and other regulatory authorities to ensure compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, failure to comply with FDA, NMPA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in reviewing or the rejection of product applications or supplements to approved applications;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's, the NMPA's and other regulatory authorities' policies may change, and 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 if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

***The FDA, the NMPA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.***

If any of our product candidates are 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 NMPA 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 NMPA or such other regulatory agencies as reflected in the product's approved labeling. 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. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. 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.

***The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.***

Our product candidates may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or others in the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any regulatory authority-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients, healthcare payors or others in the medical community, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and healthcare payors regarding the benefits of our products may require significant resources and may never be successful.

***The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the PRC, the European Union, or EU, or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or safety with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, including the PRC, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

In the PRC, the Ministry of Human Resources and Social Security of the PRC or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our product candidates will be included in the NRDL after initial approval for

commercial sale. Pharmaceutical products included in the NRDL are typically generic and essential drugs. Innovative drugs similar to our product candidates have historically been more limited on their inclusion in the NRDL due to cost constraints. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive.

Moreover, increasing efforts by governmental and third-party payors in the United States, the PRC and other jurisdictions to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Outside the United States and the PRC, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits.

***We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.***

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products or product candidates competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the fields of immunology and inflammation. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and in identifying, in-licensing and establishing intellectual property and proprietary protection for new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect to face competition from existing products and products in development for each of our product candidates as described in the section titled "Business – Competition" elsewhere in this prospectus.

We have competitors in the United States, the PRC and elsewhere, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and



commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

***If the market opportunities for our products are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.***

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases.

The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States, the PRC and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

***We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.***

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates.

If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of product candidates;
- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property and other proprietary rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- the effects of applicable non-PRC tax structures and potentially adverse tax consequences;
- changes in a specific country's or region's political and cultural climate or economic condition;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- workforce uncertainty in countries where labor unrest is common;
- failure of our employees and contracted third parties to comply with rules and regulations of the U.S. Treasury Department's Office of Foreign Assets Controls and the U.S. Foreign Corrupt Practices Act of 1977, as amended, and other applicable rules and regulations;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from an international market with low or lower prices rather than buying them locally;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, or public health epidemics, including the COVID-19 pandemic.

#### **Risks Related to Our Business Operations and Industry**

***The COVID-19 pandemic has and could continue to materially and adversely impact our business, including our clinical trials, supply chain and business development activities.***

In December 2019, a novel strain of coronavirus, COVID-19, was first reported in Wuhan, PRC and has since become a global pandemic. In an effort to contain the spread of COVID-19, many countries, including the PRC, the United States and most other jurisdictions around the world, have imposed unprecedented restrictions on travel, business closures, quarantines and lock-downs, resulting in a substantial reduction in economic activity. On January 30, 2020, the World Health Organization, or WHO, declared this COVID-19 outbreak a Public Health Emergency of International Concern. On February 28, 2020, the WHO increased the assessment of the risk of spread and the risk of impact of COVID-19 to "very high" at a global level. On March 11, 2020, the WHO declared the COVID-19 outbreak a pandemic.

As COVID-19 has evolved into a worldwide health crisis, it has resulted in adverse effects in the global economy and financial markets, such as significant declines in the global stock markets. We may experience limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 have and may continue to negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and have caused, and may further cause, disruptions to our supply

chain and may impair our ability to execute our business development strategy. For example, enrollment of our Phase 2 clinical trial of CBP-307 in patients with CD in the PRC was prematurely terminated due to challenges in recruitment caused by the COVID-19 pandemic. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be limited or curtailed.

As COVID-19 continues to spread, we may continue to experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving authorizations from local regulatory authorities to initiate our planned clinical trials;
- delays or additional difficulties in enrolling and retaining patients in our clinical trials;
- risk that patients may withdraw from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine, which could adversely influence the results of a clinical trial by increasing the number of adverse events or patients lost to follow-up;
- delays or difficulties in clinical site initiation or expansion, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- changes in regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- delays in necessary interactions with regulators, ethics committees and other agencies and contractors due to limitations in employee resources or forced furloughs of government or contractor personnel;
- interruption or delays in the operations of the FDA, the NMPA or other regulatory authorities, which may adversely affect review and approval timelines; and
- refusal of a regulatory authority to accept data from clinical trials in affected geographies outside its jurisdiction.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, at the onset of the COVID-19 pandemic, some of our clinical trial sites, including, as noted above, our Phase 2 clinical trial for CBP-307 for CD, experienced slow-down of enrollment of new patients in clinical trials, denied access to site monitors and otherwise impacted certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA on March 18, 2020 and most recently updated on December 4, 2020, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective in mitigating risks, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders related to COVID-19 or other infectious diseases, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could adversely affect personnel at third-party manufacturing facilities upon which we rely, or the

availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it has already caused, and could result in further, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our ADSs or other securities and such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the PRC, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.***

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- the timing and amount of the royalty or other payments we must make to the licensors and other third parties from whom we have in-licensed our acquired our product candidates, including payments due upon a change in control of our subsidiaries;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or

investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of the ADSs could decline substantially. Such an ADS price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

***We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon our senior management, particularly our Chief Executive Officer and our President and Chairman, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees, except for our Chief Executive Officer and Chairman. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We compete for qualified management and scientific personnel with other life science and technology companies, universities, and research institutions in the United States, the PRC and other countries. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

We had 53 full-time employees as of December 31, 2020. As we continue development and pursue the potential commercialization of our product candidates, as well as function as a public company, we will need to continue to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

***Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on specific product candidates, indications and development programs. We also plan to conduct several clinical trials for multiple product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial

technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

***We are subject to various foreign, federal, and state healthcare and privacy laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare and privacy laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the U.S. false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning January 1, 2022, manufacturers will also need to report payments and other transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; 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 and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the collection, processing, distribution, use, privacy, security, storage and other use of health information and other personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR, and the California Consumer Protection Act, or CCPA), many of which differ from each other in significant ways and often are not preempted by HIPAA.

The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Complying with such requirements can be difficult, time-consuming, expensive, and could require us to change our business practices and put in place additional compliance mechanisms. Failure to comply with laws, regulations and contractual and other obligations governing personal or other sensitive information could result in enforcement actions against us, including fines, public censure, processing penalties, claims for damages by affected individuals, damage to our reputation and loss of goodwill. It is possible that new and existing laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful.

For example, as of May 25, 2018, the GDPR replaced the Data Protection Directive with respect to the processing of personal data in the EU. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal data that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. In addition, the GDPR confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Economic Area, or EEA, including the United States and the PRC.

The GDPR increases our obligations with respect to clinical trials conducted in the EU by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. The United Kingdom has transposed the GDPR into domestic law, with its version of the GDPR having taken effect in January 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines for certain violations. Other EU countries have also passed or are considering passing similar laws.

In addition to HIPAA, privacy and data security laws and regulations are also either in place or underway in the United States. For example, the CCPA, which became effective on January 1, 2020, requires companies that process information on California residents to make new disclosures to consumers about their data collection, use

and sharing practices, provides such individuals with new data privacy rights, including the ability to opt out of certain sales of personal information, imposes new operational requirements for covered businesses, provides a private right of action for data breaches and creates a statutory damages framework. Many other states are considering similar legislation, and a broad range of legislative measures also have been introduced at the federal level. In addition, on November 3, 2020, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data.

Regulatory authorities in the PRC have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the PRC's Cyber Security Law, which became effective in June 2017, created the PRC's first national-level data protection for "network operators," which may include all organizations in the PRC that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. 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, which may, upon enactment, require security review before transferring human health-related data out of the PRC. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in the PRC. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources in May 2019, which require approval from the Science and Technology Administration Department of the State Council where human genetic resources, or HGR, are involved in any international collaborative project and additional approval for any export or cross-border transfer of the HGR samples or associated data. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in the PRC and elsewhere are often uncertain and in flux.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our data privacy practices and our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive share options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.***

In the United States, the PRC and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures



that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the Public Health program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. The Fifth Circuit Court of Appeals affirmed the District Court's ruling that the individual mandate was unconstitutional, but it remanded the case back to the District Court for further analysis of whether the mandate could be severed from the Affordable Care Act (i.e., whether the entire Affordable Care Act was therefore also invalid). The Supreme Court of the United States granted certiorari on March 2, 2020, and held oral argument on November 10, 2020, and the case is expected to be decided by mid-2021. It is unclear how the Supreme Court will rule, or how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

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, resulted in 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, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. 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.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, on March 10, 2020, the Trump 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. Additionally, the Trump administration's budget proposal for the fiscal year 2021 includes 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. Further, the Trump administration has issued a number of executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. It is difficult to predict how these executive actions will be implemented, if at all. The

policies and priorities of the new incoming Presidential administration and the impact of any new legislation governing our product candidates, if approved, are unknown.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients with life-threatening diseases or conditions to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval 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.

We expect that the Affordable Care Act, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

***We or our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We or our third-party manufacturers or suppliers will use biological materials and potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and those of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we and our third-party manufacturers or suppliers cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Also, we do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. 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 or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.***

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product 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 candidate, negligence, strict liability or a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. 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 or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- difficulty attracting or withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants, patients or other claimants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our ADS price.

We currently hold approximately \$49 million in clinical trial liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. 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 that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts 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.

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or trigger contractual and legal obligations.***

The United States federal and various state government, the PRC government and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, vendors and collaborators may fail and are vulnerable to breakdown, breach, interruption or damage from computer viruses, cybersecurity threats, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, fire and telecommunication and electrical failures. The risk of a security breach or disruption has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security

threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Our information technology and other internal infrastructure systems, including corporate firewalls, servers and connection to the Internet, face the risk of systemic failure that could disrupt our operations.

If such an event were to occur and cause interruptions in our operations or result in the unauthorized use, disclosure of or access to personally identifiable information or individually identifiable health information (potentially violating certain privacy laws such as the GDPR), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions cause us to breach our contractual obligations, subject us to mandatory corrective action, and otherwise subject us to liability under laws, regulations and contracts that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. Some applicable federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Any costs might not be covered by insurance, in whole or in part. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. 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. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 or use of confidential or proprietary information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance with certain privacy and security laws. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA, the NMPA or other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP requirements, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by

employees and other third parties, 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 or regulations.

In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We are subject to U.S., PRC and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. We are also subject to anti-bribery laws in the PRC that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. State and national anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. For example, we have in-licensed from Arena certain patents and know-how relating to H3R antagonists. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including the ADSs, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of

the nature described above, any such transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and ADS price.***

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and the price of our ADSs and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

**Risks Related to Intellectual Property**

***Our success depends on our ability to obtain, maintain, protect and enforce our intellectual property and our proprietary technologies.***

Our success depends in part on our ability to obtain and maintain patent, trade secret and other intellectual property and proprietary protection for our current and any future product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon, misappropriating or otherwise violating the intellectual property and proprietary rights of others. If we are unable to protect our intellectual property and proprietary rights or if our intellectual property and proprietary rights are inadequate for our current or any future product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States, the PRC and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents, pending patent applications and other intellectual property from third parties. For example, we have in-licensed from Arena certain patents and know-how relating to H3R antagonists. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover such technology. There can be no assurance that our current or future patent applications or the patent applications of our current and future licensors will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States, the China National Intellectual Property Administration, or NIPA, courts in the PRC or by the patent offices and courts in other jurisdictions or will result in patents being issued. In addition, there can be no assurance that any issued patents will afford sufficient protection against competitors or other third parties with similar technology, or will not be infringed, designed around or invalidated. Even issued patents may later be found invalid or unenforceable, in whole or in part, or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in the PRC is required to report to NIPA for confidentiality examination. Otherwise, if an application is later filed in the PRC, the patent right will not be granted. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our current and any future product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our current and any future product

candidates by obtaining, maintaining, defending and enforcing patents. These risks and uncertainties include the following:

- the USPTO, NIPA and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other obligations during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our current and any future product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those of the United States, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We and our current and future licensors may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of the patent applications, which may result in such patents being narrowed, invalidated or held unenforceable. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license to or from third parties. We may also require the cooperation of our licensors, licensees or other collaborators in order to enforce or defend the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospect.

***If we fail to comply with our obligations under any license, collaboration or other agreements, or otherwise experience disruptions to our business relationships with our collaborators or licensors, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future product candidates.***

We have in-licensed certain intellectual property rights relating to H3R antagonists from Arena, and we may license intellectual property rights from others in the future. If, for any reason, our license agreement with Arena or any future licensor is terminated or we otherwise lose the rights associated with such license, it could adversely affect

## [Table of Contents](#)

our business. Our license agreement with Arena imposes, and any future collaboration agreements or license agreements we enter into are likely to impose, various development, commercialization, funding, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us, as well as milestone, royalty, annual maintenance and other payment obligations. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, or if, in spite of our efforts, a collaborator or licensor concludes that we have materially breached our obligations under such agreement, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and commercialize products that are covered by the licensed technology or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor or other third party to gain access to the licensed technology. Additionally, if any future license agreement includes a sublicense from a third party who is not the original licensor of the intellectual property at issue, then we must rely on our direct licensor to comply with its obligations under the primary license agreements under which such licensor obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If such a licensor fails to comply with its obligations under its upstream license agreement, including due to the impact of the COVID-19 pandemic on its business operations, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms or at all, or such license may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. Any such events may impact our ability to continue to develop and commercialize our current and any future product candidates incorporating the relevant intellectual property.

We may need to obtain further licenses from third parties to advance our research or allow commercialization of our current and any future product candidates, and we cannot provide any assurances that third-party patents or other intellectual property or proprietary rights do not exist which might be enforced against our current and any future product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of high importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- 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, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patents and other intellectual or proprietary rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current and any future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of patents, inventions, know-how and other intellectual property and proprietary rights resulting from activities performed by our licensors, us and our partners.

These agreements may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property



that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates. In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. Any of the foregoing would have a material adverse effect on our business, financial conditions, results of operations and prospects.

***If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors and other third parties from commercializing product candidates similar or identical to ours would be adversely affected.***

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. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Similarly, in the PRC, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in the PRC. For example, a Draft Amendment to the PRC Patent Law was released in January 2019 and updated in July 2020, which proposes introduction of patent term extensions to eligible innovative drug patents. If adopted, the terms of our PRC patents may be eligible for extension and allow us to extend patent protection of our products, and the terms of the patents owned by third parties may also be extended, which may in turn affect our ability to commercialize our products candidates, if and when approved, without facing infringement risks. The length of any such patent term extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new competitor products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. During the patent examination process, we or our licensors may be required to narrow the pending claims to overcome prior art, a process that may limit the scope of patent protection. Even if patent applications we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any future patents that we own or license, now or in the future, may be challenged or circumvented by third parties or may be narrowed, modified, invalidated or revoked as a result of challenges by third parties. Consequently, we do not know whether our current or any future product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our future patents or the patents of our current and future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States, the PRC or elsewhere. The inventorship and ownership rights for patents that we own or in-license or may own or in-license in the future may be challenged by third parties. Such challenges could result in loss of exclusive rights to such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or require us to obtain a license from such third parties on commercially reasonable terms to secure exclusive rights. If any such challenges to inventorship or ownership were asserted, there is no assurance that a court would find in our favor or that, if we choose to seek a license, such license would be available to us on acceptable terms or at all.

Moreover, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents or patent applications (which submissions may be made prior to a patent's issuance) or otherwise become involved in pre- and post-issuance proceedings, including opposition, derivation, re-examination, revocation, inter partes review, post-grant review, interference or other proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. For example, if we or a licensor or other collaborator initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, in whole or in part, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Any loss of patent rights, loss of exclusivity or patent claims being narrowed, invalidated or held unenforceable, in whole or in part, could limit our ability to stop others from using or commercializing similar or identical technology and products, without payments to us, limit the duration of the patent protection of our current or any future product candidates, or result in our inability to manufacture and commercialize our product candidates, which could materially and adversely impact our business. Proceedings relating to intellectual property also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our current and future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our current or any future product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

***The patent protection and patent prosecution for our current or any future product candidates may be dependent on third parties.***

We may in the future rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect and enforce the licensed intellectual property under certain current and future license agreements. Under such arrangements, we may not have sufficient control over these activities for certain licensed patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, our current and future licensors or licensees may not be fully cooperative or disagree with us as to the prosecution, maintenance, enforcement or defense of any patent rights, which could compromise such patent rights. Therefore, we cannot be certain that such patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business.

We may in the future enter into license agreements where the licensors or licensees may have the right to control enforcement of the licensed patents or defense of any claims asserting the invalidity of these patents, and even if we are permitted to pursue such enforcement or defense, it might require the cooperation of our licensors or licensees. We cannot be certain that our licensors or licensees will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business or result in invalidation or limitation of the scope of the licensed patents or other intellectual property rights. If any of our current or future licensors, licensees or collaborators fail to appropriately prosecute and maintain patent protection for patents covering our current or any future product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products.

In addition, even where we have the right to control prosecution, maintenance, enforcement and defense of patent applications or patents we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of prior owners, licensors and/or their counsel that took place prior to us assuming control over such activities.

Licensors may retain certain rights to the technology that they license to us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether such licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to the licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If we are not successful in obtaining patent term extensions for our current and future product candidates, our business may be harmed, and the absence of patent linkage, patent term extension and data and market exclusivity for product candidates approved by the NMPA could increase the risk of early generic competition with our products in the PRC.***

Patents have a limited lifespan. In the United States, for example, the natural expiration of a patent is generally 20 years after the filing of the earliest non-provisional application to which the patent claims priority. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We may be required to disclaim a portion of patent term in order to overcome double patenting rejections from the applicable patent office, thus potentially shortening our exclusivity period. Without patent protection for our current or future product candidates, we may be open to competition, including from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Hence, we expect to seek extensions of patent terms in the United States and abroad.

Depending upon the timing, duration and specifics of FDA marketing approval of our current and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon obtaining the applicable regulatory approval for our current and any future product candidates. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

If we or our licensors are unable to extend the expiration date of our or their existing patents or obtain new patents with longer expiry dates, as applicable, our competitors and other third parties may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

The Hatch-Waxman Amendments also provide 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 Amendments provide 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.

In the PRC, however, there is no currently effective law or regulation providing for patent term extension, patent linkage or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. PRC regulators have set forth a framework for integrating patent linkage and data exclusivity into the PRC regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, no regulations have been issued. These factors result in weaker protection for us against generic competition in the PRC than could be available to us in the United States. For instance, the patents we have in the PRC are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***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 noncompliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO, NIPA and other foreign patent agencies in several stages over the lifetime of the patent. In addition, the USPTO, NIPA and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on an international patent application, failure to respond to official actions within prescribed time limits, 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 patents and patent applications, whether owned or in-licensed now or in the future, covering any of our current or future product candidates and technologies, our competitors might be able to enter the market, which would have an adverse effect on our business, financial condition, results of operations and prospects.

***Third-party claims or litigation alleging infringement, misappropriation or other violation of, or seeking to invalidate, patents or other intellectual and proprietary rights, may delay or prevent the development and commercialization of any of our current or future product candidates.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits and interference, derivation, inter partes review and post-grant review proceedings before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Litigation or other proceedings relating to intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our current and future product candidates.

One or more third parties may challenge our current or future patents, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims, or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic copy of one of our products, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book, or Orange Book, with respect to our NDA for the

applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Grounds for an unenforceability assertion includes an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Any challenge to our current or future patents could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic copy of our product.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current and future product candidates. Numerous U.S., PRC and other foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are or may in the future be developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.

Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be currently pending patent applications—including ones we are unaware of—that may later result in issued patents that our current and future product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Even if we believe that such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patents were held by a court of competent jurisdiction to be valid and enforceable and cover the manufacturing process of any of our current and future product candidates, any molecules formed during such manufacturing process, any final products resulting from such manufacturing process, or our formulations or methods of use thereof, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license would likely include significant payment and other obligations, or may not be available on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. In addition, we may be subject to claims that we are infringing, misappropriating or otherwise violating others' intellectual property rights, such as trademarks, copyrights or trade secrets, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we also may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our current and future product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. As a result, we might be unable to further develop and commercialize any affected product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ADSs or ordinary shares. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

***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.***

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 dates of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, the PRC and elsewhere that is relevant to or necessary for the commercialization of our 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 application may be incorrect, which may negatively affect our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the PRC or elsewhere that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively affect our ability to develop and market our products.

***We may need to acquire or license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

Because our development programs may require the use of intellectual property rights held by other parties, the growth of our business may depend in part on our ability to acquire, in-license or use such third-party intellectual property rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our current and any future product candidates. 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. 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. 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 applicable program and/or develop alternative approaches that do not infringe, misappropriate or otherwise violate such intellectual property rights. This could entail additional costs and development delays, and the development of such alternatives may not be feasible. Any of the foregoing could prevent us from developing or commercializing one or more of our product candidates, force us to modify such product candidates, or cease some

aspect of our business operations, and our business, financial condition, results of operations and prospects could suffer.

***We may become involved in lawsuits to protect or enforce our or our licensors' patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe, misappropriate or otherwise violate our or our licensors' patents or other intellectual property rights. To counter infringement or unauthorized use, we or our licensors may be required to file legal claims, which can be expensive and time-consuming. In addition, in such a proceeding, a court may decide that an asserted patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the asserted patent or other intellectual property right does not cover the third-party technology in question. An adverse result in any litigation or defense proceedings could put one or more asserted patents at risk of being invalidated or interpreted narrowly and could put related patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, the PRC and elsewhere, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, NIPA or any other applicable patent office, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. For patents and patent applications that we license in the future, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. 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 or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ADSs or ordinary shares. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Derivation, interference or other proceedings may be necessary to determine priority of inventions relating to our current or future product candidates, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.***

Derivation, interference or other proceedings provoked by third parties or brought by us or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our current or future patents or patent applications or those of our current and future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Our defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into

development or manufacturing partnerships that would help us bring our current and any future product candidates to market.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing, misappropriating or otherwise violating our owned or in-licensed patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing a claim or action against such third party may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our current and future patent applications or those of our current and future licensors and the enforcement or defense of our current and future issued patents or those of our current and future licensors.***

Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and are therefore costly, time-consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries could increase those uncertainties and costs.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and challenged at the USPTO and may also affect patent litigation. The USPTO has developed and continues to develop new regulations and procedures to govern administration of the Leahy-Smith Act.

The Leahy-Smith Act established a “first-to-file” system, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Therefore, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. Similarly, the PRC also adopted a “first-to-file” system.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include limiting where a patentee may file a patent infringement suit, allowing third-party submission of prior art to the USPTO during patent prosecution and providing for additional procedures to attack the validity of a patent at the USPTO by post-grant review, inter partes review and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, in whole or in part, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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 patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our future patent applications or those of our current and future licensors and the enforcement or defense of our future issued patents or those of our current and future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Changes in U.S. patent law, PRC patent law or patent laws in other countries could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.***

Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently



uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States, the PRC and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws of the PRC, the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

In the PRC, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in the PRC. For example, a Draft Amendment to the PRC Patent Law was released in January 2019 and updated in July 2020, which proposes introduction of patent term extensions to eligible innovative drug patents. If adopted, the terms of our PRC patents may be eligible for extension and allow us to extend patent protection of our products, and the terms of the patents owned by third parties may also be extended, which may in turn affect our ability to commercialize our products candidates, if and when approved, without facing infringement risks. The length of any such patent term extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new competitor products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Evolving judicial interpretation of patent law could also adversely affect our business. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued numerous precedential opinions in recent years narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce or defend patents that we have licensed or that we might own or license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our current and future owned and licensed patents.

***We may not be able to protect our intellectual property rights throughout the world, including in the PRC.***

Filing, prosecuting and defending patents for our current and future product candidates in all relevant jurisdictions throughout the world could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, the PRC has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries, including the PRC, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our current or any future product candidates, and our patents, the patents of our current and future licensors or other intellectual property rights may not be effective or sufficient to prevent them from competing. Additionally, some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights or the marketing of competing products in violation of our intellectual property or proprietary rights. In particular, the validity, enforceability and scope of protection available

under the relevant laws in the PRC are uncertain and still evolving. Implementation and enforcement of PRC intellectual property-related laws have historically been deficient and ineffective. Accordingly, intellectual property and confidentiality legal regimes in the PRC may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of intellectual property or proprietary technology in foreign jurisdictions is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or our current or future licensors or to determine the enforceability, scope and validity of our proprietary rights or those of others. Such litigations and proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our current and future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our current and future licensors at risk of not issuing and could provoke third parties to assert claims against us. Moreover, the experience and capabilities of courts in foreign jurisdictions, including PRC courts, in handling intellectual property litigation varies, and outcomes are unpredictable. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. An adverse determination in any such proceeding or litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

In addition, as permitted by the PRC laws, other parties may register trademarks which may look similar to our registered trademarks under certain circumstances, which may cause confusion among consumers. We may not be able to prevent other parties from using trademarks that are similar to ours and our consumers may confuse our treatment centers with others using similar trademarks. In such case, the goodwill and value of our trademarks and the public perception of our brand and our image may be adversely affected. A negative perception of our brand and image could have a material and adverse effect on our sales, and therefore on our business, financial condition, results of operations and prospects. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, and any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Compulsory standards for remuneration to creators or inventors of the patents they contribute to our business could be considerable.***

Under PRC laws, we are required to remunerate inventors or creators of patents they create for our business during the course of their employment. In the event of a dispute between an inventor or creator and us, there is a risk that the compulsory standards for remuneration, as set forth in relevant laws and regulations, may apply. Our policies do not include any rules regarding a predetermined lump sum or proportion of profits to award inventors as remuneration for the patents they contribute to our business and in the potential event of a dispute between us and an inventor, there is a potential risk that the compulsory standard for remuneration, as set forth in relevant laws and regulations, may apply. Such compulsory standards for remuneration could be considerable and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We also rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, CROs and advisors, we cannot provide any assurances that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information and that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose or use our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures of trade secrets and other confidential information is difficult, and we do not know whether the steps we have taken to protect our trade secrets or confidential information will be effective. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures, they may be breached.

Moreover, third parties may still lawfully obtain our trade secrets or proprietary information or may develop or otherwise come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to protect our trade secret information may be jeopardized. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.***

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of a former employer or another third party. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these claims, and there is no guarantee of success. If we fail in defending these claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, if such intellectual property rights are found to incorporate or be derived from the trade secrets or other proprietary information of the third party. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property on our behalf 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. Such agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. We may design or create new trademarks and apply to register them, but our trademark applications may not be approved in the United States, the PRC or any other relevant jurisdiction. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Competitors or other parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, they may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

***Any collaboration arrangements that we have or may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.***

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators and partners. Collaborations and partnerships are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain, protect, enforce and 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 infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future 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 current or future products;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Intellectual property rights do not necessarily address all potential threats.***

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

- others may be able to make products that are similar to our product candidates or utilize similar technologies that are not covered by the claims of the patents that we own or license now or in the future;
- 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 or license now or in the future;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' or collaboration partners' patents;
- issued patents that we hold rights to may fail to provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the ownership, validity or enforceability of our or our licensors' or collaboration partners' patents or patent applications may be challenged by third parties;
- the patents or pending or future applications of others, if issued, may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

### **Risks Related to Doing Business in the PRC**

#### ***We could be adversely affected by political tensions between the United States and the PRC.***

In March 2018, U.S. President Donald J. Trump announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018 announced further tariffs targeting goods imported from the PRC. Subsequently both the PRC and the United States have each imposed tariffs that have adversely affected trade between the two countries. In October 2019, President Trump announced that the PRC and the United States had reached a tentative agreement for the first phase of a trade deal, under which the PRC has agreed to buy up to \$50.0 billion of American products and services, while the United States has agreed to suspend new tariffs. Such agreement was signed in January 2020. Although we do not currently export any of our product candidates to the United States, it is not yet clear what impact these tariff negotiations may have or what further actions the governments may take, and tariffs could potentially impact the price of our clinical supplies.

Political tensions between the United States and the PRC have escalated since the COVID-19 outbreak, the PRC National People's Congress' passage of Hong Kong national security legislation and the executive orders issued by U.S. President Donald J. Trump in August 2020 that prohibit certain transactions with ByteDance Ltd., Tencent Holdings Ltd. and the respective subsidiaries of such companies as well as the executive order issued by President Trump in November 2020 that prohibits U.S. persons from transacting publicly traded securities of certain "Communist Chinese military companies" named in such executive order. Rising political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between the two major economies, which would have a material adverse effect on global economic conditions and the stability of global financial markets. Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations. Furthermore, there have been recent media reports on deliberations within the U.S. government regarding potentially limiting or restricting PRC-based companies from accessing U.S. capital markets. If any such deliberations were to materialize, the resulting legislation may have a material and adverse impact on the stock performance of PRC-based issuers listed in the United States. It is unclear if this proposed legislation would be enacted.

A substantial part of our drug discovery and clinical operations are conducted in the United States, and we are required to comply with the U.S. laws and regulations on export controls, including the U.S. Department of Commerce's Export Administration Regulations. Currently, such laws and regulations do not restrict our ability to offer our U.S.-origin drug discovery tools to our subsidiaries in the PRC. However, we may be affected by future changes in U.S. export control laws and regulations. If we were unable to transfer our U.S.-origin drug discovery tools to the PRC, source U.S.-origin software and components from third parties or otherwise access U.S. technology as a result of such regulatory changes, our business, results of operations and financial condition would be materially and adversely affected.

***Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.***

We have significant operations in the PRC. Accordingly, our financial condition and results of operations are affected to a significant extent by economic, political and legal developments in the PRC.

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 the PRC is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over the PRC'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 three 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 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 has implemented in the past certain measures to control the pace of economic growth. These measures may cause decreased economic activity, which in turn could lead to a reduction in demand for any of our potential products, if approved, and consequently have a material adverse effect on our businesses, financial condition and results of operations.

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

Our operations are mainly conducted in the PRC, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in the PRC. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in the PRC. However, the PRC has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in the PRC or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the nonbinding nature of such decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. 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 or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Any administrative and court proceedings in the PRC 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 the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

***The approval of the CSRC may be required in connection with this offering under a PRC regulation. The regulation also establishes more complex procedures for acquisitions conducted by foreign investors that could make it more difficult for us to grow through acquisitions.***

On August 8, 2006, six PRC regulatory agencies, including the Ministry of Commerce, or MOFCOM, the State-Owned Assets Supervision and Administration Commission, the State Administration of Taxation, or SAT, the State Administration for Industry and Commerce, currently known as the SAMR, the CSRC, and the State Administration of Foreign Exchange, or the SAFE, jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, which came into effect on September 8, 2006 and were amended on June 22, 2009. The M&A Rules include, among other things, provisions that purport to require that an offshore special purpose vehicle that is controlled by PRC domestic companies or individuals and that has been formed for the purpose of an overseas listing of securities through acquisitions of PRC domestic companies or assets to obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle's securities on an overseas stock exchange. On September 21, 2006, the CSRC published on its official website procedures regarding its approval of overseas listings by special purpose vehicles. However, substantial uncertainty remains regarding the scope and applicability of the M&A Rules to offshore special purpose vehicles.

While the application of the M&A Rules remains unclear, we believe, based on the advice of our PRC legal counsel, Han Kun Law Offices, based on its understanding of the current PRC laws and regulations, that the CSRC approval is not required in the context of this offering because (i) Connect SZ was incorporated as a domestic company in May 2012 and became a sino-foreign equity venture on August 23, 2012 in compliance with the M&A Rules, such that the M&A Rules are not applicable to it thereafter, and (ii) the CSRC currently has not issued any definitive rule or interpretation concerning whether offerings such as this offering contemplated by our company are subject to the M&A Rules. There can be no assurance that the relevant PRC government agencies, including the CSRC, would reach the same conclusion as our PRC legal counsel. If the CSRC or any other PRC regulatory body subsequently determines that we need to obtain the CSRC's approval for this offering or if the CSRC or any other PRC government authorities promulgates any interpretation or implements rules before our listing that would require us to obtain CSRC or other governmental approvals for this offering, we may face adverse actions or sanctions by the CSRC or other PRC regulatory agencies. In any such event, these regulatory agencies may impose fines and penalties on our operations in the PRC, limit our operating privileges in the PRC, delay or restrict the repatriation of the proceeds from this offering into the PRC or take other actions that could have a material adverse effect on our business, financial condition, results of operations, reputation and prospects, as well as our ability to complete this offering. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable for us, to halt this offering before settlement and delivery of the ADSs offered by this prospectus. Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that such settlement and delivery may not occur. In addition, if the CSRC or other regulatory agencies later promulgate new rules or explanations requiring us to obtain their approvals for this offering, we may be unable to obtain waivers of such approval requirements. Any uncertainties and/or negative publicity regarding such approval requirements could have a material adverse effect on the trading price of the ADSs.

These regulations also established additional procedures and requirements that are expected to make merger and acquisition activities in the PRC by foreign investors more time-consuming and complex. For example, the M&A rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. The approval from the MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies. Mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly authority under the State Council when the threshold under the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings issued by the State Council in August 2008 and amended in September 2018, is triggered. In addition, the security review rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise "national security" concerns are subject to strict review

by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review, including by structuring the transaction through a proxy or contractual control arrangement. We may grow our business in part by acquiring other companies operating in our industry. Complying with the requirements of the new regulations to complete such transactions could be time-consuming, and any required approval processes, including approval from the MOFCOM, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

***We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income.***

Under the PRC Enterprise Income Tax Law and its implementing rules, enterprises established under the laws of jurisdictions outside of the PRC with “de facto management bodies” located in the PRC may be considered PRC tax resident enterprises for tax purposes and may be subject to the PRC enterprise income tax at the rate of 25% on their global income. “De facto management body” refers to a managing body that exercises substantial and overall management and control over the production and operations, personnel, accounting and assets of an enterprise. The SAT issued the Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, on April 22, 2009, which was most recently amended on December 29, 2017. Circular 82 provides certain specific criteria for determining whether the “de facto management body” of a Chinese-controlled offshore-incorporated enterprise is located in the PRC. Although Circular 82 only applies to offshore enterprises controlled by PRC enterprises, not those controlled by foreign enterprises or individuals, the determining criteria set forth in Circular 82 may reflect the SAT’s general position on how the “de facto management body” test should be applied in determining the tax resident status of offshore enterprises, regardless of whether they are controlled by PRC enterprises. If we were to be considered a PRC resident enterprise, we would be subject to PRC enterprise income tax at the rate of 25% on our global income. In such case, our cash flow may be materially reduced as a result of our global income being taxed under the Enterprise Income Tax Law. We believe that none of our entities outside of the PRC is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term “de facto management body.”

***Dividends paid to our foreign investors and gains on the sale of the ADSs by our foreign investors may become subject to PRC tax.***

Under the Enterprise Income Tax Law and its implementation regulations issued by the State Council, a 10% PRC withholding tax is applicable to dividends paid to investors that are non-resident enterprises, which do not have an establishment or place of business in the PRC or which have such establishment or place of business but the dividends are not effectively connected with such establishment or place of business, to the extent such dividends are derived from sources within the PRC. Any gain realized on the transfer of ADSs or ordinary shares by such investors is also subject to PRC tax at a current rate of 10%, if such gain is regarded as income derived from sources within the PRC. If we are deemed a PRC resident enterprise, dividends paid on our ordinary shares or ADSs, and any gain realized from the transfer of our ordinary shares or ADSs, would be treated as income derived from sources within the PRC and would as a result be subject to PRC taxation. Furthermore, if we are deemed a PRC resident enterprise, dividends paid to individual investors who are non-PRC residents and any gain realized on the transfer of ADSs or ordinary shares by such investors may be subject to PRC tax (which in the case of dividends may be withheld at source) at a rate of 20%. Any PRC tax liability may be reduced by an applicable tax treaty. However, if we or any of our subsidiaries established outside the PRC are considered a PRC resident enterprise, it is unclear whether holders of the ADSs would be able to claim the benefit of income tax treaties or agreements entered into between the PRC and other countries or areas. If dividends paid to our non-PRC investors, or gains from the transfer of the ADSs by such investors, are deemed as income derived from sources within the PRC and thus are subject to PRC tax, the value of your investment in the ADSs may decline significantly.

***We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company, or immovable properties located in the PRC owned by non-PRC companies.***

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax on Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7. Pursuant to this Bulletin 7, an “indirect transfer” of assets, including non-publicly traded equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be re-characterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a



reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. According to Bulletin 7, "PRC taxable assets" include assets attributed to an establishment in the PRC, immovable properties located in the PRC, and equity investments in PRC resident enterprises, in respect of which gains from their transfer by a direct holder, being a non-PRC resident enterprise, would be subject to PRC enterprise income taxes. When determining whether there is a "reasonable commercial purpose" of the transaction arrangement, features to be taken into consideration include, without limitation: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be included with the enterprise income tax filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to the immovable properties located in the PRC or to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements, and the party who is obligated to make the transfer payments has the withholding obligation. Bulletin 7 does not apply to transactions of sale of shares by investors through a public stock exchange where such shares were acquired from a transaction through a public stock exchange. On October 17, 2017, the SAT promulgated the Announcement of the SAT on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or SAT Circular 37, which became effective on December 1, 2017 and was most recently amended on June 15, 2018. SAT Circular 37, among other things, simplified procedures of withholding and payment of income tax levied on non-resident enterprises.

We face uncertainties as to the reporting and other implications of certain past and future transactions where PRC taxable assets are involved, such as offshore restructuring, sale of the shares in our offshore subsidiaries or investments. Our company may be subject to filing obligations or taxed if our company is transferor in such transactions, and may be subject to withholding obligations if our company is transferee in such transactions under Bulletin 7 and SAT Circular 37. For transfer of shares in our company by investors that are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in the filing under Bulletin 7 and SAT Circular 37. As a result, we may be required to expend valuable resources to comply with Bulletin 7 and SAT Circular 37 or to request the relevant transferors from whom we purchase taxable assets to comply with these publications, or to establish that our company should not be taxed under these publications, which may have a material adverse effect on our financial condition and results of operations.

***PRC regulation of loans to, and direct investments in, PRC entities by offshore holding companies and governmental control of currency conversion may restrict or prevent us from using the proceeds of this offering to make loans or additional capital contributions to our PRC subsidiaries.***

In utilizing the proceeds of this offering, we, as an offshore holding company, are permitted under PRC laws and regulations to provide funding to our PRC subsidiaries, which are treated as "foreign-invested enterprises" under PRC laws, through loans or capital contributions. However, loans by us to our PRC subsidiaries to finance their activities cannot exceed statutory limits and must be registered with the local counterpart of SAFE and capital contributions to our PRC subsidiaries are subject to the requirement of making necessary registration with competent governmental authorities in the PRC.

SAFE promulgated the Notice of the SAFE on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises, or Circular 19, effective on June 1, 2015. According to Circular 19, the flow and use of the RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for the issuance of RMB entrusted loans, the repayment of inter-enterprise loans or the repayment of banks loans that have been transferred to a third party. Although Circular 19 allows RMB capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within the PRC, it also reiterates the principle that

RMB converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in the PRC in actual practice. SAFE promulgated the Notice of the SAFE on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of Circular 19 and Circular 16 could result in administrative penalties. Circular 19 and Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from this offering, to our PRC subsidiaries, which may adversely affect our liquidity and our ability to fund and expand our business in the PRC.

On October 23, 2019, SAFE promulgated the Circular of the SAFE on Further Promoting the Facilitation of Cross-border Trade and Investment, or Circular 28, which permits non-investment foreign-invested enterprises to use their capital funds to make equity investments in the PRC, with genuine investment projects and in compliance with effective foreign investment restrictions and other applicable laws. However, as Circular 28 was issued recently, there are still substantial uncertainties as to its interpretation and implementations in practice.

In light of the various requirements imposed by PRC regulations on loans to, and direct investments in, PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or future capital contributions by us to our PRC subsidiaries. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiaries when needed. If we fail to complete such registrations or obtain such approvals, our ability to use foreign currency, including the proceeds we received from this offering, and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

***Any failure to comply with PRC regulations regarding the registration requirements for employee share incentive plans may subject our equity incentive plan participants or us to fines and other legal or administrative sanctions.***

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, replacing earlier rules promulgated in 2007. Pursuant to these rules, PRC citizens and non-PRC citizens who reside in the PRC for a continuous period of not less than one year and participate in any share incentive plan of an overseas publicly listed company are required to register with the SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures, unless certain exceptions are available. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of share options and the purchase or sale of shares and interests. We and our executive officers and other employees who are PRC citizens or non-PRC citizens living in the PRC for a continuous period of not less than one year and have been granted options will be subject to these regulations when our company becomes an overseas-listed company upon the completion of this offering. Failure to complete SAFE registrations may subject them to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals and may also limit our ability to contribute additional capital into our PRC subsidiaries and our PRC subsidiaries' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees under PRC law. See "Management—2019 Stock Incentive Plan."

In addition, the SAT has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in the PRC who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiaries have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes for those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities. See "Management—2019 Stock Incentive Plan."

***PRC regulations relating to offshore investment activities by PRC residents may limit our PRC subsidiaries' ability to change their registered capital or distribute profits to us or otherwise expose us or our PRC resident beneficial owners to liability and penalties under PRC laws.***

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles, or Circular 37. Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purposes) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. Circular 37 further requires amendment to the SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as change of a PRC individual shareholder, name and operation term, or any significant changes with respect to the offshore special purpose vehicle, such as increase or decrease of capital contribution, share transfer or exchange, or mergers or divisions. Circular 37 is applicable to our shareholders or beneficial owners who are PRC residents and may be applicable to any offshore acquisitions that we make in the future. According to the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment released on February 13, 2015 by the SAFE, local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, under Circular 37 from June 1, 2015.

If our shareholders or beneficial owners who are PRC residents or entities do not complete their registration with the local SAFE branches or qualified local banks, our PRC subsidiaries may be prohibited from distributing to us its profits and proceeds from any reduction in capital, share transfer or liquidation, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restrictions.

We may not be informed of the identities of all the PRC residents or entities holding direct or indirect interest in our company, nor can we compel our shareholders or beneficial owners to comply with SAFE registration requirements. We cannot assure you that all shareholders or beneficial owners of ours who are PRC residents or entities have complied with, and will in the future make, obtain or update any applicable registrations or approvals required by, SAFE regulations.

The failure or inability of such shareholders or beneficial owners to comply with SAFE regulations, or failure by us to amend the foreign exchange registrations of our PRC subsidiaries, could subject us or the non-complaint shareholders or beneficial owners to fines or legal sanctions, restrict our overseas or cross-border investment activities, limit our PRC subsidiaries' ability to make distributions or pay dividends to us or affect our ownership structure. As a result, our business operations and our ability to distribute any future profits to you could be materially and adversely affected.

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

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

In light of the flood of capital outflows of the PRC in 2016 due to the weakening renminbi, the PRC government has imposed more restrictive foreign exchange policies and stepped-up scrutiny of major outbound capital movement including overseas direct investment. More restrictions and a substantial vetting process have been put in place by SAFE to regulate cross-border transactions falling under the capital account. If any of our shareholders regulated by such policies fails to satisfy the applicable overseas direct investment filing or approval requirement timely or at all, it may be subject to penalties from the relevant PRC authorities. The PRC government may at its discretion further restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the ADSs.

***Recent litigation and negative publicity surrounding PRC-based companies listed in the United States may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs.***

We believe that litigation and negative publicity surrounding companies with operations in the PRC that are listed in the United States have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on PRC-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the ADS trading price, and increased directors and officers insurance premiums, and could have a material adverse effect upon our business, results of operations and financial condition.

***The enforcement of the PRC Labor Contract Law, and other labor-related regulations in the PRC may increase our labor costs and limit our flexibility to use labor. Our failure to comply with PRC labor-related laws may expose us to penalties.***

On June 29, 2007, the Standing Committee of the National People's Congress of the PRC enacted the PRC Labor Contract Law, which became effective on January 1, 2008 and was amended on December 28, 2012. The PRC Labor Contract Law introduces specific provisions related to fixed-term employment contracts, part-time employment, probation, consultation with labor unions and employee assemblies, employment without a written contract, dismissal of employees, severance, and collective bargaining, which together represent enhanced enforcement of labor laws and regulations. According to the PRC Labor Contract Law, an employer is obliged to sign an unfixed-term labor contract with any employee who has worked for the employer for 10 consecutive years and will reach the statutory retirement age within ten years. Further, if an employee requests or agrees to renew a fixed-term labor contract that has already been entered into twice consecutively, the resulting contract must have an unfixed term, with certain exceptions. The employer must pay economic compensation to an employee where a labor contract is terminated or expires in accordance with the PRC Labor Contract Law, except for certain situations which are specifically regulated. As a result, our ability to terminate employees is significantly restricted. In addition, the government has issued various labor-related regulations to further protect the rights of employees. According to such laws and regulations, employees are entitled to annual leave ranging from five to 15 days and are able to be compensated for any untaken annual leave days in the amount of three times their daily salary, subject to certain exceptions. In the event that we decide to change our employment or labor practices, the PRC Labor Contract Law and its implementation rules may also limit our ability to effect those changes in a manner that we believe to be cost-effective. In addition, as the interpretation and implementation of these new regulations are still evolving, our employment practices may not be at all times deemed in compliance with the new regulations. If we are subject to severe penalties or incur significant liabilities in connection with labor disputes or investigations, our business and financial conditions may be adversely affected.

Companies operating in the PRC are required to participate in various government sponsored employee benefit plans, including certain social insurance, housing funds and other welfare-oriented payment obligations, and contribute to the plans in amounts equal to certain percentages of salaries, including bonuses and allowances, of their employees up to a maximum amount specified by the local government from time to time. The requirement to maintain employee benefit plans has not been implemented consistently by local governments in the PRC given the different levels of economic development in different locations. We may not pay social security and housing fund contributions in strict compliance with the relevant PRC regulations for and on behalf of our employees due to differences in local regulations and inconsistent implementation or interpretation by local authorities in the PRC and varying levels of acceptance of the housing fund system by our employees. We may be subject to fines and penalties

for any such failure to make payments in accordance with the applicable PRC laws and regulations. We may be required to make up the contributions for these plans as well as to pay late fees and fines. If we are subject to penalties, late fees or fines in relation to any underpaid employee benefits, our financial condition and results of operations may be adversely affected.

***Certain of our leasehold interests in leased properties have not been registered with the relevant PRC governmental authorities as required by relevant PRC laws. The failure to register leasehold interests may expose us to potential fines.***

We have not registered certain of our lease agreements with the relevant government authorities. Under the relevant PRC laws and regulations, we may be required to register and file with the relevant government authority executed leases. The failure to register the lease agreements for our leased properties will not affect the validity of these lease agreements, but the competent housing authorities may order us to register the lease agreements in a prescribed period of time and impose a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease if we fail to complete the registration within the prescribed timeframe.

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

In the past, local governments in the PRC granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The Circular on the Relevant Tax Policies in Respect of Medical and Hygiene Institutions issued by the SAT and Ministry of Finance that became effective in July 2000 and was amended in 2009, specifies that to support the development of profitable medical institutions, the following preferential policy shall be applied to the income derived by profitable medical institutions as is directly used to improve the medical and hygiene service conditions within three years after the date of obtaining practice registration: (1) the self-produced preparation for its own use shall be exempted from any value-added tax; and (2) the property, land, vehicles and vessels for the profitable medical institution's own use shall be exempted from real estate tax, land-use tax of cities and towns and operation tax of vehicle and ship. Upon the expiration of the term of three years for exempting from tax, the tax collection shall be restored. The Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax issued by the SAT and Ministry of Finance that became effective in May 2016, specifies that medical institutions which provide medical services are exempted from value-added tax during the pilot scheme period for levying VAT in place of business tax. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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

Most of our research and development operations and manufacturing facilities are in the PRC, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See "Business—Government Regulation and Product Approval—PRC Regulation" for a discussion of the regulatory requirements that are applicable to our current and planned business activities in the PRC. In recent years, the regulatory framework in the PRC regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in the PRC and reduce the current benefits we believe are available to us from developing and manufacturing product candidates in the PRC. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in the PRC. We believe

our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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

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

***The ability of U.S. authorities to bring actions for violations of U.S. securities law and regulations against us, our directors, executive officers or the expert named in this prospectus may be limited. Therefore, you may not be afforded the same protection as provided to investors in U.S. domestic companies.***

The SEC, the U.S. Department of Justice, or the DOJ, and other U.S. authorities often have substantial difficulties in bringing and enforcing actions against non-U.S. companies such as us, and non-U.S. persons, such as our directors and executive officers in the PRC. Due to jurisdictional limitations, matters of comity and various other factors, the SEC, the DOJ and other U.S. authorities may be limited in their ability to pursue bad actors, including in instances of fraud, in emerging markets such as the PRC. We conduct our operations mainly in the PRC and our assets are mainly located in the PRC. There are significant legal and other obstacles for U.S. authorities to obtain information needed for investigations or litigation against us or our directors, executive officers or other gatekeepers in case we or any of these individuals engage in fraud or other wrongdoing. In addition, local authorities in the PRC may be constrained in their ability to assist U.S. authorities and overseas investors in connection with legal proceedings. As a result, if we, our directors, executive officers or other gatekeepers commit any securities law violation, fraud or other financial misconduct, the U.S. authorities may not be able to conduct effective investigations or bring and enforce actions against us, our directors, executive officers or other gatekeepers. Therefore, you may not be able to enjoy the same protection provided by various U.S. authorities as it is provided to investors in U.S. domestic companies.

***You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in the PRC, based on United States or other foreign laws, against us, our directors, executive officers or the expert named in this prospectus. Therefore, you may not be able to enjoy the protection of such laws in an effective manner.***

We are a company incorporated under the laws of the Cayman Islands, we conduct our operations mainly in the PRC, and our assets are mainly located in the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon us, our directors and executive officers, including with respect to matters arising under U.S. federal securities laws or applicable state securities laws. Even if you obtain a judgment against us, our directors, executive officers or the expert named in this prospectus in a U.S. court or other court outside the PRC, you may not be able to enforce such judgment against us or them in the PRC. The PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts in the United States, the United Kingdom, Japan or most other western countries. Therefore, recognition and enforcement in the PRC of judgments of a court in any of these jurisdictions may be difficult or impossible. In addition, you may not be able to bring original actions in the PRC based on the U.S. or other foreign laws against us, our directors, executive officers or the expert named in this prospectus. As a result, shareholder claims that are common in the United States, including class actions based on securities law and fraud claims, are difficult or impossible to pursue as a matter of law and practicality in the PRC.

For example, in the PRC, there are significant legal and other obstacles to obtaining information needed for shareholder investigations or litigation outside the PRC or otherwise with respect to foreign entities. Although the local authorities in the PRC may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such regulatory cooperation with the securities regulatory authorities in the United States have not been efficient in the absence of mutual and practical cooperation mechanism. According to Article 177 of the PRC Securities Law which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no organization or individual may provide the documents and materials relating to securities business activities to overseas parties. While detailed interpretation of or implementation rules under Article 177 of the PRC Securities Law is not yet available, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within the PRC may further increase difficulties faced by investors in protecting your interests. Therefore, you may not be able to effectively enjoy the protection offered by the U.S. laws and regulations that are intended to protect public investors.

***Additional remedial measures could be imposed on certain PRC-based accounting firms, including our independent registered public accounting firm, in administrative proceedings instituted by the SEC, as a result of which our consolidated financial statements may be determined to not be in compliance with the requirements of the Exchange Act, if at all.***

In December 2012, the SEC brought administrative proceedings against the PRC-based “big four” accounting firms, including our independent registered public accounting firm, alleging that they had violated U.S. securities laws by failing to provide audit work papers and other documents related to certain other PRC-based companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring and suspending these accounting firms from practicing before the SEC for a period of six months. The decision was neither final nor legally effective until reviewed and approved by the SEC, and on February 12, 2014, the PRC-based accounting firms appealed to the SEC against this decision. In February 2015, each of the four PRC-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and to audit U.S.-listed companies. The settlement required the firms to follow detailed procedures to seek to provide the SEC with access to such firms’ audit documents via the CSRC. If the firms did not follow these procedures or if there is a failure in the process between the SEC and the CSRC, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. Under the terms of the settlement, the underlying proceeding against the four PRC-based accounting firms was deemed dismissed with prejudice four years after entry of the settlement. The four-year mark occurred on February 6, 2019. While we cannot predict if the SEC will further challenge the four PRC-based accounting firms’ compliance with U.S. law in connection with U.S. regulatory requests for audit work papers or if the results of such challenge would result in the SEC imposing penalties such as suspensions, if the accounting firms are subject to additional remedial measures, our ability to file our consolidated financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed consolidated financial statements in compliance with SEC requirements could ultimately lead to our delisting from Nasdaq or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of the ADSs in the United States.

In the event that the PRC-based “big four” accounting firms become subject to additional legal challenges by the SEC or the PCAOB depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about any such future proceedings against these audit firms may cause investor uncertainty regarding PRC-based, U.S.-listed companies and the market price of the ADSs may be adversely affected.

If our independent registered public accounting firm were denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our consolidated financial statements, our consolidated financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delay or abandonment of this offering, delisting of the ADSs from Nasdaq or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of the ADSs in the United States.

## Risks Related to the ADSs and This Offering

***An active, liquid and orderly market for the ADSs may not develop, and you may not be able to resell your ADSs at or above the public offering price.***

Prior to this offering, there has been no public market for our ordinary shares or ADSs. Although we have applied to list the ADSs on the Nasdaq Global Market, or Nasdaq, an active trading market for the ADSs may never develop or be sustained following this offering. Our ordinary shares will not be listed on any other exchange, or quoted for trading on any over-the-counter trading system, in the United States. We and the representatives of the underwriters will determine the initial public offering price of the ADSs through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell the ADSs following this offering. In addition, an active trading market for the ADSs may not develop following the consummation of this offering or, if it does develop, may not be sustained. The lack of an active market may impair your ability to sell your ADSs at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling ADSs and may impair our ability to acquire other businesses or technologies using the ADSs as consideration, which, in turn, could materially adversely affect our business.

***The trading price of the ADSs could be highly volatile, and purchasers of the ADSs could incur substantial losses.***

The trading price of the ADSs is likely to be volatile. The stock market in general and the market for shares of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ADSs at or above the initial public offering price. The market price for the ADSs may be influenced by those factors discussed in this “Risk Factors” section and many others, including:

- our ability to enroll subjects in our ongoing and planned clinical trials;
- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States, the PRC and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts’ reports or recommendations;
- trading volume of the ADSs;
- an inability to obtain additional funding;
- sales of our securities by insiders and shareholders;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- additions or departures of key personnel;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, shareholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies’ shares. Such litigation, if instituted against



us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of the ADSs.***

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist the ADSs. Such a delisting would likely have a negative effect on the price of the ADSs and would impair your ability to sell or purchase the ADSs when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow the ADSs to become listed again, stabilize the market price or improve the liquidity of the ADSs, prevent the ADSs from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

***We may allocate the net proceeds from this offering in ways that you and other ADS holders may not approve.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply the net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing obligations and certificates of deposit. These investments may not yield a favorable return to our ADS holders. If we do not invest or apply the net proceeds from this offering in ways that enhance ADS holder value, we may fail to achieve expected results, which could cause the price of the ADSs to decline.

***You will suffer immediate and substantial dilution in the net tangible book value of the ADSs you purchase.***

The initial public offering price of the ADSs is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding ordinary shares on a per ADS basis immediately after the completion of this offering. Purchasers of the ADSs in this offering will experience immediate dilution of approximately \$ \_\_\_\_\_ per ADS, assuming an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated initial public offering price range shown on the front cover page of this prospectus. In the past, we issued options to acquire ordinary shares at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing ADSs in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

***After this offering, our executive officers, directors and principal shareholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to shareholders for approval. Furthermore, many of our current directors were appointed by our principal shareholders.***

Following the completion of this offering, our executive officers, directors and greater than 5% shareholders, in the aggregate, will own approximately \_\_\_\_\_ % of our outstanding ordinary shares (including \_\_\_\_\_ ordinary shares represented by ADSs and assuming no exercise of the underwriters' option to purchase additional ADSs and no exercise of outstanding options). Furthermore, many of our current directors were appointed by our principal shareholders. As a result, such persons or their appointees to our board of directors, acting together, will have the ability to control or significantly influence all matters submitted to our board of directors or shareholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other shareholders.

Moreover, certain of our existing shareholders, including certain affiliates of our directors, have indicated an interest in purchasing ADSs in this offering at the initial public offering price. Based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated initial public offering price range shown on the front cover page of this prospectus, if our greater than 5% shareholders purchase all of the ADSs they have indicated an interest in purchasing in this offering, the number of ordinary shares beneficially owned by our executive officers, directors and greater than 5% shareholders will, in the aggregate, increase to approximately \_\_\_\_\_ % of our outstanding ordinary shares (including \_\_\_\_\_ ordinary shares represented by ADSs and assuming no exercise of the

underwriters' option to purchase additional shares and no exercise of our outstanding options). However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these shareholders, or any of these shareholders may determine to purchase more, less or no shares in this offering.

***We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of the ADSs.***

We have never declared or paid any cash dividend on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends.

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 its share premium account of our company, provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. 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 depend on 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.

***Sales of a substantial number of our ordinary shares by our existing shareholders in the public market could cause the price of the ADSs to fall.***

Sales of a substantial number of our ordinary shares in the public market or the perception that these sales might occur could significantly reduce the market price of the ADSs and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on ordinary shares outstanding as of December 31, 2020, upon the closing of this offering, we will have outstanding a total of \_\_\_\_\_ ordinary shares after this offering, including \_\_\_\_\_ ordinary shares represented by ADSs, assuming no exercise of the underwriters' option to purchase additional ADSs and no exercise of outstanding options. Of these shares, only the \_\_\_\_\_ ordinary shares represented by ADSs sold in this offering by us, plus any ordinary shares represented by ADSs sold upon exercise of the underwriters' option to purchase additional ADSs, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Jefferies LLC, SVB Leerink LLC, Piper Sandler & Co. and China International Capital Corporation Hong Kong Securities Limited. The underwriters may permit our officers, directors and other shareholders and the holders of our outstanding options who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements, subject to limitations. See "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of the ADSs to decline. After the lock-up agreements expire, up to an additional \_\_\_\_\_ ordinary shares will be eligible for sale in the public market of which \_\_\_\_\_ shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of December 31, 2020, up to \_\_\_\_\_ ordinary shares that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule

701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ADSs could decline.

After this offering, the holders of \_\_\_\_\_ of our outstanding ordinary shares, or approximately \_\_\_\_\_ % of our total outstanding ordinary shares as of December 31, 2020, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See “Description of Share Capital—Registration Rights.” Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these shareholders could have a material adverse effect on the trading price of the ADSs.

***We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make the ADSs less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply 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;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find the ADSs less attractive if we rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the trading price of the ADSs may be reduced or more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***As a foreign private issuer, we are not subject to certain U.S. securities law disclosure requirements that apply to a domestic U.S. issuer, which may limit the information publicly available to our shareholders.***

As a foreign private issuer, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act and therefore there may be less publicly available information about us than if we were a U.S. domestic issuer. For example, we are not subject to the proxy rules in the United States and disclosure with respect to our annual general meetings will be governed by the Cayman Islands’ requirements. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery

provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our ordinary shares or ADSs.

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

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process. To the extent we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

***Under our amended and restated memorandum and articles of association, you will not have the same rights with respect to shareholder meetings and voting that shareholders of certain U.S. corporations have.***

As a company incorporated under the laws of the Cayman Islands, our amended and restated memorandum and articles of association will provide that a quorum required for the transaction of business at any general meeting of shareholders shall consist of one or more shareholders present in person or by proxy, holding shares which carry in aggregate not less than one-third of all votes attaching to all of our shares in issue and entitled to vote. Additionally, our amended and restated memorandum and articles of association will provide that any voting at any shareholders' meeting shall be decided by a show of hands unless a poll is demanded (before or on the declaration of the result of the show of hands) by the chairman of such meeting or by any one or more shareholders who together hold not less than 10% of the votes attaching to the total ordinary shares which are present in person or by proxy at the meeting. Although our minority quorum provisions satisfy the requirements applicable to Nasdaq-listed companies, some U.S. corporations have stricter quorum requirements than these. Additionally, shareholder votes of some U.S. corporations, such as corporations incorporated under the laws of the State of Delaware, must be in written form and cannot be conducted by a show of hands. Therefore, as a result of our amended and restated memorandum and articles of association, you will not have the benefit of the procedural protections relating to shareholder meetings and voting that shareholders of certain U.S. corporations enjoy.

***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. We would lose our foreign private issuer status if, for example, 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 this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We 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 Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S.-listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

***The audit report included in this prospectus was prepared by an auditor who is not inspected by the PCAOB and, as such, our investors are deprived of the benefits of such inspection. In addition, the adoption of any rules, legislations or other efforts to increase U.S. regulatory access to audit information could cause uncertainty, and we could be delisted or prohibited from being traded “over-the-counter” if we are unable to meet the PCAOB inspection requirement in time. This could have a material and adverse impact on the value of your investment.***

Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this prospectus, as an auditor of companies that are traded publicly in the United States and a firm registered with the PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Since our auditor is located in the PRC, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the PRC authorities, our auditor is not currently inspected by the PCAOB.

In May 2013, the PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the CSRC, and the PRC Ministry of Finance, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB, the CSRC or the PRC Ministry of Finance in the United States and the PRC, respectively. The PCAOB continues to be in discussions with the CSRC, and the PRC Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with PCAOB and audit PRC companies that trade on U.S. exchanges.

On December 7, 2018, the SEC and the PCAOB issued a joint statement highlighting continued challenges faced by the U.S. regulators in their oversight of financial statement audits of U.S.-listed companies with significant operations in the PRC. The joint statement reflects a heightened interest in an issue that has vexed U.S. regulators in recent years.

On April 21, 2020, the SEC and the PCAOB issued another joint statement reiterating the greater risk that disclosures will be insufficient in many emerging markets, including the PRC, compared to those made by U.S. domestic companies. In discussing the specific issues related to the greater risk, the statement again highlights the PCAOB's inability to inspect audit work paper and practices of accounting firms in the PRC, with respect to their audit work of U.S. reporting companies.

On June 4, 2020, President Donald J. Trump issued a memorandum ordering the President's Working Group on Financial Markets, or the PWG, to submit a report to the President within 60 days of the memorandum that includes recommendations for actions that can be taken by the executive branch and by the SEC or PCAOB on PRC companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States.

On August 6, 2020, the PWG released a report recommending that the SEC take steps to implement the five recommendations outlined in the report, or the PWG Report. In particular, to address companies from jurisdictions that do not provide the PCAOB with sufficient access to fulfill its statutory mandate, or NCJs, the PWG recommends enhanced listing standards on U.S. stock exchanges. This would require, as a condition to initial and continued exchange listing, PCAOB access to work papers of the principal audit firm for the audit of the listed company. Companies unable to satisfy this standard as a result of governmental restrictions on access to audit work papers and practices in NCJs may satisfy this standard by providing a co-audit from an audit firm with comparable resources and experience where the PCAOB determines it has sufficient access to audit work papers and practices to conduct an appropriate inspection of the co-audit firm. The PWG Report permits the new listing standards to provide for a transition period until January 1, 2022 for listed companies, but would apply immediately to new listings once the necessary rulemakings and/or standard-setting are effective. The measures in the PWG Report are presumably subject to the standard SEC rulemaking process before becoming effective. On August 10, 2020, the SEC announced that the SEC Chairman had directed the SEC staff to prepare proposals in response to the PWG Report, and that the SEC was soliciting public comments and information with respect to these proposals. After we are listed on Nasdaq, if we fail to meet the new listing standards before the deadline specified thereunder due to factors beyond our control, we could face possible de-listing from Nasdaq, deregistration from the SEC and/or other risks, which may materially and adversely affect the market price and liquidity of, or effectively terminate, the ADSs trading in the United States.

This lack of the PCAOB inspections in the PRC prevents the PCAOB from fully evaluating audits and quality control procedures of our independent registered public accounting firm. As a result, we and investors in our ordinary shares

are deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in the PRC makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to auditors outside of the PRC that are subject to the PCAOB inspections, which could cause investors and potential investors in our stock to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

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 PRC's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which, if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate an auditor report issued by a foreign public accounting firm. 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 of issuers included on the SEC's list for three consecutive years. On May 20, 2020, the U.S. Senate passed S. 945, the Holding Foreign Companies Accountable Act, which was subsequently passed by the U.S. House of Representatives on December 2, 2020. The Holding Foreign Companies Accountable Act was then signed into law by the President of the United States on December 18, 2020, amending the Sarbanes-Oxley Act of 2002 to direct the SEC to prohibit securities of any registrant from being listed on any of the U.S. securities exchanges or traded "over-the-counter" if the auditor of the registrant's financial statements is not subject to PCAOB inspection for three consecutive years after the enactment date of the law. Implementation of this legislation by the SEC or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of the ADSs could be adversely affected, and we could be delisted or prohibited from being traded "over-the-counter" if we are unable to cure the situation to meet the PCAOB inspection requirement in time. Furthermore, there has been recent media reports on deliberations within the U.S. government regarding potentially limiting or restricting PRC-based companies from accessing U.S. capital markets. If any such deliberations were to materialize, the resulting legislation may have material and adverse impact on the stock performance of PRC-based issuers listed in the United States.

***The requirements of being a U.S. public company may strain our resources, result in more litigation and divert management's attention.***

As a U.S. public company following this offering, we will be subject to various reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" and/or a foreign private issuer. For example, for so long as we remain a foreign private issuer, we will not be required to file with the SEC quarterly reports with respect to our business and results of operations, which are required to be made by domestic issuers pursuant to the Exchange Act.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for U.S. public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Further, being a U.S. public company and a Cayman Islands company will have an impact on disclosure of information and require compliance with two sets of applicable rules. This could result in uncertainty regarding compliance matters and higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices.

We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this prospectus and in future filings required of a U.S. public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, the price and trading volume of the ADSs could decline.***

The trading market for the ADSs will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for the ADSs would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades the ADSs, the trading price of the ADSs would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in the ADSs could decrease, which could cause the price or trading volume of the ADSs to decline.

***Fluctuations in currency exchange rates may have a material adverse effect on our results of operations and the value of your investment.***

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. On July 21, 2005, the PRC government changed its decade-old policy of pegging the value of the renminbi to the U.S. dollar, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the People's Bank of China, or PBOC, announced that the PRC government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the renminbi by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively. On October 1, 2016, the renminbi joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right, or SDR, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, the renminbi depreciated significantly while the U.S. dollar surged and the PRC experienced persistent capital outflows. With the development of the foreign exchange market and progress towards interest rate liberalization and renminbi internationalization, the PRC government may in the future announce further changes to the exchange rate system. There is no guarantee that the renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces, PRC and U.S. government's policies and regulations may impact the exchange rate between the renminbi and the U.S. dollar in the future.

Significant revaluation of the renminbi may have a material adverse effect on your investment. For example, to the extent that we need to convert U.S. dollars into renminbi for our operations, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we would receive from the conversion. Conversely, if we decide to convert our renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the renminbi relative to U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in the PRC to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these

hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert renminbi into foreign currency.

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

Holders of ADSs do not have the same rights as our registered shareholders. As a holder of the 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 which are represented by your ADSs indirectly by giving voting instructions to the depositary in accordance with the provisions of 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. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to withdraw the 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 post-offering memorandum and articles of association that will become effective immediately prior to completion of this offering, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may close our register of members and/or fix in advance a record date for such meeting, and such closure of our register of members or 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 ordinary 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 shares underlying your ADSs are voted and you may have no legal remedy if the 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 vote at shareholders' meetings, which could adversely affect your interests.**

Under the deposit agreement for the ADSs, if you do not vote, 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 a material adverse impact on shareholders; or
- the voting at the meeting is to be conducted via a show of hands unless voting by poll is required by the applicable listing rules or our articles of association.

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 will not be subject to this discretionary proxy.



***You may not receive distributions on the ADSs or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distribution available to you.***

Although we do not have any present plan to pay any dividends, the depository of the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depository is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption from registration. The depository may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depository may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

***Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.***

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

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

We would be classified as a passive foreign investment company, or PFIC, for any taxable year if, after the application of certain look-through rules, either: (i) 75% or more of our gross income for such year is "passive income" (as defined in the relevant provisions of the Internal Revenue Code of 1986, as amended) (the income test), or (ii) 50% or more of the value of our assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income (the asset test). Based on the expected market price of our ordinary shares and ADSs following this offering and the composition of our income and assets, including goodwill, although not clear, we do not expect to be treated as a PFIC for U.S. federal income tax purposes for the current taxable year or in the foreseeable future. However, this is a factual determination that must be made annually after the close of each taxable year, and the application of the PFIC rules is subject to uncertainty in several respects. Moreover, the value of our assets for purposes of the PFIC determination will generally be determined by reference to the market price of our ordinary shares and ADSs, which could fluctuate significantly. Therefore, there can be no assurance that we are not a PFIC for the current taxable year or will not be classified as a PFIC in the future. Certain adverse U.S. federal income tax consequences could apply to a U.S. Holder (as defined in "Taxation—United States Federal Income Taxation Considerations") if we are treated as a PFIC for any taxable year during which such U.S. Holder holds our ADSs.

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

Your ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

***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 the 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. See “Description of American Depositary Shares” for more information.

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

The deposit agreement governing the ADSs representing our ordinary shares provides that 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. 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 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. 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 serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

***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 our amended and restated memorandum and articles of association, the Companies Law (2020 Revision) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against our directors and the fiduciary duties of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedents in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the

Cayman Islands. In addition, Cayman Islands companies may not have the standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records (other than the memorandum and articles of association and any special resolutions passed by such companies, and the registers of mortgages and charges of such companies) or to obtain copies of lists of shareholders of these companies. Under Cayman Islands law, the names of our current directors can be obtained from a search conducted at the Registrar of Companies. Our directors have discretion under our amended and restated articles of association that will become effective immediately prior to completion of this offering to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

As a result of all of the above, our public shareholders may have more difficulty in protecting their interests in the face of actions taken by management or members of our board of directors 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 Law 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.”

***We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of the ADSs may decline.***

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If we or, if required, our auditor is unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of the ADSs may decline.

In connection with the audit of our consolidated financial statements, as of and for the years ended December 31, 2018 and 2019, we and our independent registered public accounting firm identified two material weaknesses in our internal control over the financial statement closing process. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of IFRS and reporting requirements set forth by the SEC to address complex IFRS technical accounting issues, and to prepare and review consolidated financial statements and related disclosures in accordance with IFRS and SEC reporting requirements; and (ii) our lack of formal and effective financial closing policies and procedures, specifically those related to period end expenses cut-off and accruals.

We are working to remediate these material weaknesses and are taking steps to strengthen our internal control over financial reporting through the development and implementation of processes and controls over the financial reporting process. Specifically, we are working to develop and implement period-end financial closing policies and procedures, including expense reconciliation between finance and operation departments, develop and implement a staffing plan for hiring additional accounting and finance personnel in 2021, hire additional qualified resources with appropriate knowledge and expertise to handle complex accounting issues and effectively prepare financial

statements and conduct regular and continuous IFRS accounting and financial reporting training programs for our financial reporting and accounting personnel. However, we cannot assure you that these measures will significantly improve or remediate the material weaknesses described above.

We cannot assure you that there will not be additional material weaknesses or any significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of the ADSs could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***Our post-offering amended and restated memorandum and articles of association contain anti-takeover provisions that could discourage a third party from acquiring us, which could limit our shareholders' opportunity to sell their shares, including ordinary shares represented by the ADSs, at a premium.***

Our post-offering amended and restated memorandum and articles of association that will become effective immediately prior to the completion of this offering contain provisions to limit the ability of others to acquire control of our company or cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. For example, our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix their designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares, in the form of ADS or otherwise. Preferred shares could be issued quickly with terms calculated to delay or prevent a change in control of our company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of the ADSs may fall and the voting and other rights of the holders of our ordinary shares and ADSs may be materially and adversely affected.

***Our post-offering amended and restated memorandum and articles of association provide that the courts of the Cayman Islands and the U.S. federal courts will be the exclusive forums for substantially all disputes between us and our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for complaints against us or our directors, officers or employees.***

Our post-offering amended and restated memorandum and articles of association that will become effective immediately prior to the completion of this offering provide that, unless otherwise agreed by us, (i) the federal courts of the United States shall have exclusive jurisdiction to hear, settle and/or determine any dispute, controversy or claim arising under the provisions of the Securities Act or the Exchange Act, which are referred to as the "U.S. Actions;" and (ii) save for such U.S. Actions, the courts of the Cayman Islands shall have exclusive jurisdiction to hear, settle and/or determine any dispute, controversy or claim whether arising out of or in connection with our articles of association or otherwise, including without limitation:

- any derivative action or proceeding brought on behalf of our company;
- any action asserting a claim of breach of a fiduciary duty owed by any of our director, officer or other employee to our company or our shareholders;
- any action asserting a claim under any provision of the Companies Law (Revised) of the Cayman Islands or our articles of association; or
- any action asserting a claim against our company which if brought in the United States would be a claim arising under the internal affairs doctrine (as such concept is recognized under the laws of the United States).

These exclusive-forum provisions may increase a shareholder's cost and limit the shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees,

which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any of our shares or other security, such as the ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable, and if a court were to find this provision in our post-offering amended and restated memorandum and articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could have adverse effect on our business and financial performance.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the market opportunity and competitive landscape for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the timing of initiation and completion, and the progress of our drug discovery and research programs;
- the timing or likelihood of regulatory filings and approvals for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, the PRC, Europe and other jurisdictions;
- risks associated with the COVID-19 outbreak, which has and may continue to materially and adversely impact our business, preclinical studies and clinical trials;
- our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our plans regarding, and our ability to enter into, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;

## Table of Contents

- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

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

## MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.



## **TRADEMARKS, SERVICE MARKS AND TRADENAMES**

Solely for convenience, the trademarks, service marks, logos, copyrights and trade names referred to in this prospectus are without the ® and ™ symbols. Such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks, logos, copyrights and trade names or that the applicable owner will not assert its rights to these trademarks, service marks, logos, copyrights and trade names. This prospectus contains additional trademarks, service marks, logos, copyrights and trade names of others, which are the property of their respective owners. All trademarks, service marks, logos, copyrights and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, logos, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the ADSs that we are offering in this offering will be approximately \$ \_\_\_\_\_ million (or approximately \$ \_\_\_\_\_ million if the underwriters exercise in full their option to purchase additional ADSs), assuming an initial public offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per ADS would increase or decrease our net proceeds by approximately \$ \_\_\_\_\_ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. Each increase or decrease of 1,000,000 in the number of ADSs offered by us in this offering, as set forth on the cover page of this prospectus, would increase or decrease our net proceeds by approximately \$ \_\_\_\_\_ million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the assumed initial public offering price per ADS stays the same.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our securities and to facilitate our future access to the public equity markets.

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

- approximately \$ \_\_\_\_\_ to fund the research and development of our product candidates, including CBP-201, CBP-307 and CBP-174;
- approximately \$ \_\_\_\_\_ to fund the research and preclinical and clinical development of our other development programs, including CBP-233; and
- the remainder to fund other current and future research and development activities and for working capital and other general corporate purposes, which may include capital projects.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the costs necessary to develop product candidates can be difficult. We expect that the net proceeds from the sale of the ADSs from this offering, together with our cash and cash equivalents, will be sufficient to enable us to complete Phase 2 clinical trials for CBP-201 and CBP-307, advance CBP-174 through a planned Phase 1 clinical trial, and commence a Phase 1 clinical trial of CBP-233. The net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of all of our product candidates.

The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from ongoing preclinical studies and clinical trials or those we may commence in the future and other factors described under "Risk Factors" in this prospectus, as well as any collaborations that we may enter into with third parties and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure

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[Table of Contents](#)

requirements for at least the next \_\_\_\_\_ months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing obligations and certificates of deposit.

## DIVIDEND POLICY

We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares or ADSs in the foreseeable future. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business. Any future determination related to a dividend policy will be made at the discretion of our board of directors, and subject to Cayman Islands Law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Under Cayman Islands law, a Cayman Islands company may pay a dividend out of either profit or its 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 be based upon conditions then existing, including our results of operations, financial condition, current and anticipated capital requirements, business prospects, contractual restrictions and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Any dividend we declare and pay on our ordinary shares will be paid to the depository bank, as the registered holder of those ordinary shares, and the depository bank will then pay such amounts to the holders of ADSs, subject to the terms of the deposit agreement, who will receive such amounts to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. See “Description of American Depositary Shares—Dividends and Other Distributions.”

## CAPITALIZATION

The table below sets forth our cash and cash equivalents and capitalization as of December 31, 2019:

- on an actual basis;
- on a pro forma basis to reflect (i) the receipt of approximately \$135.0 million of gross proceeds from the sale of 21,349,537 shares of our Series C Preferred Shares, (ii) the automatic conversion of all of our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares and the resultant reclassification of the carrying value of the convertible preferred shares to permanent equity immediately prior to the completion of this offering and (iii) the filing and effectiveness of our amended and restated memorandum and articles of association immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of \_\_\_\_\_ ADSs in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price, the actual number of ADSs offered by us and other terms of this offering determined at pricing. You should read this table in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	AS OF DECEMBER 31, 2019		
	ACTUAL	PRO FORMA (in thousands)	PRO FORMA AS ADJUSTED (1)
Cash and cash equivalents	\$ 44,289	\$ _____	\$ _____
Financial assets at fair value through profit or loss	4,391	_____	_____
	<u>\$ 48,680</u>	_____	_____
Financial instruments with preferred rights	\$ 92,172	\$ _____	\$ _____
Shareholders’ deficit:			
Share capital	3		
Share premium	5,465		
Share-based compensation reserves	632		
Other reserves	(6,984)		
Accumulated losses	(41,873)		
Total shareholders’ deficit	<u>(42,757)</u>	_____	_____
Total capitalization	<u>\$ 49,415</u>	\$ _____	\$ _____

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total shareholders’ deficit and total capitalization by \$ \_\_\_\_\_ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of ADSs we are offering. Each increase or decrease of 1,000,000 ADSs offered by us in this offering, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total shareholders’ deficit and total capitalization by approximately \$ \_\_\_\_\_ million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming that the assumed initial public offering price per ADS remains the same.

## Table of Contents

The number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering is based on ordinary shares outstanding as of December 31, 2020, inclusive of the 4,473,305 ordinary shares issued to Connect Union as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company pursuant to the 2019 Plan, and after giving effect to the automatic conversion of all our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares immediately prior to the completion of this offering. The number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering excludes (i) \_\_\_\_\_ ordinary shares we have agreed to issue to our founders upon the completion of this offering pursuant to the Shareholders Agreement and (ii) \_\_\_\_\_ ordinary shares to be reserved for future issuance under our 2021 Plan, which have not previously been issued to Connect Union, and \_\_\_\_\_ ordinary shares to be reserved for future issuance under our 2021 ESPP, which will become effective in connection with the completion of this offering.

To implement the 2019 Plan, the 4,473,305 ordinary shares to be issued pursuant to awards under our 2019 Plan were issued to Connect Union as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company under the 2019 Plan. The 4,473,305 ordinary shares issuable under our 2019 Plan includes \_\_\_\_\_ shares issuable upon the exercise of share options outstanding as of December 31, 2020, with a weighted-average exercise price of \$ \_\_\_\_\_ per ordinary share. See "Management—2019 Stock Incentive Plan" for additional information regarding the 2019 Plan and the settlement of share options described above.

## DILUTION

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

Our historical net tangible book value as of September 30, 2020 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per ordinary share, corresponding to a net tangible book value of \$ \_\_\_\_\_ per ADS, based on 34,197,601 ordinary shares outstanding as of such date, inclusive of the 4,473,305 ordinary shares issued to Connect Union as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company pursuant to the 2019 Plan (including the 166,468 additional ordinary shares issued to Connect Union in December 2020). Historical net tangible book value per ADS represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by the total number of our ordinary shares outstanding as of September 30, 2020, multiplied by \_\_\_\_\_, which is the number of ordinary shares represented by one ADS.

On a pro forma basis, after giving effect to (i) the receipt of approximately \$30.0 million of gross proceeds from the sale of 4,744,341 shares of our Series C Preferred Shares in December 2020, (ii) the automatic conversion of all of our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares (including the conversion of 4,744,341 shares of our Series C Preferred Shares issued in December 2020 into 4,744,341 ordinary shares) and the resultant reclassification of the carrying value of the convertible preferred shares to permanent equity, and (iii) the filing and effectiveness of our amended and restated memorandum and articles of association (items (ii)-(iii) of which will occur immediately prior to the completion of this offering), our pro forma net tangible book value as of September 30, 2020 was \$ \_\_\_\_\_ million, corresponding to a net tangible book value of \$ \_\_\_\_\_ per ADS.

After giving effect to the sale by us of \_\_\_\_\_ ADSs (and the issuance of \_\_\_\_\_ ordinary shares represented by the ADSs) in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth in the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2020 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per ordinary share, corresponding to a pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per ADS. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS to existing shareholders and an immediate dilution of \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS to new investors purchasing ADSs in this offering. Dilution per ADS to new investors is determined by subtracting our pro forma as adjusted net tangible book value per ADS after this offering from the assumed initial public offering price of \$ \_\_\_\_\_ per ADS.

The following table illustrates such dilution.

	PER ORDINARY SHARE	PER ADS
Assumed initial public offering price	\$ _____	\$ _____
Historical net tangible book value as of September 30, 2020	\$ _____	\$ _____
Pro forma increase in historical net tangible book value as of September 30, 2020	_____	_____
Pro forma net tangible book value as of September 30, 2020	_____	_____
Increase in net tangible book value to new investors participating in this offering	_____	_____
Pro forma as adjusted net tangible book value after this offering	_____	_____
Dilution to new investors participating in this offering	\$ _____	\$ _____

## Table of Contents

Each \$1.00 increase or decrease in the assumed initial offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth in the cover page of this prospectus, would increase or decrease the pro forma as adjusted net tangible book value after this offering by \$ \_\_\_\_\_, the pro forma as adjusted net tangible book value per ordinary share and per ADS after giving effect to this offering by \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS, and the dilution to new investors in this offering by \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

Each increase or decrease of 1,000,000 in the number of ADSs offered by us in this offering, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted net tangible book value after this offering by \$ \_\_\_\_\_, the pro forma as adjusted net tangible book value per ordinary share and per ADS after giving effect to this offering by \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS, and the dilution to new investors participating in this offering by \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS, assuming no change in the assumed initial public offering price per ADS and after deducting the estimated underwriting discounts and commissions.

If the underwriters exercise in full their option to purchase an additional \_\_\_\_\_ ADSs (representing \_\_\_\_\_ ordinary shares), our pro forma as adjusted net tangible book value after this offering would be \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS, representing an immediate increase in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS to existing shareholders and immediate dilution of \$ \_\_\_\_\_ per ordinary share and \$ \_\_\_\_\_ per ADS to new investors purchasing ADSs in this offering, based on the assumed initial public offering price of \$ \_\_\_\_\_ per ADS in this offering, which is the midpoint of the price range set forth in the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2020, on the pro forma as adjusted basis described above, the number of ordinary shares purchased from us (including ordinary shares represented by ADSs purchased in this offering), the total consideration paid to us and the average price per ordinary share and ADS paid by existing shareholders and by new investors purchasing ADSs in this offering. The table below is based on the assumed initial public offering price of \$ \_\_\_\_\_ per ADS in this offering, which is the midpoint of the price range set forth in the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	ORDINARY SHARES PURCHASED <sup>(1)</sup>		TOTAL CONSIDERATION		AVERAGE PRICE PER ORDINARY SHARE	AVERAGE PRICE PER ADS
	NUMBER	PERCENT	AMOUNT	PERCENT		
Existing shareholders		%	\$	%	\$	\$
New investors						
Total		%	\$	%		

(1) Includes ordinary shares represented by ADSs.

Each \$1.00 increase or decrease in the assumed initial offering price of \$ \_\_\_\_\_ per ADS, which is the midpoint of the price range set forth in the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ \_\_\_\_\_ million, assuming that the number of ADSs offered by us in this offering, as set forth on the cover page of this prospectus, remains the same. Each increase or decrease of 1,000,000 in the number of ADSs offered by us, as set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per ADS.



If the underwriters exercise in full their option to purchase an additional ADSs, the following will occur:

- the percentage of our ordinary shares held by existing shareholders will decrease to % of the total number of our ordinary shares outstanding after this offering; and
- the percentage of our ordinary shares (including ordinary shares in the form of ADSs) held by new investors will increase to approximately % of the total number of our ordinary shares outstanding after this offering.

If all outstanding options had been exercised as of September 30, 2020, the pro forma as adjusted net tangible book value per ordinary share after this offering would be \$ , and total dilution per ordinary share to new investors would be \$ .

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 77,254,917 ordinary shares outstanding as of September 30, 2020, inclusive of the 4,473,305 ordinary shares issued to Connect Union as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company pursuant to the 2019 Plan (including the 166,468 additional ordinary shares issued to Connect Union in December 2020), and after giving effect to the automatic conversion of all our issued and outstanding convertible preferred shares into 43,057,316 ordinary shares (including the conversion of 4,744,341 shares of our Series C redeemable convertible preferred shares, or the Series C Preferred Shares, issued in December 2020 into 4,744,341 ordinary shares) immediately prior to the completion of this offering. The number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering excludes (i) ordinary shares we have agreed to issue to our founders upon the completion of this offering pursuant to the Shareholders Agreement and (ii) ordinary shares to be reserved for future issuance under our 2021 Plan, which have not previously been issued to Connect Union, and ordinary shares to be reserved for future issuance under our 2021 ESPP, both of which will become effective in connection with the completion of this offering.

To implement the 2019 Plan, the 4,473,305 ordinary shares to be issued pursuant to awards under our 2019 Plan were issued to Connect Union as nominee for purposes of the implementation of awards issued or to be issued to employees, directors and consultants of our company under the 2019 Plan. The 4,473,305 ordinary shares issuable under our 2019 Plan includes (i) 822,149 shares issuable upon the exercise of share options outstanding as of September 30, 2020, with a weighted-average exercise price of \$0.55 per ordinary share; (ii) 12,705 ordinary shares issued pursuant to share options exercised prior to September 30, 2020 and (iii) 1,977,488 shares issuable upon the exercise of share options granted after September 30, 2020, with an exercise price of \$4.69 per ordinary share. See “Management—2019 Stock Incentive Plan” for additional information regarding the 2019 Plan and the settlement of share options described above.

To the extent that we issue additional ADSs or ordinary shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

## OUR HISTORY AND CORPORATE STRUCTURE

In May 2012, Suzhou Connect Biopharma Co., Ltd., or Connect SZ, was incorporated as a limited liability under the laws of the PRC. At such time, Connect SZ held 100% of the equity interests of Connect Biopharm LLC, or Connect US, a single member LLC incorporated under the laws of the State of California. Connect US commenced its operations in January 2012.

In July 2014, Connect Biopharma Australia PTY LTD, or Connect AU, was formed as a limited liability company incorporated under the laws of Australia.

In October 2015, Connect Biopharma (Shanghai) Co., Ltd., or Connect SH, was formed as a limited liability company incorporated under the laws of the PRC.

In November 2015, Connect Biopharma Holdings Limited was formed as a Cayman Islands exempted company with limited liability, and in December 2015, Connect Biopharma Hong Kong Limited, or Connect HK, was formed as a limited liability company under the laws of Hong Kong. Connect Biopharma Holdings Limited and Connect HK were formed for the purpose of effecting the reorganization described below as holding companies for the majority shareholders of Connect SZ.

In January 2016, the Company and its subsidiaries underwent a reorganization, or the Reorganization, pursuant to which Connect Biopharma Holdings Limited issued ordinary shares to Dr. Wei and Dr. Pan, each of whom were founders of the company group, in exchange for their equity interests held in Connect SZ. As a result of issuance of the ordinary shares, Dr. Wei and Dr. Pan held 100% of the equity interests in the Company and Connect HK and retained joint control over the Company and its subsidiaries.

Following the issuance of equity interests in the Company to Dr. Wei and Dr. Pan, the remaining 30% of the equity interests in Connect SZ were held by an existing investor. These interests are referred to as the Non-Controlling Interests.

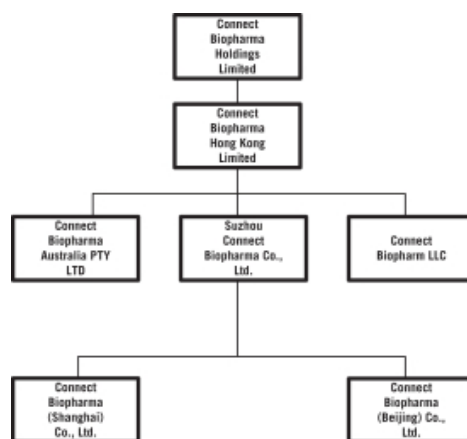
In October 2018, we underwent a restructuring, or the Restructuring, pursuant to which we transferred 100% of the outstanding shares of our subsidiaries Connect US and Connect AU (which were then held by Connect SZ) to Connect HK. Following such transfer, Connect US and Connect AU become wholly owned subsidiaries of Connect HK. Also in October 2018, we issued ordinary shares of Connect Biopharma Holdings Limited to the holders of Non-Controlling Interests in Connect SZ in exchange for such Non-Controlling Interests and Connect Biopharma Holdings Limited issued Series Pre-A convertible preferred shares, par value \$0.0001 per share, or the Series Pre-A Preferred Shares, and Series A convertible preferred shares, par value \$0.0001 per share, or the Series A Preferred Shares, to the preferred holders of Connect SZ as consideration for the same equity interests they held in Connect SZ, respectively. Following these transactions, the shareholders of Connect SZ became shareholders of our company and Connect SZ became a wholly owned subsidiary of Connect HK. We refer to the 2018 events described above as the Restructuring.

Connect SZ continues to hold 100% of the equity interest in Connect SH and Connect Biopharma (Beijing) Co., Ltd., or Connect BJ, which was formed subsequent to the Restructuring in July 2019 as a limited liability company incorporated under the laws of the PRC.

Following the Reorganization and the Restructuring, each as described above, Connect Biopharma Holdings Limited became the ultimate parent of the Company and all its subsidiaries.

[Table of Contents](#)

The following diagram illustrates our corporate structure as of the date of this prospectus:



The following table illustrates the principal activities and percentage equity interest as of December 31, 2018 and 2019 for each of our subsidiaries:

NAME	PRINCIPAL ACTIVITIES	COUNTRY OF INCORPORATION	% EQUITY INTEREST DECEMBER 31,	
			2018	2019
Connect Biopharma Hong Kong Limited	Investment holding	PRC	100	100
Connect BioPharm LLC	Pharmaceutical R&D	U.S.	100	100
Connect Biopharma Australia PTY LTD	Pharmaceutical R&D	Australia	100	100
Suzhou Connect Biopharma Co., Ltd.	Pharmaceutical R&D	PRC	100	100
Connect Biopharma (Shanghai) Co., Ltd	Dormant	PRC	100	100
Connect Biopharma (Beijing) Co., Ltd	Dormant	PRC	—	100

**SELECTED CONSOLIDATED FINANCIAL DATA**

The following tables present certain selected consolidated financial data as of the dates and for the periods indicated for our business. We have derived actual historical amounts included in the following selected consolidated financial data as of and for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements appearing elsewhere in this prospectus. The historical results presented are not necessarily indicative of our future results. The selected consolidated financial data set forth below should be read together with our audited consolidated financial statements for the years ended December 31, 2018 and 2019 and the related notes to those statements, as well as the section "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB.

	YEAR ENDED DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 <sup>(1)</sup>
<b>Consolidated Statements of Loss Data:</b>			
Research and development expenses (2)	(59,275)	(106,414)	(15,254)
Administrative expenses (2)	(7,175)	(9,713)	(1,392)
Other income	433	2,836	407
Other gains—net	3,802	3,050	437
<b>Operating loss</b>	<b>(62,215)</b>	<b>(110,241)</b>	<b>(15,802)</b>
Finance income	1,255	1,066	153
Finance cost	(9,905)	(53)	(8)
Finance (cost) income—net	(8,650)	1,013	145
Fair value loss of financial instruments with preferred rights	(23,012)	(59,397)	(8,514)
<b>Loss before income tax</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
Income tax expense	—	—	—
<b>Loss for the year</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss attributable to:</b>			
Owners of the Company	(76,965)	(168,625)	(24,171)
Non-controlling interests	(16,912)	—	—
	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss per share:</b>			
Basic and diluted	RMB (3.58)	RMB (5.74)	USD (0.82)

(1) USD1.00 = RMB6.9762.

(2) Included share-based compensation as follows:

	AS OF DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 <sup>(1)</sup>
Research and development expenses	584	3,635	521
Administrative expenses	—	240	34
<b>Total</b>	<b>584</b>	<b>3,875</b>	<b>555</b>

(1) USD1.00 = RMB6.9762.

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	AS OF DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000(1)
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	401,597	308,972	44,289
Financial assets at fair value through profit or loss	27,565	30,632	4,391
Working capital (2)	439,397	335,415	48,079
Total assets	453,616	372,588	53,410
Financial instruments with preferred rights (3)	573,499	643,008	92,172
Total liabilities	580,709	670,875	96,167
Total shareholders' deficit	(127,093)	(298,287)	(42,757)

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(1) USD1.00 = RMB6.9762.

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

(3) Financial instruments with preferred rights will be settled at the time of this offering through the issuance of ordinary shares.

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

*You should read the following discussion of our financial condition and results of operations in conjunction with the "Selected Consolidated Financial Data" and our audited consolidated financial statements as of and for the years ended December 31, 2018 and 2019 and the related notes thereto, included elsewhere in this prospectus. In addition to historical information, the following discussion and analysis includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, including but not limited to those described in sections titled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements." The consolidated financial statements as of and for the years ended December 31, 2018 and 2019 were prepared in accordance with IFRS, as issued by the IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including generally accepted accounting principles in the United States. As permitted by the rules of the SEC for foreign private issuers, we do not reconcile our consolidated financial statements to U.S. GAAP.*

*Our consolidated financial statements are presented in Renminbi, or RMB. For the convenience of the reader, we have translated information in the tables below presented in RMB into U.S. dollars at the rate of RMB6.9762 to \$1.00, the exchange rate set forth in the China Foreign Exchange Trade System on December 31, 2019. These translations should not be considered representations that any such amounts have been, could have been, or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.*

### Overview

We are a global clinical-stage biopharmaceutical company developing therapies for the treatment of T cell-driven inflammatory diseases. Our core expertise is in the use of functional cellular assays with T cells to screen and discover potent product candidates against immune targets. Our two most advanced clinical-stage programs include highly differentiated product candidates against validated targets. Our lead product candidate, CBP-201, is an antibody designed to target IL-4Ra, which is a validated target for the treatment of inflammatory diseases such as AD and asthma. The estimated global market for AD was approximately \$10.4 billion in 2020 and is expected to grow to \$19.3 billion by 2025, a CAGR of 13.2%. We have initiated a Phase 2b trial of CBP-201 in the United States, Australia and New Zealand in AD patients with moderate-to-severe AD, and plan to initiate additional trials in asthma and CRSwNP in the first half of 2021 and in AD patients in China in the second half of 2021. We anticipate reporting top-line results from our ongoing clinical trial in AD patients in the second half of 2021. Furthermore, we are developing CBP-307, a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1, or S1P1, for the treatment of IBD. Specifically, we are developing CBP-307 for two types of IBD, UC and CD. We anticipate reporting top-line results from a global Phase 2 trial in UC before the end of the first quarter of 2022 and also intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.

Since inception, we have devoted our resources to developing a differentiated drug discovery approach based on our deep understanding of the immune system, preparing for and conducting preclinical studies and clinical trials and protecting our intellectual property estate comprising multiple patent families and know-how. Additionally, we have applied resources to business planning and capital raising to develop a pipeline of product candidates. We have funded our operations primarily through equity financing and the receipt of government subsidies and tax credits in China and Australia. From inception, we have received more than RMB 590.9 million (USD84.7 million) from such transactions as of December 31, 2019. As of December 31, 2019, we had RMB339.6 million (USD48.7 million) in cash, cash equivalents and short-term investments in wealth management products.

As a research intensive, innovation-focused entity, we have also incurred losses and experienced negative operating cash flows since inception. Our net losses were RMB93.9 million and RMB168.6 million (USD24.2 million) for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of RMB292.1 million (USD41.9 million). We expect to continue to incur significant expenses and operating losses for the foreseeable future as we conduct our ongoing and planned preclinical studies and clinical trials, continue our research and development activities, build our manufacturing facilities, increase our production capacity, and seek

regulatory approvals for our product candidates, as well as hire additional personnel, obtain and protect our intellectual property and incur additional costs for commercialization or to expand our pipeline of product candidates.

As our product candidates move further into clinical development stages, we may receive milestone and other payments from third parties with whom we may choose to collaborate. In addition, we also expect to receive revenues from product commercialization if we obtain regulatory approval for any of our product candidates. However, as we plan to continue our research and development efforts and broaden our pipeline of product candidates, we may continue to experience losses and negative operating cash flows. We expect to finance our cash needs through a combination of equity offerings, debt financing or other capital sources. For instance, on August 21, 2020 and December 1, 2020, we completed our Series C preferred shares offerings for a total cash consideration of USD135 million. We believe that our existing cash and cash equivalents and the net proceeds from this offering will be sufficient to meet our anticipated cash and capital expenditure requirements for at least the next 12 months.

### **Key Factors and Trends Affecting Our Business**

The future success of our business is predicated on the continuation of our research and development programs, initially by developing CBP-201 and CBP-307 through Phase 2 and Phase 3 clinical trials and then seeking regulatory approval in the United States, China, Europe and other jurisdictions. We also have product candidates in our pipeline which may commence clinical trials during 2021.

#### **COVID-19**

In December 2019, a novel strain of coronavirus was reported in Wuhan, China and on March 11, 2020 the WHO declared COVID-19 a pandemic. The COVID-19 pandemic has resulted in a widespread health crisis and numerous disease control measures being taken to limit its spread. As the pandemic unfolds throughout the world, the healthcare systems of the various countries in which we are conducting our ongoing clinical trials of CBP-201 and CBP-307 have and may continue to experience great disruption.

The COVID-19 situation is very fluid across the world, and each country or the sites within a country could be impacted differently. However, as we conduct our trials globally, we were able to shift some resources to less affected areas. We are in the process of assessing the situation case by case as the pandemic evolves. For example, in China, clinical studies slowed down due to clinical sites priority shifting to COVID-19 related work and local policy of quarantine after Chinese New Year 2020. The situation has improved since and the majority of our clinical trial work has resumed since March 2020. Patient treatment has continued unabated in China during the second half 2020.

We will continue to monitor and assess the impact of the ongoing development of the pandemic on our financial position and operating results and respond accordingly. We expect the most significant potential impact of COVID-19 on our business to be a delay in the completion of our CBP-307 Phase 2 clinical trial with the resultant impact on our cashflow and funding requirements. Enrollment of our Phase 2 clinical trial of CBP-307 in patients with CD in China was prematurely terminated due to challenges in recruitment caused by the COVID-19 pandemic.

### **Key Components of Our Results of Operations**

#### **Revenue**

We do not currently have any approved products. Accordingly, we have not generated any revenue and do not expect to do so unless we obtain regulatory approval and commercialize any of our product candidates or until we receive revenues from collaborations or other arrangements with third parties, neither of which may occur.

#### **Operating Expenses**

##### *Research and Development Expenses*

Research and development expenses are primarily related to preclinical and clinical development of our product candidates and discovery efforts. Research expenditures are expensed in the period the expenditure is incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed service or product and all the following can be demonstrated:

- the technical feasibility to complete the development project so that it will be available for use or sale;
- the intention to complete the development project to use or sell the product;
- the ability to use or sell the product;

## Table of Contents

- the manner in which the development project will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development project and use or sell the product; and
- the expenditure attributable to the asset during its development can be reliably measured.

Elements of research and development expenses primarily include (1) expenses related to preclinical testing of our technologies under development and clinical trials such as payments to CROs, investigators and clinical trial sites that conduct the clinical studies; (2) consultant service related to the design of clinical trials and data analysis, (3) payroll and other related expenses of personnel engaged in research and development activities, (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility-related expenses, and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

The majority of our third-party expenses have been related to the development of CBP-201 and CBP-307. During the years ended December 31, 2018 and 2019, we spent RMB22.7 million and RMB32.1 million (USD4.6 million) in CRO related costs relating to CBP-201 and RMB20.1 million and RMB47.0 million (USD 6.7 million) in CRO related costs relating to CBP-307 respectively. We deploy our personnel and facility-related resources across all of our research and development activities. We have substantially increased our research and development expenditures as we continue the development of our product candidates and conduct discovery and research activities for our preclinical programs. Product candidates in a later stage of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We expect that our research and development costs will continue to increase as we conduct ongoing, and plan and conduct new, preclinical studies and clinical trials and manufacture our product candidates.

We cannot determine with certainty the timing of initiation, the duration, or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. It is likely that we will need to raise additional capital in the future for commercialization of our products, assuming that we obtain regulatory approval.

Our clinical development costs are highly uncertain and may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

Any of these variables with respect to the development of our product candidates or any other future candidate that we may develop could result in a significant change in the costs and timing associated with their development. For example, if the FDA, the NMPA, or another regulatory authority were to require us to conduct preclinical studies and



clinical trials beyond those we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs. We may never succeed in obtaining regulatory approval for any of our product candidates.

**Administrative Expenses**

Administrative expenses primarily include payroll and related expenses for employees involved in general corporate functions including finance, legal and human resources, rental and depreciation expenses related to facilities and equipment used by these functions, professional service expenses and other general corporate related expenses.

We expect our administrative expenses to increase in the future to support our continued research and development activities and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipated increased expenses related to professional fees, including audit, legal, regulatory and tax-related services, associated with maintaining compliance with Nasdaq listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

**Other Income**

Other income consists of government grants received by us. Grants from the government are recognized at their fair value where there is a reasonable assurance that the grant will be received and we will comply with all attached conditions. Government grants relating to costs are deferred and recognized in profit or loss over the period necessary to match them with the costs that they are intended to compensate.

**Other Gains—Net**

Other gains or losses consist of foreign exchange gains and losses resulting from the settlement of foreign currency transactions which are translated into the functional currency using the exchange rates at the year-end exchange rates. All other foreign exchange gains and losses are presented in the consolidated statements of loss on a net basis within other gains-net.

We also have short-term investments in wealth management products with various maturities bear floating interest rates. The fair value of short-term investments in wealth management products is based on discounted cash flows using their expected returns. Changes in fair value of these financial assets are recorded in other gains-net.

**Finance Income**

Finance income is comprised primarily of interest income earned from bank and term deposits that are held for cash management purposes.

**Finance Cost**

Finance cost is mainly comprised of issuance costs for our financial instruments with preferred rights and interests for lease liabilities.

**Fair Value Loss of Financial Instruments with Preferred Rights**

The fair value of financial instruments with preferred rights that are not traded in an active market is determined using valuation techniques. We first determine the equity value and then allocated the equity value to each element of our capital structure using either an option pricing back-solve method, or OPM, or a hybrid method, which employs the concepts of the OPM and the probability-weighted expected return method, or PWERM, that merged into a single framework. The fair value difference is accounted for as fair value loss of financial instruments with preferred rights within the consolidated statements of loss.

**Income Taxes**

Income tax expense is recognized based on the income tax rates in the following main tax jurisdictions where we operate.

*(a) Cayman Islands*

We are incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands and accordingly, are exempted from Cayman Islands income tax.

*(b) Hong Kong*

Hong Kong profits tax rate is 16.5% as of April 1, 2018 when the two-tiered profits tax regime took effect, under which the tax rate is 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 during the years ended December 31, 2018 and 2019.

*(c) United States*

Our subsidiary, Connect US, is incorporated in the United States and is a disregarded entity wholly owned by Connect SZ (before September 2018) and then by Connect HK, from a tax perspective. Therefore, from a U.S. tax perspective, it is Connect US that is subject to U.S. federal corporate income tax at a rate of 21% during the reporting periods. Connect US is also subject to state income tax in California at a rate of 8.84%, to the extent of the income attributable to Connect US. Connect US had no profit that is subject to income tax for all periods presented, therefore, no provision for income taxes has been provided.

*(d) Australia*

Our subsidiary, Connect AU, is incorporated in Australia. Companies registered in Australia are subject to Australian profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Australian tax laws. The applicable tax rate in Australia is 30%. Connect AU had no taxable income for all periods presented, therefore, no provision for income taxes has been provided.

*(e) People's Republic of China*

Provision for PRC corporate income tax is calculated based on the statutory income tax rate of 25% on the assessable income of our respective subsidiaries in the PRC during the years ended December 31, 2018 and 2019 in accordance with relevant PRC enterprise income tax rules and regulations.

No provision for PRC corporate income tax has been made for the years ended December 31, 2018 and 2019 as we have no such assessable profit for the years.

**Results of Operations**

**Comparison of the Years Ended December 31, 2018 and 2019**

The following table summarizes key components of our results of operations for the periods indicated:

	YEAR ENDED DECEMBER 31,			CHANGE %
	2018 RMB'000	2019 RMB'000	2019 USD'000 <sup>(1)</sup>	
Research and development expenses	(59,275)	(106,414)	(15,254)	80
Administrative expenses	(7,175)	(9,713)	(1,392)	35
Other income	433	2,836	407	555
Other gains—net	3,802	3,050	437	(20)
<b>Operating loss</b>	<b>(62,215)</b>	<b>(110,241)</b>	<b>(15,802)</b>	<b>77</b>
Finance income	1,255	1,066	153	(15)
Finance cost	(9,905)	(53)	(8)	(99)
Finance cost—net	(8,650)	1,013	145	(112)
Fair value loss of financial instruments with preferred rights	(23,012)	(59,397)	(8,514)	158
<b>Loss before income tax</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>	<b>80</b>
Income tax expense	—	—	—	—
<b>Loss for the year</b>	<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>	<b>80</b>

<sup>(1)</sup> USD1.00 = RMB6.9762.

*Research and Development Expenses*

Research and development expenses increased by 80% from RMB59.3 million for the year ended December 31, 2018 to RMB106.4 million (USD15.3 million) for the year ended December 31, 2019. As our product candidates further advance into later clinical trial phases, our research and development activities increased significantly. For example, one of our leading product candidates, CBP-307, entered into a Phase 2 clinical trial in October 2018 for UC, with significantly increased CRO spending in 2019.

*Administrative Expenses*

Administrative expenses increased by 35% from RMB7.2 million for the year ended December 31, 2018 to RMB9.7 million (USD1.4 million) for the year ended December 31, 2019. The increase in administrative expenses was primarily due to more headcount and resources needed in support of the growth in research and development activities.

*Other Income*

Other income increased by 555% from RMB0.4 million for the year ended December 31, 2018 to RMB2.8 million (USD0.4 million) for the year ended December 31, 2019. This increase was related to a government grant to encourage research and development activities in China and research and development credits in Australia.

*Other Gains—Net*

Other gains—net decreased by 20% from RMB3.8 million for the year ended December 31, 2018 to RMB3.1 million (USD0.4 million) for the year ended December 31, 2019. The decrease was primarily attributable to fluctuations in foreign exchange rates in 2018. We maintained a majority of cash and cash equivalents in USD while our functional currency is in RMB. During 2018, USD exchange rates against RMB rose more than those during 2019, leading to a decrease in exchange gains.

*Finance Income*

Finance income decreased by 15% from RMB1.3 million for the year ended December 31, 2018 to RMB1.1 million (USD0.2 million) for the year ended December 31, 2019, which was primarily due to the decrease in interest earned from bank deposits and term deposits.

*Finance Costs*

Finance costs decreased by 99% from RMB9.9 million for the year ended December 31, 2018 to RMB0.1 million (USD8,000) for the year ended December 31, 2019. This decrease in finance costs was primarily related to the decrease in issuance costs for our financial instruments with preferred rights.

*Fair Value Loss of Financial Instruments with Preferred Rights*

Fair value loss of financial instruments with preferred rights increased 158% from RMB23.0 million for the year ended December 31, 2018 to RMB59.4 million (USD8.5 million) for the year ended December 31, 2019. The increase is primarily related to the increase in enterprise value resulting from our Series B redeemable convertible preferred shares offering and related allocation to preferred rights.

**Liquidity and Capital Resources**

**Overview**

We are a clinical development stage company that has generated no revenues and are exposed to a variety of financial risks including liquidity risks. We have incurred significant losses and negative cash flows from operations since our inception. As of December 31, 2019, we had an accumulated deficit of RMB292.1 million (USD41.9 million), and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2019, we had cash, cash equivalents and short-term investments in wealth management products of approximately RMB339.6 million (USD48.7 million). Historically, we have financed our operations principally through proceeds from the issuance and sale of preferred shares in private placement transactions, including the Series C Preferred Shares offerings that we completed on August 1, 2020 and December 1, 2020 for total cash consideration of USD135.0 million.

We believe, based on our current operating plan and expected expenditures, that our existing cash and cash equivalents will be sufficient to meet our anticipated cash and capital expenditure requirements for at least the next 12 months and meet the requirements of a going concern. We intend to use the net proceeds from this offering to fund the research and development of our product candidates, including CBP-201, CBP-307 and CBP-174, to fund the research and preclinical and clinical development of our other development programs, including CBP-233, and to fund other current and future research and development activities and for working capital and other general corporate purposes, which may include capital projects. However, the forecast of the period of time through which our financial resources will be adequate to support operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove

to be wrong, and we could use capital resources sooner than expected. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses is uncertain.

**Cash Flows for the Years Ended December 31, 2018 and 2019**

The following table summarizes our cash flows for the periods indicated:

	YEAR ENDED DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 <sup>(1)</sup>
<b>Cash Flow Data:</b>			
Net cash used in operating activities	(69,032)	(90,256)	(12,938)
Net cash generated from / (used in) investing activities	58,075	(3,341)	(479)
Net cash generated from / (used in) financing activities	368,955	(396)	(57)
Net increase/ (decrease) in cash and cash equivalents	<u>357,998</u>	<u>(93,993)</u>	<u>(13,474)</u>

(1) USD1.00 = RMB6.9762.

**Operating Activities**

During the year ended December 31, 2019, net cash used in operating activities was RMB90.3 million (USD12.9 million), primarily due to our net loss of RMB168.6 million (USD24.2 million), offset by non-cash charges of RMB61.9 million (USD8.9 million) and positive working capital change in our operating assets and liabilities of RMB16.4 million (USD2.4 million). The non-cash charges consisted of fair value changes of financial instruments with preferred rights of RMB59.4 million (USD8.5 million) and share-based compensation expense of RMB3.9 million (USD0.6 million), offset by the net foreign exchange differences of RMB1.4 million (USD0.2 million). The positive working capital change in operating assets and liabilities was primarily due to increases in trade payables and other payables and accruals of RMB21.0 million (USD3.0 million) due to timing of payments on outstanding payables and an increase in research and development activities related to CBP-307 Phase 2 clinical trials, partially offset by an increase in other receivables and prepayments of RMB3.0 million (USD0.4 million) primarily related to the prepayments to the CROs for CBP-307 Phase 2 clinical trials and an increase in other non-current assets of RMB1.6 million (USD0.2 million) due to higher long-term value-added tax, or VAT, balances which can offset against future VAT payables.

During the year ended December 31, 2018, net cash used in operating activities was RMB69.0 million, primarily due to our net loss of RMB93.9 million and negative working capital change in our operating assets and liabilities of RMB6.1 million, offset by non-cash charges of RMB30.9 million. The non-cash charges primarily consisted of fair value changes of financial instruments with preferred rights of RMB23.0 million and the issuance cost of financial instruments with preferred rights of RMB9.9 million, which were partially offset by net foreign exchange differences of RMB2.7 million. The negative working capital change in operating assets and liabilities was primarily due to an increase in other receivables and prepayments of RMB7.0 million due to higher prepayments to CROs and an increase in non-current assets of RMB2.9 million due to higher long-term VAT balance which can offset against future VAT payables. The changes were partially offset by increases in trade payables and other payables and accruals of RMB3.8 million due to higher payables to CROs as a result of additional clinical studies.

**Investing Activities**

During the year ended December 31, 2019, net cash used in investing activities of RMB3.3 million (USD0.5 million) was primarily related to the purchase of financial assets of RMB163.0 million (USD23.4) and the purchase of property, plant and equipment of RMB1.1 million (USD0.2 million), offset by the proceeds of RMB160.7 million (USD23.0 million) from disposal of financial assets.

During the year ended December 31, 2018, net cash generated from investing activities of RMB58.1 million was primarily related to the proceeds of RMB107.0 million from disposal of financial assets at fair value through profit or loss and maturity of term deposits of RMB 59.0 million, which were partially offset by the purchase of financial assets at fair value through profit or loss of RMB106.7 million and the purchase of property, plant and equipment of RMB1.2 million.

*Financing Activities*

During the year ended December 31, 2019, net cash used in financing activities was RMB0.4 million (USD57,000), primarily related to the payments of lease liabilities.

During the year ended December 31, 2018, net cash generated from financing activities was RMB369.0 million, primarily resulting from the proceeds from issuance of financial instruments with preferred rights of RMB379.1 million, partially offset by the related issuance cost of RMB9.9 million and the payments of lease liabilities of RMB0.3 million.

**Critical Accounting Policies and Estimates**

Our consolidated financial statements are the first consolidated financial statements prepared by us in accordance with IFRS issued by the IASB, with transition date being January 1, 2018. The financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through profit or loss and financial instruments with preferred rights. Our consolidated financial statements previously had not been prepared under any other accounting standards.

The preparation of financial statements requires the use of accounting estimates which, by definition, may not equal the actual results. Management also needs to exercise judgment in applying the accounting policies.

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact and that are believed to be reasonable under the circumstances. These estimates may not equal actual results.

**a) Research and development expenses**

We incur costs and effort on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditure is incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed service or product and all the following can be demonstrated:

- the technical feasibility to complete the development project so that it will be available for use or sale;
- the intention to complete the development project to use or sell the product;
- the ability to use or sell the product;
- the manner in which the development project will generate probable future economic benefits for us;
- the availability of adequate technical, financial and other resources to complete the development project and use or sell the product; and
- the expenditure attributable to the asset during its development can be reliably measured.

Elements of research and development expenses primarily include (1) expenses related to preclinical testing of our technologies under development and clinical trials such as payments to CROs and clinical trial sites that conduct the clinical studies; (2) consultant service related to the design of clinical trials and data analysis, (3) payroll and other related expenses of personnel engaged in research and development activities, (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

**b) Fair value of financial instruments with preferred rights**

Financial instruments with preferred rights issued by us will be convertible into ordinary shares upon the closing of a qualified initial public offering or at the option of the holders and redeemable upon occurrence of certain future events. Financial instruments with preferred rights are compound instruments with discretionary dividend right. The Company elected to designate the entire hybrid contracts that include a host contract and embedded derivatives as financial liabilities at fair value through profit or loss considering the fact that the instruments also have contingent settlement provisions. Our preferred shares are not traded in an active market and the respective fair value is determined by using valuation techniques. We first determined the equity value and then allocated the equity value to each element of our capital structure using either an OPM or a hybrid method. We make assumptions and estimates concerning variables such as discount rate for lack of marketability, or DLOM, expected volatility and risk-free interest rates.

Key valuation assumptions used to determine the fair value of our financial instruments with preferred rights are as follows:

- *DLOM*—we estimated the DLOM based on an OPM. Under the OPM, the cost of a put option, which can hedge price changes before privately held shares are sold, was considered as a basis to determine the DLOM. DLOM reflects the fact that there is no ready market for shares in a closely held corporation. It is derived by reference to the put option based on the Black-Scholes Option Pricing Model, adjusted for the volatility of different equity classes by Merton's formulation.
- *Expected Volatility*—volatility was estimated based on the annualized standard deviation of daily stock price returns of comparable companies for periods from respective valuation dates and with similar span as time to exit. Comparable companies are selected to be in similar industry and within similar range of market capitalizations that are publicly traded with easy access to daily trading data.
- *Risk-free interest rates*—risk-free interest rates were estimated based on the yield of U.S. Treasury strips as of each valuation date.

**c) Recognition of share-based compensation expenses**

In order to attract and retain the right talent, we offer share-based compensation incentives to our employees, directors and consultants. We used a Binomial Option Pricing model to determine the total fair value of the awarded options, which is to be expensed over the vesting period. Significant estimate on assumptions, such as the grant date share price, expected volatility, expected early exercise multiple, option life, risk-free interest rate and dividend yield, are required to derive such expense amounts. As we continue to grow and move into key stages of product development, we expect to continue offering share-based incentives to our employees, directors and consultants and the amount of expenses may increase in future.

Key assumptions are estimated as follows:

- *Grant date share price*—Because our ordinary shares are not yet publicly traded, we are required to estimate the fair value of our ordinary shares, as discussed in "Ordinary Share Valuation" below.
- *Expected volatility*—We adopted the average volatility of the comparable companies as the proxy of the expected volatility of the underlying share. The volatility of each comparable company was based on the historical daily stock prices for a period with length commensurate to the remaining maturity life of the stock options.
- *Expected early exercise multiple*—We estimated expected early exercise multiple for employee grantees and senior management grantees respectively by making reference to academic research.
- *Option life*—We adopted option life in accordance with the contractual terms of the options.
- *Risk-free interest rate*—The risk-free rate is based on the U.S. Treasury yield for our risk-free interest rate that corresponds with the expected term.
- *Dividend yield*—We have no history of paying cash dividends on our ordinary shares and do not expect to pay dividends in the foreseeable future.

**d) Ordinary Share Valuation**

The fair value of the ordinary shares underlying our share options has historically been determined by us, with input from management and contemporaneous third-party valuations, as there has been no public market for our ordinary shares. Given the absence of a public trading market of our ordinary shares, and in accordance with the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation*, our board of directors exercised reasonable judgement and considered numerous objective and subjective factors to determine the best estimate of the fair value of our ordinary shares at each grant date and reporting period. These factors include important developments in our operations, including research and development activities, sales of preferred shares, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general and the stock price performance and volatility of comparable public companies used to determine our enterprise value, which is allocated to our different classes of ordinary and preferred shares. In addition, the valuation of our ordinary shares considers the lack of liquidity of our ordinary shares. We have used either an OPM or the hybrid method to estimate the equity value and adopted an equity allocation model to determine each element of our capital structure. After the closing of this offering, the fair value of each ordinary share will be determined based on the closing price of our ordinary shares on the date of grant.

**e) Current and deferred income taxes**

We recognize deferred tax assets based on estimates that it is probable to generate sufficient taxable profits in the foreseeable future against which the deductible losses and temporary differences will be utilized. The recognition of deferred tax assets mainly involves management's judgments and estimations about the timing and the amount of taxable profits of the companies which have tax losses. As we expect continued operating losses in the near future, we do not expect to utilize historical tax losses. We have not recognized our deferred income assets as of December 31, 2018 and 2019.

**Quantitative and Qualitative Disclosures About Market Risk**

Market risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to changes in market prices. The type of market risk that primarily impacts us is foreign currency risk.

**Interest rate risk**

Our interest rate risk primarily arises from short-term investments in wealth management products measured at fair value through profit or loss and cash and cash equivalents. Those carried at variable rates expose us to cash flow interest rate risk whereas those at fixed rates expose us to fair value interest rate risk. We believe we did not have significant interest rate risk during the periods presented.

**Exchange risk**

As discussed above, we operate internationally and can be exposed to foreign exchange risk, primarily the USD. Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities denominated in a currency that is not the functional currency of the relevant group entity. See detail to our potential exposure to foreign currency risk at the end of the reporting periods in the consolidated financial statements and the related footnote disclosure.

Most foreign exchange transactions were denominated in USD for the subsidiaries that have functional currency in RMB. At December 31, 2018 and 2019, had the USD strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years then ended would have been RMB0.6 million lower/higher and RMB1.6 million lower/higher (USD0.2 million), respectively. We plan to monitor the exchange rate movement between USD and RMB to minimize potential risks.

**Credit risk**

Credit risk primarily arises from cash and cash equivalents, financial assets at fair value through profit or loss, and other receivables. The maximum exposure to credit risk is represented by the carrying amount of each financial asset in the balance sheets.

The credit risk of cash and cash equivalents and financial assets at fair value through profit or loss is limited because the counterparties are mainly state-owned or reputable commercial institutions located in the PRC and other reputable financial institutions located in Australia and the United States.

For other receivables, management makes periodic as well as individual assessments on the recoverability based on historical settlement records and past experience and adjusts for forward looking information based on macroeconomic factors affecting the ability of the debtors to settle the receivables.

We apply the expected credit loss model to financial assets measured at cost. Impairment on other receivables is measured as either 12-month expected credit losses or lifetime expected credit losses, depending on whether there has been a significant increase in credit risk since initial recognition. To assess whether there is a significant increase in credit risk, we compare the risk of default occurring on the asset as of the reporting date with the risk of default as of the date of initial recognition by considering available, reasonable and supportive forwarding-looking information.

In view of the history of cooperation with debtors, the sound collection history of other receivables as well as forward-looking factors, we believe that the credit risk inherent in these outstanding receivables is not significant.

**Liquidity risk**

We aim to maintain sufficient cash to meet obligations coming due as well as future operating and capital requirements.

## Contractual Obligations

The table below summarizes our financial liabilities into relevant maturity groupings based on the remaining period at each year-end date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows except for financial instruments with preferred rights, which are presented on a fair value basis. The maturity dates are determined by the terms in financing agreements.

	AS OF DECEMBER 31, 2019				
	LESS THAN 1 YEAR	BETWEEN 1 AND 2 YEARS	BETWEEN 2 AND 5 YEARS	MORE THAN 5 YEARS	TOTAL
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Financial instruments with preferred rights	—	—	643,008	—	643,008
Trade payables	22,788	—	—	—	22,788
Other payables	664	—	—	—	664
Lease liabilities	445	445	37	—	927
Total	23,897	445	643,045	—	667,387

## Off-Balance Sheet Commitments and 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. 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.

## Recently Adopted Accounting Standards and Accounting Standards Not Yet Adopted

A description of recently adopted accounting pronouncements and accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is disclosed in Note 2 to our annual consolidated financial statements appearing at the end of this prospectus.

## Internal Control Over Financial Reporting

As a public company listed on Nasdaq, we will be required under the Sarbanes-Oxley Act, among other things, to assess the effectiveness of our internal controls over financial reporting at the end of each fiscal year. We anticipate being required to issue management's assessment of internal control over financial reporting pursuant to Section 404(a) of the Sarbanes-Oxley Act for the first time in connection with issuing our annual consolidated financial statements as of and for the year ending December 31, 2022.

In connection with the preparation and audit of our consolidated financial statements, as of and for the years ended December 31, 2018 and 2019, we and our independent registered public accounting firm identified two material weaknesses in our internal control over the financial statement closing process. The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of IFRS and the reporting and compliance requirements of the SEC to address complex IFRS technical accounting issues, and to prepare and review consolidated financial statements and related disclosures in accordance with IFRS and SEC reporting requirements; and (ii) our lack of formal and effective financial closing policies and procedures, specifically those related to period-end expenses cut-off and accruals.

We are working to remediate this material weakness and are taking steps to strengthen our internal control over financial reporting through the development and implementation of processes and controls over the financial reporting process. Specifically, we are working to:

- develop and implement period-end financial closing policies and procedures, including expense reconciliation between finance and operation departments;



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## Table of Contents

- develop and implement a staffing plan for hiring additional accounting and finance personnel in 2021;
- hire additional qualified resources with appropriate knowledge and expertise to handle complex accounting issues and effectively prepare financial statements; and
- conduct regular and continuous IFRS accounting and financial reporting training programs for our financial reporting and accounting personnel.

We expect that we will 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 weakness in time, or at all. See “Risk Factors—We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of the ADSs may decline.”

## BUSINESS

### Overview

We are a global clinical-stage biopharmaceutical company developing therapies for the treatment of T cell-driven inflammatory diseases. Our core expertise is in the use of functional cellular assays with T cells to screen and discover potent product candidates against immune targets. Our two most advanced clinical-stage programs include highly differentiated product candidates against validated targets. Our lead product candidate, CBP-201, is an antibody designed to target interleukin-4 receptor alpha, or IL-4Ra, which is a validated target for the treatment of inflammatory diseases such as atopic dermatitis, or AD, and asthma. The estimated global market for AD was approximately \$10.4 billion in 2020 and is expected to grow to \$19.3 billion by 2025, a compound annual growth rate, or CAGR, of 13.2%. Based on observed results in preliminary clinical studies, CBP-201 has the potential to be differentiated from dupilumab, an antibody that also targets IL-4Ra, which is now approved by the U.S. Food and Drug Administration, or FDA. We have initiated a Phase 2b trial of CBP-201 in the United States, Australia and New Zealand in AD patients with moderate-to-severe AD, and plan to initiate additional trials in asthma and chronic rhinosinusitis with nasal polyps, or CRSwNP, in the first half of 2021 and in AD patients in China in the second half of 2021. We anticipate reporting top-line results from our ongoing clinical trial in AD patients in the second half of 2021. Furthermore, we are developing CBP-307, a modulator of a T cell receptor known as sphingosine 1-phosphate receptor 1, or S1P1, for the treatment of inflammatory bowel disease, or IBD. Specifically, we are developing CBP-307 for two types of IBD, ulcerative colitis, or UC, and Crohn's disease, or CD. We anticipate reporting top-line results from a global Phase 2 trial in UC before the end of the first quarter of 2022 and also intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.

Our immune modulator product candidates originate from our approach to drug discovery based on using biologically relevant functional cellular assays to conduct primary drug screens instead of high-throughput biochemical assays. The clinical and preclinical results we have observed for our product candidates support the potential for this physiologically relevant methodology to yield highly differentiated solutions, in a more efficient manner. Our approach is agnostic to drug modalities and has been used to identify both small molecule and antibody product candidates.

We are advancing CBP-201, an anti-IL-4Ra antibody, for the treatment of inflammatory allergic diseases such as AD, asthma, and CRSwNP. Inhibition of IL-4Ra blocks the action of two inflammatory cytokines: interleukin-4, or IL-4, and interleukin-13, or IL-13. In a randomized, placebo-controlled Phase 1a trial in healthy volunteers, administration of a single dose of CBP-201 was well-tolerated and led to suppression of a serum biomarker of inflammation. In a randomized, placebo-controlled phase 1b trial in AD patients, we observed decreases at four weeks in Eczema Area and Severity Index, or EASI, score, a validated measure of extent and severity of AD, in average weekly rating on the Pruritus Numerical Rating Scale for severity, or PNRS-Severity scale, a validated patient-reported instrument to measure itch intensity, and PNRS-Frequency scale, a patient-reported instrument to measure itch frequency, all of which demonstrated rapid improvements in signs and symptoms of itching, or pruritus, and AD disease severity. Although no head-to-head trials have been conducted, we believe that CBP-201 has three potential advantages over the current standard of care: (1) CBP-201 binds to a region of IL-4Ra that is distinct from that bound by dupilumab and associated with high binding affinity and potency for IL-4Ra, which we believe may lead to improved clinical response; (2) a faster onset of action, as demonstrated by data from our Phase 1b trial which reported 100% of patients receiving a 300mg dose of CBP-201 (n=7) achieved EASI-50 at four weeks as compared to data reported in independent clinical trials of dupilumab which reported 69% of patients receiving a 300 mg dose of dupilumab (n=55) achieving EASI-50 at four weeks and 85% achieving EASI-50 at 12 weeks; and (3) a longer duration between injections, as evidenced by data from our Phase 1a trial which reported a longer time taken of 57 days for the mean plasma concentration of a single subcutaneous dose of CBP-201 300 mg to fall below the equivalent lower limit of quantification, or LLOQ, of 640 ng/mL vs. 42 to 49 days for a single subcutaneous dose of dupilumab 300 mg to fall below the LLOQ of 0.078 mg/L. We have initiated a Phase 2b trial of CBP-201 in AD patients with moderate-to-severe AD, and plan to initiate additional trials in asthma and CRSwNP in the first half of 2021 and in AD patients in China in the second half of 2021. We anticipate reporting top-line results from our ongoing clinical trial in AD patients in the second half of 2021.

CBP-307 is a small molecule modulator of S1P1, a regulator of T cell mobilization out of lymph nodes into the periphery. Inhibiting S1P1 leads to reduction in the levels of these T cells in circulation and a reduction in autoimmune-related inflammation. S1P1 is a validated therapeutic target with three drugs approved to treat multiple sclerosis: fingolimod, marketed as Gilenya® by Novartis, siponimod, marketed as Mayzent® by Novartis, and ozanimod, marketed as Zeposia®, by Bristol Myers Squibb. Evidence from third-party clinical trials suggests that the potential of S1P1 modulators is far broader than multiple sclerosis and includes highly prevalent diseases with unmet need such as UC and CD. The estimated global market for UC was approximately \$5.4 billion in 2020, and the estimated global market for CD was approximately \$7.4 billion in 2019. We believe that CBP-307 is well-positioned to address these diseases due to its potency, specificity and pharmacokinetics observed in our preclinical studies and early clinical trials. We are conducting a global Phase 2 trial in UC and anticipate reporting top-line results before the end of the first quarter of 2022. In addition, we intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.

We are developing CBP-174, a peripherally acting, small molecule H3R antagonist, for oral administration to treat chronic itch associated with skin inflammation. We have exclusively licensed global rights to CBP-174 from Arena Pharmaceuticals, Inc., or Arena, to complement our CBP-201 program in AD. We believe that the ability to quickly alleviate itch in the setting of AD has the potential to complement the anti-pruritic effect of disease-modifying IL-4Ra antagonists such as our CBP-201 product candidate or dupilumab. In clinical trials, these IL-4Ra targeted products required weeks of treatment for many AD patients to obtain significant relief of itching, or pruritus. Our preclinical mouse model study has indicated that CBP-174 led to reductions in scratching within the first 30 minutes of dosing, which could potentially translate to rapid reduction in pruritus in the clinic. We intend to initiate a Phase 1 dose escalation study with CBP-174 in healthy adults in the first half of 2021 and anticipate reporting top-line results in the second half of 2021.

We are building a rich pipeline of internally designed, wholly owned small molecules and antibodies targeting other aspects of T cell biology. CBP-233, one of our preclinical product candidates, is a highly potent, humanized antibody against interleukin-33, or IL-33, a cytokine involved in Th2 inflammation. IL-33 is up-regulated in patients with allergic inflammatory diseases such as asthma and AD compared to healthy individuals. IL-33 initiates a diverse array of cellular immune responses, including the activation of mast cells, basophils and eosinophils, leading to production of downstream inflammatory cytokines, such as IL-4, IL-5, IL-13, interferon gamma and TNF alpha, or TNFα. Preliminary evidence of the therapeutic potential of an anti-IL-33 antibody has been reported in several indications including asthma, AD, and food allergy. We are currently conducting preclinical studies to support a future IND submission for CBP-233 with the FDA.

With operations and expertise in China, the United States and Australia and clinical development activities in those geographies as well as Europe, we are on the way to building a global company. Our founders are from China and have spent a majority of their careers in the United States. With respect to our operations in China, we leverage our relationships with clinical research organizations, large patient population and local infrastructure in ways that we believe provide us with a competitive advantage. We intend to continue recruiting top talent and operating in these geographies for the foreseeable future.

We were founded by a team with broad knowledge of the drug discovery industry and domain expertise in targeting immunological pathways. Zheng Wei, Ph.D., our Chief Executive Officer, has over 25 years of experience at drug discovery organizations including Arena and was a scientist and program leader at ChemoCentryx. Wubin (Bill) Pan, Ph.D., our President and Chairman, was a co-founder, China President, and Chief Operation Officer of Crown Bioscience. We believe that our experience and professional networks in both the drug discovery and contract research industry provide us with critical insights on best practices to optimally build a highly efficient and cost-effective discovery and development organization. Our physical presence in China and the United States enables us to take advantage of high-quality local talent while facilitating access to other global resources. We have raised approximately \$220 million to date and are supported by top tier investors including RA Capital Management, BlackRock, Lilly Asia Ventures, Boxer Capital, HBM Healthcare, Qiming Venture Partners, Northern Light Venture Capital and Cowin Venture.



## **Dysregulation of T Cells in Inflammatory Diseases**

T cells are a type of lymphocyte, or white blood cell, responsible for controlling and shaping the immune response to foreign substances such as pathogens and allergens. Dysregulation of T cells often leads to the development of multiple diseases related to autoimmunity and inflammation. These diseases include respiratory diseases such as asthma; dermatological diseases such as AD; gastrointestinal diseases such as IBD; and neurodegenerative diseases such as multiple sclerosis. As understanding of the details of T cell biology has evolved over the last two decades, a number of targeted drugs have been developed for these diseases that directly modulate T cell biology.

A subclass of T cells called T helper cells assists in determining the appropriate immune response based on the nature of the attack on the body. T helper cells themselves belong to two major subcategories, leading to two types of immune responses known as Th1 and Th2 immune responses.

Broadly speaking, Th1 immune responses are pro-inflammatory in nature. When the body needs to respond to pathogens inside the cell, it triggers a Th1 response. Dysregulation of this Th1 response is also associated with pathologies such as autoimmune diseases, including multiple sclerosis, psoriasis and IBD. In those cases, the body reacts to a part of itself as if it is a threat, and the inflammation that results is part of the Th1 response. Therapies that interfere with Th1 signaling include glucocorticoids, inhibitors of TNF $\alpha$  and inhibitors of interleukin 12 and interleukin 23, or IL-12/IL-23. These therapies have been approved to treat multiple diseases such as rheumatoid arthritis, psoriasis and IBD.

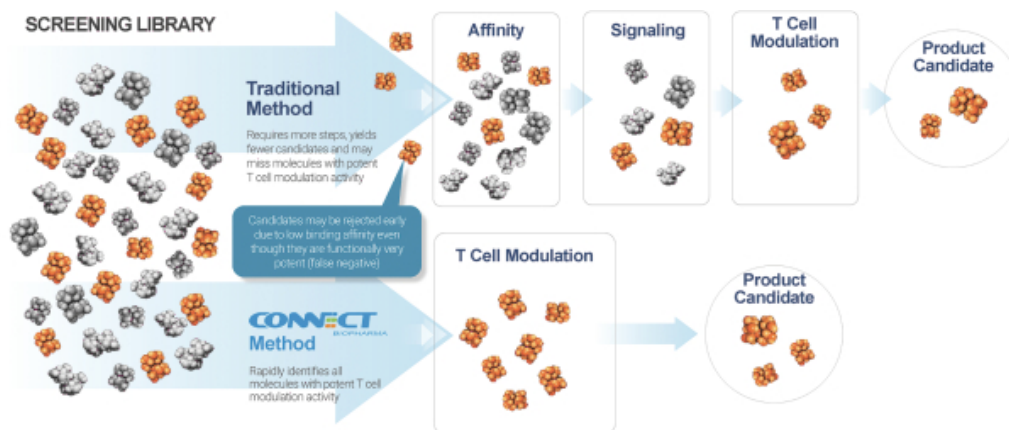
Th2 immune responses help the body attack extracellular pathogens and drive allergic reactions. Diseases caused by Th2 dysregulation include asthma, AD and allergies. Dupilumab, which blocks the activity of Th2 cytokines by inhibiting IL-4 and IL-13, has been approved to treat AD, asthma and CRSwNP.

Previously approved modulators of the Th1 and Th2 immune responses have illustrated both the broad therapeutic potential and the sizeable commercial market associated with targeted T cell therapies. We believe, however, that there exist multiple opportunities to develop next-generation therapeutics directed against clinically validated as well as novel targets that regulate Th1 and Th2 immune responses.

## **Our Approach**

Our differentiated approach is designed to specifically identify product candidates based on our deep understanding of the immune system, particularly T cell biology, and ability to develop sophisticated functional assays using T cells. In contrast to traditional drug discovery approaches, which often begin with high throughput screening based on biochemical properties, we directly screen our molecules with these functional assays. We believe our approach leads to more rapid identification of relevant molecules and avoids the elimination of attractive molecules that could fail to advance through traditional screening assays.

We apply our approach to develop product candidates against targets in T cell modulation related to inflammatory diseases with large unmet need. Our goal is to produce first-in-class or best-in-class product candidates to address these targets.



**Figure 1. Our drug screening approach**

**Our Product Candidates**

**CBP-201, an Anti-IL-4Ra Antibody**

We are advancing CBP-201, an anti-IL-4Ra antibody, for the treatment of inflammatory allergic diseases such as AD, asthma, and CRSwNP. Inhibition of IL-4Ra blocks the action of two inflammatory cytokines: IL-4 and IL-13. Dupilumab, marketed as Dupixent® by Sanofi and Regeneron, an antibody that targets IL-4Ra, has been demonstrated to lead to significant therapeutic benefit in patients with these diseases. Despite being on the market for only three years, sales of dupilumab were over €2 billion in 2019 and are expected to grow to over €10 billion according to Sanofi’s estimates. In a randomized, placebo-controlled Phase 1a trial in healthy volunteers, administration of a single dose of CBP-201 was well-tolerated and led to suppression of a serum biomarker of inflammation. In a randomized, placebo-controlled phase 1b trial in AD patients, we observed decreases at four weeks in EASI score in average weekly rating on the PNRS-Severity scale, a validated patient-reported instrument to measure itch intensity, and PNRS-Frequency scale, a patient-reported instrument to measure itch frequency, all of which demonstrated rapid improvements in signs and symptoms of itching, or pruritis, and AD disease severity. Although no head-to-head trials have been conducted, we believe that CBP-201 has three potential advantages over the current standard of care: (1) CBP-201 binds to a region of IL-4Ra that is distinct from that bound by dupilumab and associated with high binding affinity and potency for IL-4Ra, which we believe may lead to improved clinical response; (2) a faster onset of action, as demonstrated by data from our Phase 1b trial which reported 100% of patients receiving a 300mg dose of CBP-201 (n=7) achieved EASI-50 at four weeks as compared to data reported in independent clinical trials of dupilumab which reported 69% of patients receiving a 300 mg dose of dupilumab (n=55) achieving EASI-50 at four weeks and 85% achieving EASI-50 at 12 weeks; and (3) a longer duration between injections, as evidenced by data from our Phase 1a trial which reported a longer time taken of 57 days for the mean plasma concentration of a single subcutaneous dose of CBP-201 300 mg to fall below the equivalent lower limit of quantification, or LLOQ, of 640 ng/mL vs. 42 to 49 days for a single subcutaneous dose of dupilumab 300 mg to fall below the LLOQ of 0.078 mg/L. Potency is the amount of a drug that is needed to produce a given pharmacological effect and is determined by the receptor affinity of a drug. As these data were generated in independent studies and do not come from head-to-head analysis, caution should be exercised in drawing any conclusions from a comparison of the data. Nevertheless, we believe that CBP-201 has the potential to bring improved therapeutic benefit to AD patients with less frequent dosing than the current standard of care. We have initiated a Phase 2b trial of CBP-201 in AD patients with moderate-to-severe AD, and plan to initiate additional trials in asthma and CRSwNP in the first half of 2021 and in AD patients in China in the second half of 2021. We anticipate reporting top-line results from our ongoing clinical trial in AD patients in the second half of 2021.

### **Atopic dermatitis disease overview**

Atopic dermatitis, or AD, also referred to as eczema, is one of the most commonly diagnosed chronic inflammatory skin disease characterized by skin barrier disruption and immune dysregulation. Chronically inflamed skin lesions cause persistent itch, which is the primary symptom associated with the disease, as well as localized pain and sleep disturbances. According to the National Eczema Association, 26.1 million people in the United States have AD. Of these, 6.6 million adults have moderate-to-severe disease. Globally, prevalence of AD is increasing and, as of 2018, had an estimated lifetime prevalence of up to 20%. In China, the prevalence of clinically diagnosed AD in children aged one to seven is estimated to be approximately 13% as of 2016. Although AD prevalence is stabilizing in high-income nations, it has historically increased two- to three-fold in industrialized nations since the 1970s. The estimated global market for AD was approximately \$10.4 billion in 2020 and is expected to grow to \$19.3 billion by 2025, a compound annual growth rate, or CAGR, of 13.2%.

Topical anti-inflammatory agents, such as corticosteroids and calcineurin inhibitors, are routinely used to manage skin health and to reduce skin inflammation in patients with mild-to-moderate AD. Patients whose disease flares despite topical treatments may be prescribed systemic agents such as oral corticosteroids or oral cyclosporine to rapidly relieve severe signs and symptoms of the disease. While these are effective as temporary treatments of flare-ups, extended use has been associated with many potential side effects or adverse events. Systemic steroids, such as prednisone, can lead to symptom relief but their use is not recommended to induce stable remission due to numerous side effects associated with steroids and the propensity of severe disease flares upon abrupt treatment cessation. Cyclosporine is also generally not recommended for use lasting longer than one to two years, as it has been associated with renal toxicity, hirsutism, nausea and lymphoma. Based on data from the 2014 Adelpi US AD Disease Specific Programme, over 58% of adults with moderate-to-severe AD have disease which physicians consider to be inadequately controlled by these therapeutic modalities.

To address the shortcomings of traditional therapies for AD, specific biologic targets implicated in the pathogenesis of AD have been explored, a key focus of which has been interleukin-4, or IL-4 and interleukin-13, or IL-13. IL-4 production leads to increased levels of immunoglobulin E, or IgE, and eosinophils in the peripheral blood and tissue. IL-13 is a Th2-related cytokine that affects B cells and monocytes thereby regulating inflammatory and immune responses. Both cytokines exert their effects via IL-4Ra, which is expressed on the surface of T cells, B cells and macrophages amongst others and is involved in activation of the inflammatory immune response to allergens. IL-4Ra can form a heterodimer with the IL-13 receptor, or IL-13Ra, and can thus be activated by binding of either IL-4 or IL-13. IL-4 and IL-13 have redundant activities and both serve as the main drivers of allergic inflammation in the body. Activation of IL-4Ra leads to cytokine production, macrophage activation, IgE production by B cells, mucus production by airway epithelial cells, and dermal inflammation and remodeling.

In 2017, dupilumab, marketed as Dupixent® by Sanofi and Regeneron, was approved as an alternative treatment for patients with moderate-to-severe AD. Dupilumab blocks signaling through IL-4Ra, preventing IL-4 and IL-13 from binding and reducing levels of serum cytokines and IgE levels. Treatment with dupilumab has been shown to alleviate symptoms in patients suffering from AD and other inflammatory diseases such as asthma, CRSwNP and, in clinical studies, eosinophilic esophagitis. Dupilumab has been approved by the FDA for the treatment of AD that is not adequately controlled with topical prescription therapies and as an add-on maintenance treatment for moderate-to-severe asthma and inadequately controlled CRSwNP. Despite being on the market for only three years, sales of dupilumab were over €2 billion in 2019 and are expected to grow to over €10 billion according to Sanofi's estimates, highlighting the high demand for effective treatments for AD. The global market opportunity for asthma biologics is likewise growing rapidly, with a total market size of approximately \$1.8 billion in 2015 and projected growth to \$6.1 billion by 2024, a CAGR of 14.5%.

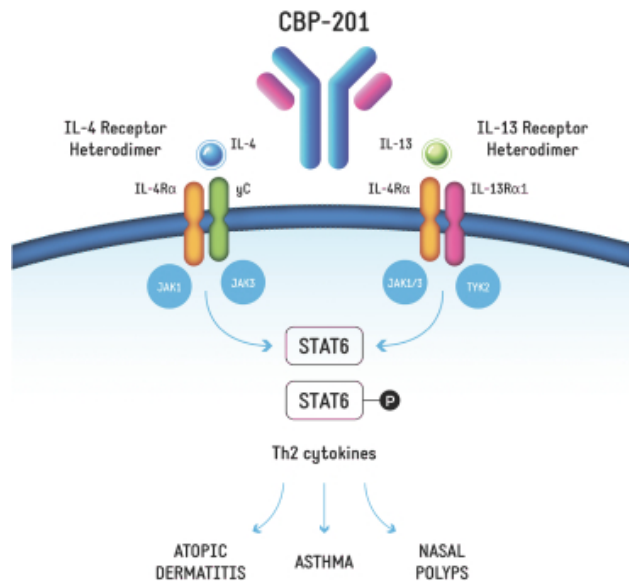
### **Limitations of dupilumab**

Despite the impressive results, a significant number of patients treated with dupilumab continue to have significant active uncontrolled disease. In SOLO 1 and SOLO 2, two Phase 3 clinical trials in moderate-to-severe AD patients whose disease was not adequately controlled with topical prescription therapies, both of which were conducted by Sanofi and Regeneron, a 75% reduction in the Eczema Area and Severity Index score, or EASI-75, was achieved at week 16 by 44 to 51% of patients receiving dupilumab every two weeks and, in another long-term efficacy study conducted by Sanofi and Regeneron, LIBERTY AD CHRONOS, 39% of patients in the dupilumab plus topical corticosteroids groups achieved the Investigator's Global Assessment endpoint of a score of zero or one, with at least

a two point or greater reduction from baseline, at weeks 16 and 52. These results indicate that up to 60% of patients do not achieve sufficient control of disease. Further, even for patients that respond to treatment with dupilumab, it can take 12 to 16 weeks to achieve adequate control. Lastly, dupilumab is not approved for dosing less frequently than every two weeks for adults.

**Our solution, CBP-201**

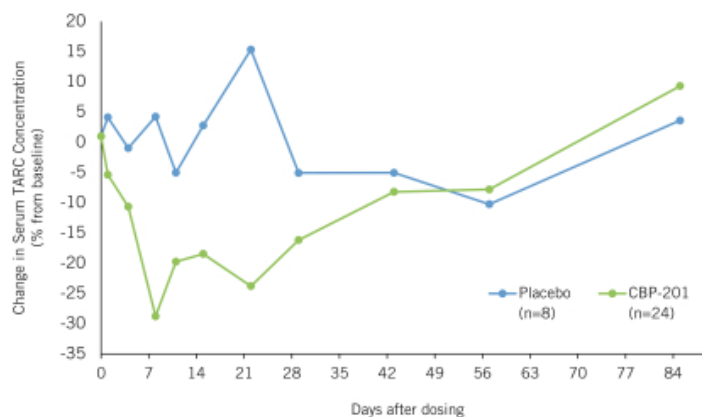
CBP-201 is a human monoclonal antibody targeting IL-4Ra. As an inhibitor of IL-4Ra, CBP-201 blocks inflammatory signaling by both IL-4 and IL-13. CBP-201 binds to a region of IL-4Ra that is distinct from that bound by dupilumab and associated with high binding affinity and potency for IL-4Ra, which we believe may lead to improved clinical response. Our clinical development program is focused on differentiating CBP-201 from dupilumab in three areas: clinical response, onset of action and less frequent dosing.



**Figure 2. CBP-201 is an anti-IL-1Ra antibody designed to block the signaling of both IL-4 and IL-13.**



We conducted a dose-escalation Phase 1a trial of CBP-201 in 40 healthy volunteers. In this trial we observed that a single dose of CBP-201 was well-tolerated. Single doses of 75 mg, 150 mg, 300 mg and 600 mg subcutaneously led to a decrease in the serum level of a T helper 2, or Th2, an inflammatory clinical biomarker that is elevated in AD: thymus and activation-regulated chemokine, or TARC. Although this trial was not powered to show statistically significant treatment group differences due to small numbers of subjects in each group, a post-hoc analysis was performed combining all CBP-201 subcutaneous dose groups comparing response at each timepoint as compared to baseline, the results of which showed a statistically significant reduction in TARC levels as compared to baseline ( $P < 0.05$ ) at days eight, 11, 15 and 22. Furthermore, despite this trial being conducted in healthy volunteers with very low baseline TARC levels to begin with (and with variable levels across the groups (14.6-172.1 pg/mL)), the average TARC level across all subcutaneous dose groups fell on dosing with a single administration of CBP-201 with a trough at day eight, -38% with 300 mg of CBP-201, -9% at day 57 with 300 mg of CBP-201 and returned towards baseline levels by day 85 at the same dose level. In comparison, TARC levels did not appear to fall significantly from baseline over the course of the study in the placebo group.



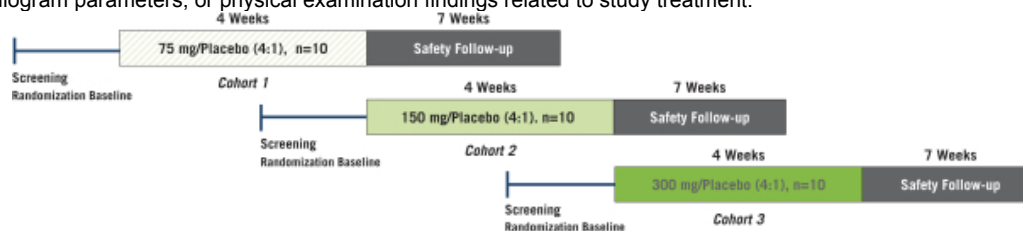
**Figure 3. CBP-201 led to a reduction of serum TARC levels that was sustained for at least 28 days. Data represents the average across all participants receiving subcutaneous doses including 75 mg, 150 mg, 300 mg, and 600 mg.**

In contrast to the reduction in TARC levels in our Phase 1a trial, in dupilumab's Phase 1 clinical trials, dupilumab 300mg showed median decreases in TARC levels of 36% and 16% at days eight and 85, respectively, in one study and a median decrease of 8% and median increase of 4% in TARC levels at days five and 56, respectively, in another study. We believe that the comparison of the TARC level reduction data from our Phase 1a trial and dupilumab's clinical trials is meaningful because these are the only reported studies of dupilumab in healthy volunteers that analyze TARC levels, and these levels are a key pharmacodynamic marker in AD. Therefore, understanding the relationship between TARC levels in healthy volunteers and the future clinical activity in AD patients with dupilumab allows us to consider how CBP-201's effects on TARC levels reported in healthy volunteers may also be related to potential future clinical activity in future clinical trials of CBP-201. Although no head-to-head trials have been conducted, we believe that based on these results, namely the reduction in TARC at all dose levels tested, the rapid decrease in TARC levels, and the prolonged suppression of TARC after a single dose, there is evidence of a potentially favorable drug profile of CBP-201 if approved.

We have completed a double-blind, randomized, placebo-controlled Phase 1b trial of CBP-201 in 31 patients with moderate-to-severe AD whose disease was inadequately controlled with topical corticosteroids or calcineurin inhibitors. This trial was conducted in 13 centers in Australia and New Zealand and enrolled 32 patients, with one patient withdrawing consent prior to dosing after randomization. Our trial design involved four dose cohorts of approximately 10 patients each who received 75 mg, 150 mg, or 300 mg of CBP-201 or placebo. Patients were dosed every week for four weeks then followed for an additional seven weeks. The primary endpoints were safety and tolerability at week eleven with exploratory endpoints on standard measures of clinical efficacy at week four. Exploratory endpoints included the percentage change in the EASI score from baseline, the proportion of patients

achieving a score on the Investigator Global Assessment, or IGA, of zero or one, or IGA 0,1, on a scale of zero to four, the change in total affected body surface area, or BSA, from baseline and change in Peak Pruritus Numerical Rating Scale, or PNRS, a validated patient-reported instrument to measure itch intensity, from baseline.

In patients with moderate-to-severe AD, multiple subcutaneous doses of CBP-201 up to 300 mg, administered once a week for four weeks, were observed to be well-tolerated. There were no reported serious adverse events, or SAEs, no clinically significant adverse events, or AEs, of injection site reaction or conjunctivitis/keratitis and no change in peripheral blood eosinophil counts compared to baseline or placebo. There were no apparent differences between the CBP-201 dose cohorts and placebo cohort in terms of study treatment-related adverse events, or TEAEs. Most TEAEs were mild in severity, with the majority deemed unrelated to CBP-201. A single TEAE (AD flare) leading to study treatment discontinuation occurred in one subject in each of the CBP-201 75 mg and placebo groups. There were no clinically significant changes in vital signs, electrocardiogram parameters, or physical examination findings related to study treatment.



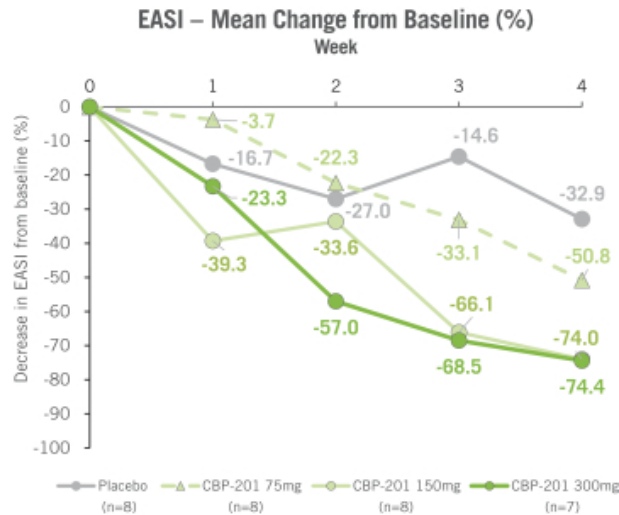
**Figure 4. Design of the Phase 1b trial of CBP-201 in moderate-to-severe AD**

Patients With	75 mg CBP-201 N = 8 n (%) Event	150 mg CBP-201 N = 8 n (%) Event	300 mg CBP-201 N = 7 n (%) Event	Pooled CBP-201 N = 23 n (%) Event	Placebo Group N = 8 n (%) Event
≥ one TEAE	7 (87.5%) 12	7 (87.5%) 22	6 (85.7%) 17	20 (87.0%) 51	5 (62.5%) 11
≥ one serious TEAE	0	0	0	0	0
≥ one severe TEAE	0	0	1 (14.3%) 1	1 (4.3%) 1	1 (12.5%) 1
≥ one IP: CBP-201 related TEAE	1 (12.5%) 2	2 (25.0%) 4	1 (14.3%) 3	4 (17.4%) 9	1 (12.5%) 3
≥ one TEAE leading to IP: CBP-201 withdrawal	1 (12.5%) 1	0	0	1 (4.3%) 1	1 (12.5%) 1
≥ one TEAE pertaining to injection site reactions	0	0	0	0	0
≥ one TEAE leading to premature withdrawal	0	0	0	0	0

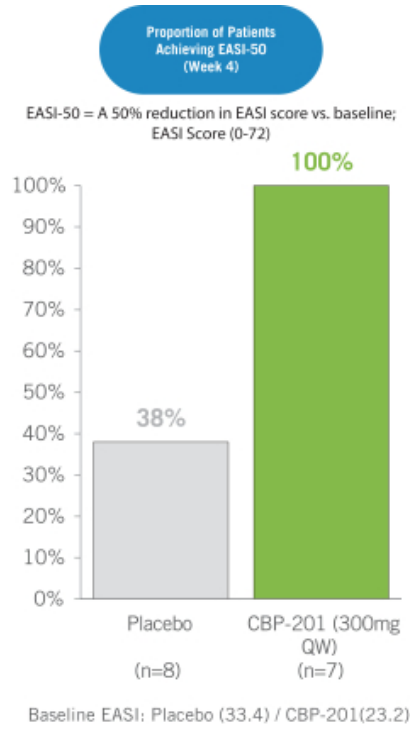
**Figure 5. Safety results from the Phase 1b trial of CBP-201 in moderate-to-severe AD**

At week four, 38%, 25%, 88% and 100% of patients treated with placebo (n=8), 75mg (n=8), 150 mg (n=8) or 300 mg (n=7) of CBP-201 respectively, achieved a 50% reduction in EASI, or EASI-50. By Day 15, 86% of patients

treated with 300 mg of CBP-201 achieved EASI-50. Patients treated with 150 mg of CBP-201 also had an early robust response, with 38% achieving EASI-50 at Day 15.

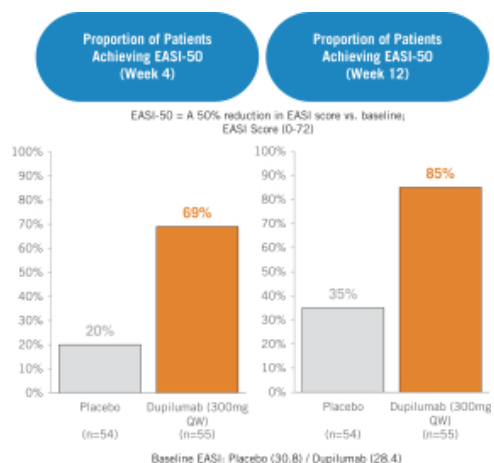


**Figure 6. CBP-201 led to a significant decrease in EASI from baseline at four weeks.**



**Figure 7. Treatment with 300 mg of CBP-201 resulted in all patients achieving EASI-50 at week four.**

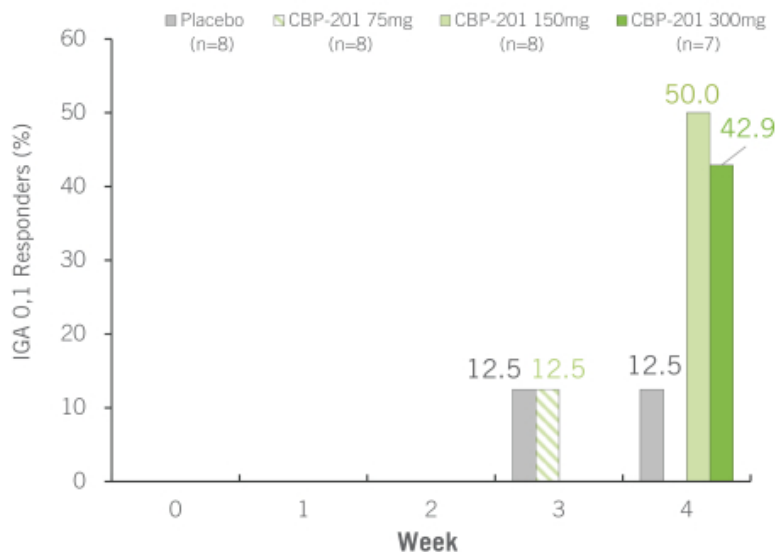
We believe that observed data from our Phase 1b trial in AD patients, which reported 100% of patients receiving a 300mg dose of CBP-201 (n=7) achieved EASI-50 at four weeks, suggests the potential for a fast onset of action. Although no head-to-head trials have been conducted, this data compares favorably with data reported in independent clinical trials of dupilumab, as described below. In a 12-week monotherapy trial in moderate-to-severe AD patients, treatment with 300 mg of dupilumab (n=55) every week resulted in 69% of patients achieving EASI-50 at four weeks and 85% of patients achieving EASI-50 at 12 weeks compared to 20% and 35% of patients in the placebo group (n=54) achieving EASI-50 at four weeks and 12 weeks, respectively.



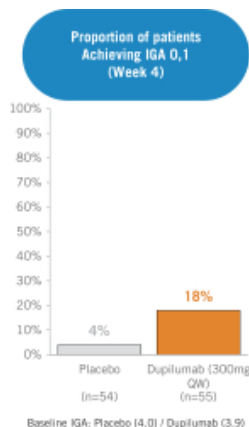
**Figure 8. Treatment with 300 mg of dupilumab resulted in 69 and 85% of AD patients achieving EASI-50 at weeks four and 12, respectively.**

Furthermore, patients in our Phase 1b trial of CBP-201 improved on the IGA. Although this trial was not powered to achieve statistical significance, the proportion of patients achieving IGA 0,1 at week four, indicating a response to the therapy, was 0% in patients treated with 75 mg of CBP-201 (n=8), 50% in patients treated with 150 mg of CBP-201 (n=8) and 42.9% in patients treated with 300 mg of CBP-201 (n=7), compared to 12.5% with placebo (n=8) (with a baseline IGA score of 3.3). The IGA 0,1 response rate observed with 300 mg of CBP-201 was substantially higher than the IGA 0,1 response rate of 18% for four-week data independently reported for 300 mg of dupilumab in 55 patients with a baseline IGA score of 3.9 on a scale of zero to five (where the placebo group had an IGA 0,1 response rate of 4%, with a baseline IGA score of 4.0).

### IGA 0,1 Responders (%)



**Figure 9. Treatment with 300 mg of CBP-201 led to 42.9% of patients achieving IGA 0,1 at week four.**



**Figure 10. Treatment with 300 mg of dupilumab led to 18% of patients achieving IGA 0,1 at week four.**

The impact of the difference in IGA score at baseline between our Phase 1b trial of CBP-201 and the independent Phase 2 trial of dupilumab can be determined as follows: Firstly, the IGA baseline score in the Phase 2 trial of dupilumab was likely higher than that seen in our Phase 1b trial of CBP-201 because of the use of a six-point scale of zero to five, where scores of four or five (severe and very severe) in the dupilumab trial were equivalent to a score of four (severe) in the CBP-201 trial. Scores of zero, one, two or three (with three being moderate) did not differ between the trials. The breakout of the IGA scores is not stated in the dupilumab publication, but because the mean score is approximately four and the trial recruited moderate AD patients (i.e., patients with a baseline IGA score of three), we expect that the patients in the Phase 2 trial of dupilumab had either similar proportions with an IGA of

three or five or equal numbers of patients with scores of three, four, or five. In either scenario, if we combined groups four and five, this would give a mean IGA baseline score of approximately 3.67 rather than four, a baseline figure closer to the baseline observed in our trial of CBP-201.

Secondly, the magnitude of effect of a change in IGA baseline score can be inferred by looking within the datasets for dupilumab trials with different IGA baseline scores. The proportion of patients achieving an IGA 0,1 response at week four in dupilumab's independent pooled Phase 3 clinical trials was 12% in the dupilumab 300 mg every week cohort (baseline IGA score of approximately 3.47) and 2% in the placebo group (baseline IGA score of approximately 3.48). Further, by modifying the response rates seen with the active groups in each of the trials by subtracting the placebo response rate (placebo-corrected response rates), we believe this further helps to reduce potential differences in trial populations to ensure a more like-for-like comparison across trials. Thus in the pooled Phase 3 dupilumab trials, we see a placebo-corrected response rate of 10% and only a small effect that differences in baseline IGA score have on the placebo-corrected IGA 0,1 response rate at week four (14% in the Phase 2 trial of dupilumab). As such, we believe that the comparison of the proportion of patients in our Phase 1b trial receiving 300 mg of CBP-201 weekly that achieved an IGA 0,1 corrected for the placebo response (30%) to the proportion of patients achieving these levels of reduction in the Phase 2 trial of dupilumab (14%) is meaningful due to small baseline differences with limited clinical impact.

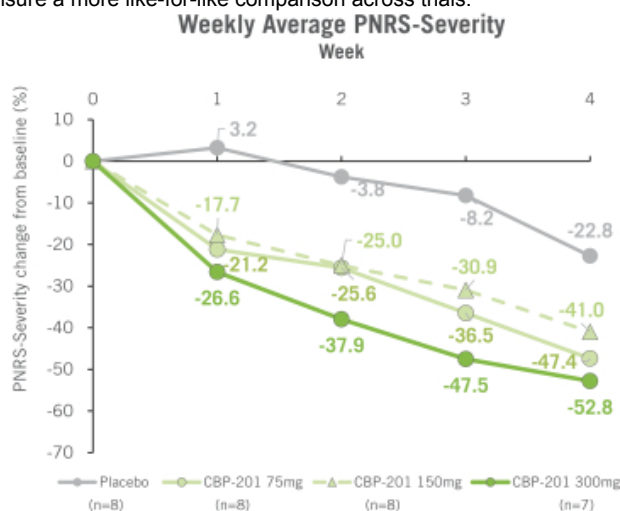
Likewise, independent trials of biologics in development with AD patients have reported significantly lower proportions of patients achieving an IGA 0,1 in patient cohorts with comparable baseline IGA scores. For example, in one such trial, 14% of AD patients with a baseline IGA score of 3.3 who were treated with 250 mg of lebrikizumab once every two weeks (n=75) achieved IGA 0,1 at week four. The same proportion of AD patients achieved IGA 0,1 at week four in an independent trial of weekly 400 mg doses of bermekimab in 28 patients with a baseline IGA score of 3.4 and in a separate trial of 10mg/kg intravenous infusions of KHK-4083 once every two weeks in 22 patients with a baseline IGA score of 3.8. In an independent trial of 10mg/kg intravenous infusions of GBR-830 once every four weeks in 46 AD patients with a baseline IGA score of 3.4, only 5.1% of patients achieved IGA 0,1 at week four. Therefore, we believe that the comparison of the proportion of patients achieving an IGA 0,1 response in our Phase 1b trial to those achieving an IGA 0,1 response in these other trials is meaningful because each of these trials included patients with similar recruitment criteria, at a similar phase of clinical development to establish proof of concept, such that the IGA baselines are broadly similar. Further, we believe comparing placebo-corrected response rates helps to reduce potential differences in trial populations between trials to ensure a more like-for-like comparison across trials.

Additionally, data observed from our Phase 1a trial of CBP-201 in healthy volunteers, reported that it took a mean duration of 57 days for CBP-201 plasma levels to fall below the LLOQ of 640 ng/mL, following a single subcutaneous dose of 300 mg of CBP-201. In contrast, independent third-party data in a Phase 1 clinical trial reported that healthy volunteers treated with dupilumab reported a duration of 42 to 49 days to fall below the LLOQ of 0.078 mg/L after a single subcutaneous dose of 300mg of dupilumab. Although no head-to-head trials have been conducted, we believe that this longer detectable presence of CBP-201 in plasma compared to dupilumab potentially reflects slower target IL-4Ra receptor mediated clearance of CBP-201 than for dupilumab, and may support the potential for an increase in the dosing interval from an injection every two weeks to one injection every four weeks. A dosing interval of one injection of CBP-201 every four weeks is currently being evaluated in Phase 2b trial of CBP-201 in patients with moderate-to-severe AD.

Itching, or pruritus, is one of the most common symptoms in inflammatory skin diseases and allergic disorders and is a hallmark feature of AD. A diagnosis of AD usually includes a history of pruritus, and itching is one of the earliest signs of a disease flare-up. The urgency to relieve the itch by scratching often causes breakage in the skin barrier and increases the risk of infection. Addressing pruritus is an important goal for any AD therapy as it is a symptom that has a great impact on the patient's quality of life.

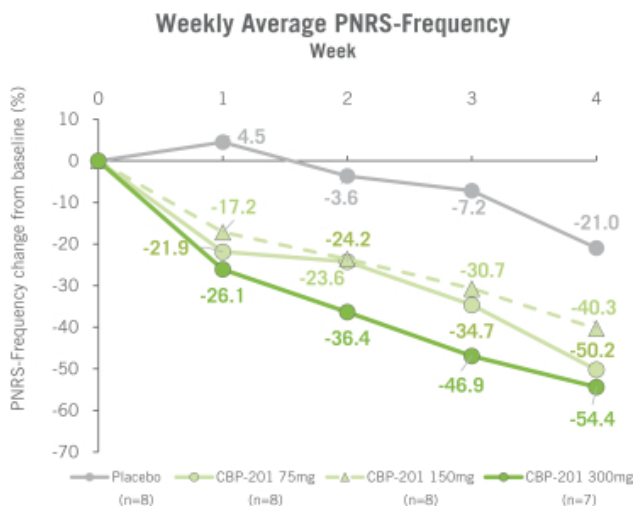
At four weeks, patients treated with 300 mg of CBP-201 reported a 52.8% decrease in average weekly rating on the PNRS-Severity scale, a validated patient-reported instrument to measure itch intensity. For comparison, placebo-treated patients in this trial reported a 22.8% decrease in PNRS-Severity from baseline at four weeks. The decrease in PNRS-Severity for dupilumab was 44.5% at week four and 55.7% at week 12, versus an 11.2% and 15.1% reduction at weeks four and 12 respectively, for placebo. We believe that the comparison of the decrease in PNRS-

Severity between this trial and dupilumab's is meaningful because each of these trials included patients with broadly similar PNRS-Severity baselines (7.1 in our trial and 6.1 in dupilumab) and by using placebo-corrected response rates this further helps to reduce potential differences in study populations between studies to ensure a more like-for-like comparison across trials.



**Figure 11. CBP-201 led to a significant decrease in PNRS-Severity at four weeks.**

Additionally, at four weeks, patients treated with 300 mg of CBP-201 reported a 54.4% decrease in average weekly rating on the PNRS-Frequency, a patient-reported instrument to measure itch frequency. For comparison, placebo-treated patients in this trial reported a 21% decrease in PNRS-Frequency from baseline at four weeks.

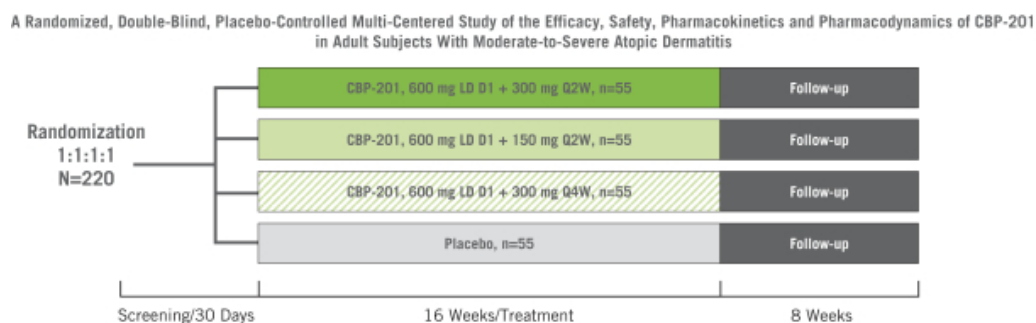


**Figure 12. CBP-201 led to a significant decrease in PNRS-Frequency at four weeks.**

We have initiated a Phase 2b trial of CBP-201 in the United States, Australia and New Zealand designed to assess efficacy, safety, pharmacokinetics and pharmacodynamics in patients with moderate-to-severe AD with longer term, alternate dosing schedules. The prolonged pharmacodynamic TARC response following a single dose of CBP-201 observed in our initial Phase 1a trial suggests that it may be possible to achieve suppression of IL-4Ra on a once

every two weeks or once every four weeks dosing schedule. We believe that the totality of the efficacy, safety, pharmacokinetics and pharmacodynamics data observed in our Phase 1 trials of CBP-201 shows evidence of proof of concept of biological, pharmacological and clinical activity in a moderate-to-severe AD population and justifies the advancement of CBP-201 into this Phase 2b dose ranging clinical trial in order to provide confirmation of the early efficacy signal we observed and explore the potential for differentiated greater clinical response and less frequent dosing.

Key inclusion criteria for our Phase 2b trial of CBP-201 are moderate-to-severe AD that is inadequately controlled with topical corticosteroids and calcineurin inhibitors, AD duration of at least one year, an EASI score of at least 16, and IGA score of at least 3 and at least 10% BSA involvement. This trial will enroll three cohorts of 55 patients each to receive CBP-201 and a 55-patient placebo control. The first cohort will receive one loading dose of 600 mg of CBP-201 followed by 150 mg every two weeks. The second cohort will receive one loading dose of 600 mg, then 300 mg every two weeks. The third CBP-201 cohort will receive one loading dose of 600mg followed by 300 mg every four weeks. All patients will be dosed for a total of 16 weeks. The primary endpoint will be the percentage change in EASI from baseline to week 16. Exploratory endpoints include the proportion of patients achieving IGA 0,1, EASI-75, EASI-90 and the change in PNRS from baseline to week 16. We expect to report top-line data from this trial in the second half of 2021.



**Figure 13. Design of the Phase 2b trial of CBP-201 in moderate-to-severe AD**

**Planned clinical trials**

We intend to conduct clinical trials to assess the potential of CBP-201 in other diseases driven by dysregulation of the Th2 immune response where dupilumab has already demonstrated efficacy. These include Phase 2 trials of CBP-201 in asthma and CRSwNP, which we intend to initiate in the first half of 2021, and a Phase 2 trial of CBP-201 in AD in China, which we intend to initiate in the second half of 2021.

**CBP-307, a Sphingosine 1-Phosphate Receptor 1 Modulator**

CBP-307 is a selective modulator of sphingosine 1-phosphate receptor 1, or S1P1, which we are developing for the treatment of UC and CD. Modulation of S1P1 activity has been shown to suppress T cell migration and reduce inflammation and approved S1P1 modulators such as fingolimod, siponimod, and ozanimod are used to treat multiple sclerosis. We have observed in vitro potency, selectivity and pharmacokinetics for CBP-307 that we believe suggest advantages over other S1P1 modulators. Based on the accumulating clinical evidence seen with other S1P1 modulators, and the class mechanism of preventing T cells from entering circulation and therefore reducing the likelihood of their migration into inflamed gastrointestinal parenchymal tissue, we believe that CBP-307 has potential to address unmet needs in UC and CD. We have completed a Phase 1 trial in healthy volunteers in which CBP-307 was generally well-tolerated. Administration of CBP-307 led to reductions in circulating lymphocytes, which recovered within one week of treatment completion. We anticipate reporting top-line results from a global Phase 2 trial in UC before the end of the first quarter of 2022 and also intend to initiate a global clinical trial in CD based on the preliminary clinical responses observed in a limited number of patients in an earlier CD clinical trial.

**Ulcerative colitis and Crohn’s disease overview**

UC and CD are forms of IBD that are distinguished by the portion of the intestinal tract that is affected. In CD, segments of local inflammation can be found anywhere along the digestive tract, whereas UC is characterized by



inflammation and ulceration of just the inner lining of the colon and rectum. Both diseases are associated with symptoms, that dependent upon the extent and severity of the disease, include abdominal pain, bloody diarrhea, rectal bleeding, urgency, fecal incontinence, and fatigue. Both UC and CD are diseases that undergo cycles of remissions and relapses.

Approximately 1.3% of adults in the United States, or approximately three million people, were estimated to be diagnosed with UC or CD in 2015. Worldwide in 2017, there were approximately 6.8 million people affected by IBD, and the majority of IBD patients had UC. The estimated global market for UC was approximately \$5.4 billion in 2020, and the estimated global market for CD was approximately \$7.4 billion in 2019. The UC market is estimated to grow at a CAGR of 6.8% to \$7.5 billion in 2025. The CD market is estimated to reach \$12.6 billion in 2029, a CAGR of 5.5%.

Mesalamine is typically used for first-line treatment and maintenance of remission in mild-to-moderate active UC and CD and can be supplemented with oral corticosteroids for disease flares. Patients who have moderate-to-severe disease or are refractory to mesalamine and oral corticosteroids may be treated with intravenous steroids, or biologics, including anti-TNF $\alpha$ , anti-integrin  $\alpha 4\beta 7$ , anti-IL-12/23, or small molecule inhibitors of JAK.

#### **Limitations of Existing Therapies**

Despite the multiple therapeutic options available for IBD, significant unmet medical need remains due to the tolerability, inadequate clinical responses and remissions, speed of action and burden of administration associated with existing therapies. Prolonged exposure to intravenous steroids is associated with a side effect profile that may outweigh clinical benefit. Anti-TNF $\alpha$  agents have been associated with a risk of infection or malignancy, while the approved labeling for certain JAK inhibitors includes a “black box” warning for risks including serious infections, mortality, malignancy and thrombosis. Beyond the safety concerns associated with existing therapies, clinical management of UC and CD remains unsatisfactory, with one 2013 study reporting that less than half of patients achieved long-term remissions. Further, some advanced therapies have a delay in onset of up to three months, and maximal clinical remission may require up to one year of treatment. Some therapies also involve complicated administration regimens, with biologics requiring either regular subcutaneous injections or intravenous infusions. There is therefore an unmet medical need for novel oral agents with an enhanced risk-benefit profile and more convenient administration for the treatment of moderate-to-severe active IBD.

#### **Role of S1P1 in inflammation**

S1P1 is a clinically validated anti-inflammatory target with three marketed drugs directed against it: fingolimod, marketed as Gilenya<sup>®</sup> by Novartis, siponimod, marketed as Mayzent<sup>®</sup> by Novartis, and ozanimod, marketed as Zeposia<sup>®</sup>, by Bristol Myers Squibb. All three drugs are approved to treat multiple sclerosis. Sales of fingolimod were \$3.2 billion in 2019.

There are five sphingosine 1-phosphate receptors: S1P1-S1P5. S1P1, in particular, is expressed on lymphocytes that are associated with the underlying inflammation of autoimmune diseases. Importantly, modulation of the S1P1 receptor causes selective and reversible sequestration of circulating lymphocytes in the thymus and peripheral lymphoid tissues. This sequestration is achieved through changes in the trafficking of lymphocytes. These changes, in turn, prevent the migration of autoreactive lymphocytes to sites of inflammation, including the central nervous system in multiple sclerosis and the gastrointestinal tract in IBD. It is exactly this reduction in the migration of potentially damaging lymphocytes that is a desirable result of intervention in S1P1 signaling.

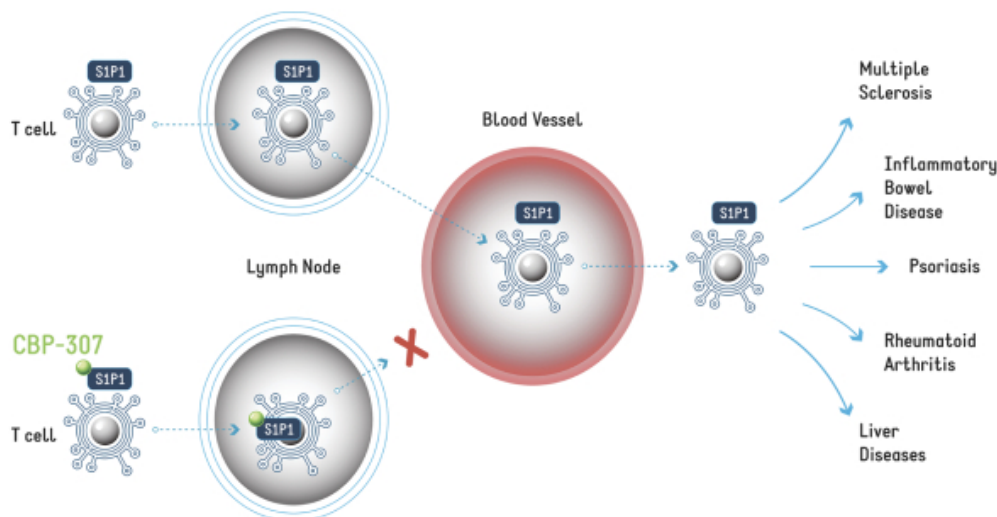
Other sphingosine 1-phosphate receptors have physiological roles that do not involve inflammation. Inhibition of S1P3, for example, with poorly selective S1P1 modulators, such as fingolimod, is associated with fibrosis in mice models. S1P2 and S1P3 are also expressed on myofibroblasts and their modulation leads to vasoconstriction and an increase in blood pressure. The clinical relevance of S1P4 and S1P5 is currently unknown. Fingolimod, which lacks high selectivity, has been associated with significant AEs and is contraindicated for patients with a history of cardiac disease.

We believe that this lack of selectivity can be overcome with a more targeted approach to drug discovery. Furthermore, we believe that S1P1 modulation of lymphocyte trafficking may have utility in other autoimmune diseases, including highly prevalent diseases with unmet need such as UC and CD. S1P1 modulators with high specificity for S1P1 may lead to reductions in those cardiovascular effects that limit the potential of less selective modulators to be used in broad populations. Prior clinical trials of second generation S1P1 modulators, ozanimod

and etrasimod, demonstrated results in IBD, but are not yet approved for any IBD indication. Further optimization of pharmacokinetics and pharmacodynamics of a highly selective S1P1 modulator has the potential to lead to a best-in-class agent for autoimmune diseases, particularly in UC and CD.

**Our solution CBP-307**

CBP-307 is an orally available, next generation, small molecule modulator of S1P1 that is designed to reduce inflammation without killing T cells or targeting a specific cytokine. By design, CBP-307 is highly selective for S1P1 without significant activity for S1P2 and S1P3 receptor subtypes allowing it to potentially have an optimized effect on circulating T lymphocytes, which we believe may result in significant anti-inflammatory activity. In preclinical studies, CBP-307 demonstrated strong pharmacokinetics and pharmacodynamics, with rapid onset of action and rapid recovery of T lymphocytes. These enhanced characteristics were evidenced by CBP-307's short half-life as well as ability to rapidly induce an absolute lymphocyte reduction to ~400 to ~750 cells per  $\mu\text{L}$  and >60-70% reduction in lymphocyte count from baseline, which compares favorably to targets achieved by approved S1P1 modulators. Further, its pharmacokinetics characteristics could allow CBP-307 to be dosed once daily orally. CBP-307 is not a pro-drug and does not require in vivo conversion to produce its effects. We believe these characteristics position CBP-307 to potentially address the unmet efficacy, safety and convenience needs of currently approved agents in UC and CD.



**Figure 14. Mechanism of CBP-307**

We discovered CBP-307 by running a functional screen for the desired biological property, which in this case was the ability of a small molecule to cause internalization of S1P1 from its native location on the surface of T cells. It is because of this internalization that T cells are not able to leave the lymph node and enter circulation. By focusing our discovery efforts on this desired result, we were able to identify CBP-307 as a highly potent S1P1 modulator while avoiding false positive results for compounds that bound tightly to S1P1 but did not cause internalization and false negative results for compounds that failed to bind tightly to recombinant S1P1.

CBP-307 is a highly potent and selective modulator of S1P1, which in preclinical studies has shown selectivity of over 80,000-fold in S1P1 versus S1P3. Furthermore, in preclinical studies, 10  $\mu\text{M}$  of CBP-307 did not show meaningful interactions in a broad receptor panel screen against other G-protein-coupled receptors and ion channels that have important physiologic functions in the body except for an inhibition effect of 57% on the histamine receptor H1. In preclinical studies, CBP-307 was only significantly inhibited by two of the seven major cytochrome P450 metabolizing enzymes that were profiled.

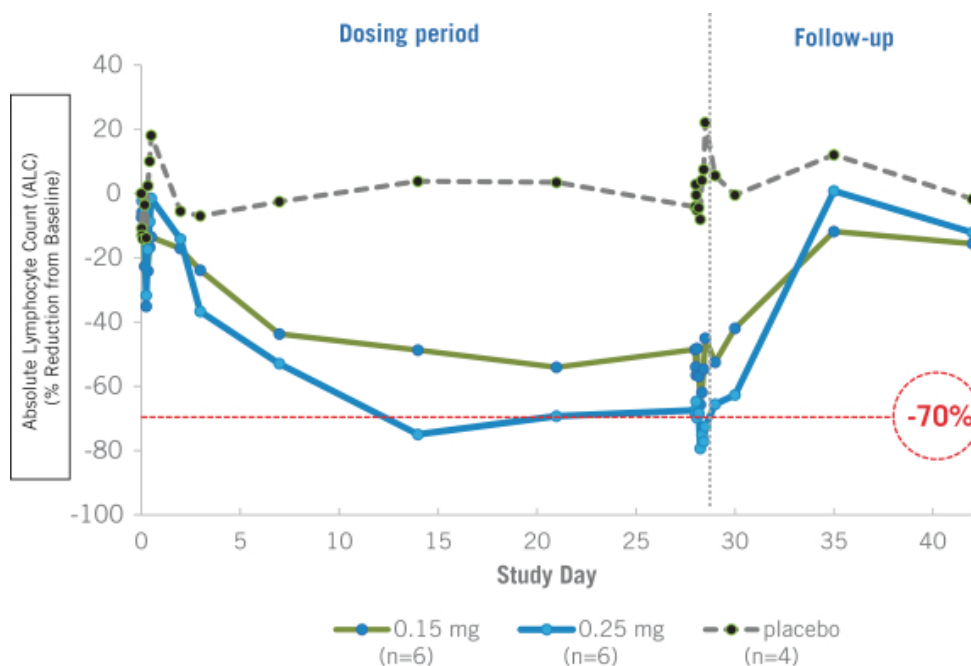
Name	EC <sub>50</sub> (nM)				
	S1P1	S1P2	S1P3	S1P4	S1P5
<b>CBP-307</b>	<b>0.09<sup>(1)</sup></b>	<b>&gt;10,000<sup>(2)</sup></b>	<b>7,900<sup>(2)</sup></b>	<b>19<sup>(2)</sup></b>	<b>3.97<sup>(2)</sup></b>
<b>Ozanimod</b> (CC-1122273)	<b>2.99</b>	<b>&gt;10,000</b>	<b>&gt;10,000</b>	<b>&gt;10,000</b>	<b>29.32</b>
<b>Etrasimod<sup>(2)</sup></b> (APD334)	<b>6.10</b>	<b>&gt;10,000</b>	<b>&gt;10,000</b>	<b>147</b>	<b>24.4</b>

- (1) cAMP Assay  
(2)  $\beta$ -Arrestin Assay

**Figure 15. CBP-307 potently and selectively modulated S1P1 in vitro. Information provided in the table above is for illustrative purposes only and is not a head-to-head comparison. Differences exist between study or trial designs and subject characteristics, and caution should be exercised when comparing data across studies.**

We have completed a Phase 1 trial of CBP-307 in 44 healthy adults in Australia, which consisted of a 7-day single ascending dose regimen and a 28-day multiple ascending dose regimen, and another in 30 healthy adults in China. The single dose regimen in the trial in Australia included 0.1 mg, 0.25 mg, 0.5 mg, 2.5 mg and placebo cohorts. The multiple dose regimen in the trial in Australia included 0.15 mg, 0.25 mg and placebo cohorts. In the trial in China, the single and multiple dose regimens included 0.1 mg, 0.2 mg and placebo cohorts, and the multiple dose regimen also included a 0.3 mg cohort. Once daily doses of up to 0.25 mg of CBP-307 were generally well-tolerated. The most frequent AEs observed across all regimens included low white blood cells and headache. Most AEs were mild or moderate. There were no clinically significant changes in lung function, a range of ophthalmological tests, blood pressure, or liver enzyme levels. Consistent with observations from clinical trials of other S1P1 modulators, a dose-dependent decrease in heart rate was observed early in all regimens. One healthy adult treated with a single dose of 2.5mg of CBP-307 experienced bradycardia associated with transient asystole, which was deemed to be a treatment-related serious adverse event. The healthy adult was treated with high-flow oxygen and fully recovered.

Sequestration of lymphocytes in the lymphoid tissues results in decreased lymphocyte count in peripheral circulation, which can be measured through blood sampling and thereby provide a robust mechanistic pharmacodynamic biomarker for preclinical and clinical studies. Although our trials were not powered to achieve statistical significance, in six healthy adults, CBP-307 at 0.25 mg led to a 75% decrease in number of circulating lymphocytes by day 14 of dosing and this level of lymphocyte suppression was maintained for the rest of the daily dosing period. Upon completion of dosing, the levels of lymphocytes returned to baseline within one week.



**Figure 16. CBP-307 led to a reduction in the level of circulating lymphocytes in healthy volunteers.**

Data from a separately conducted Phase 1 clinical trial in healthy adults showed a median reduction of 65% with a 1 mg dose of ozanimod after 28 days, while a 2 mg dose of etrasimod in a Phase 1 trial was associated with a mean reduction of 69% at steady state from days seven to 21. We believe that the comparison of the reduction in circulating lymphocytes across our trials and these independent clinical trials is meaningful because all were conducted in healthy volunteers using a 21-day or 28-day multiple-dose regimen. Healthy individuals share the same normal range of absolute lymphocyte count, or ALC, and the percentage of lymphocytes as a proportion of total white blood cells. Like our trial, the Phase 1 clinical trial of ozanimod and Phase 1 clinical trial of etrasimod required the healthy volunteers to have normal hematology. Consequently, we believe these subjects have similar baseline levels of circulating lymphocytes. Based on their known and validated pharmacological mode of action, S1P1 modulators reduce circulating lymphocyte counts, and as such, the reduction of circulating lymphocytes seen across trials in these healthy subjects are believed to be due to the effect of the investigational drugs studied, including, in the case of our trial, CBP-307.

We hypothesize that the selectivity and potency of CBP-307 observed in healthy adults will translate into similar effects on lymphocyte levels in UC patients. Independent clinical trials of ozanimod and etrasimod in UC patients have shown weaker activity on reductions in circulating lymphocytes compared to healthy volunteers of 49% and 40%, for ozanimod 1 mg at eight weeks and etrasimod 2 mg at steady state of four weeks, respectively. We believe the lower ALC reductions seen in these Phase 2 trials potentially reflect sub-optimal dosing. It has been confirmed by Arena that they intend to test a dose of 3 mg of etrasimod in the CULTIVATE trial in CD, which is greater than the 2 mg of etrasimod previously tested in UC and AD. Arena has also confirmed that it intends to apply the higher 3 mg dose of etrasimod to clinical programs other than UC.

In addition, we observed the restoration of lymphocyte levels upon completion of dosing with CBP-307, which was faster than that reported for other S1P1 modulators. We attribute these results to the shorter half-life of CBP-307 of approximately 25 hours observed in healthy subjects. This is in contrast to fingolimod, which reported a half-life of six to nine days and a lymphocyte recovery time of 30 days to 60 days. We believe the ability to rapidly restore lymphocyte levels is important as it could minimize the length of time that a patient treated with CBP-307 may have

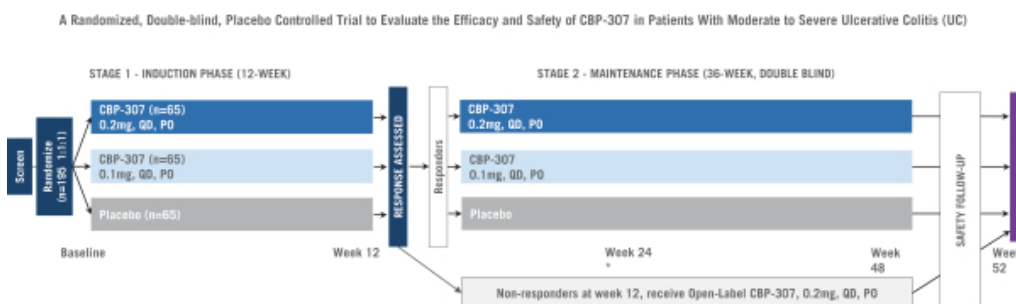
compromised immunity, which may lower the risk of patients developing infections. Patients treated with fingolimod may be at risk of developing infections for up to two months beyond completion of dosing.

Drug Name	T½ h (days)	Lymphocyte Recovery Time
Fingolimod (0.5 mg, QD)	~216h (6-9d)	30-60d
MT-1303 (0.4 mg, QD)	451h (19d)	>48d
Ozanimod (1 mg, QD) (CC1122373)	~264h (11d)	>7d (no report beyond this time)
Etrasimod (2 mg, QD)	35h (1.5d)	<7d
<b>CBP-307 (0.25 mg, QD)</b>	<b>25h (1d)</b>	<b>&lt;7d</b>

**Figure 17. The shorter half-life of CBP-307 compared to other S1P1 modulators correlates with a shorter lymphocyte recovery time. Information provided in the table above is for illustrative purposes only and is not a head-to-head comparison. Differences exist between study or trial designs and subject characteristics, and caution should be exercised when comparing data across studies.**

**Clinical Development of CBP-307 in Patients with IBD**

We initiated a double-blind, placebo-controlled global Phase 2 trial of CBP-307 in 195 patients with moderate-to-severe UC. The primary endpoint of this trial is the clinical response at week 12 in the 0.2 mg CBP-307 group versus the placebo group, as measured by the Mayo score, an objective measure of disease severity based on stool frequency, rectal bleeding, endoscopic findings, and physician overall evaluation. Specifically, clinical response is defined as a decrease of at least 3 points and at least 30% from baseline in the complete Mayo score, accompanied by a decrease of at least 1 point from baseline in the rectal bleeding subscore or an absolute rectal bleeding subscore of at least 1 point. This trial is still ongoing. We anticipate reporting top-line results from this trial before the end of the first quarter of 2022.

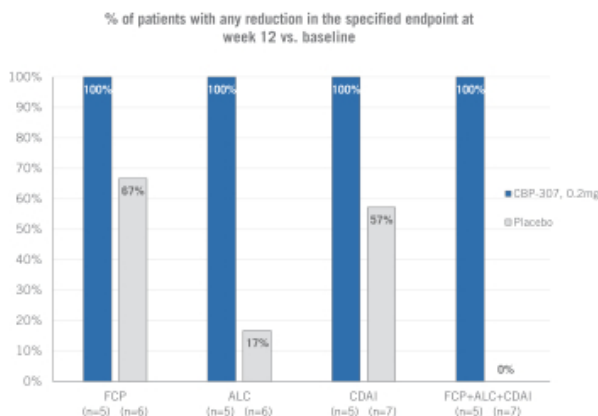


**Figure 18. Design of the Phase 2 trial of CBP-307 in UC**

In parallel, we initiated a Phase 2 trial of CBP-307 in patients with moderate-to-severe CD in China. The primary endpoint of this trial was the clinical response, as measured by the Crohn's Disease Activity Index, or CDAI.

Enrollment in this trial was ended prematurely with only 22 patients completing 12 weeks of dosing due to challenges in recruitment caused by the COVID-19 pandemic.

Nevertheless, from this limited number of patients who were able to complete 12 weeks of dosing, CBP-307 was generally well-tolerated and the safety profile was consistent with our earlier CBP-307 phase 1 studies as well as with the safety profiles seen with emerging data from other second generation S1P1 modulators currently in clinical development in IBD. Although this trial ended prematurely and thus was not powered to show statistically significant treatment group differences, exploratory efficacy assessments in the per protocol dataset of 18 patients suggested clear evidence of biological activity of CBP-307, with all patients on the 0.2 mg dose showing benefits on biomarkers of disease at week 12, such as reductions compared to baseline in ALC and reductions compared to baseline in Fecal Calprotectin, or FCP. In addition, all patients on the 0.2 mg dose had a reduction in the key clinical endpoint of the CDAI score at week 12, an efficacy parameter accepted by the FDA in trials of other drugs approved to date. In contrast, in the placebo group, changes in the ALC, FCP and CDAI score at week 12 compared to baseline were variable, with the majority of these placebo patients showing worsening of these markers.



**Figure 19. We observed evidence of biological activity in CD patients treated with 0.2 mg doses of CBP-307.**

Based on this data, and the evidence of CBP-307's biological effect, we are continuing the development of CBP-307 in IBD with our ongoing UC clinical trial and are planning further clinical trials of CBP-307 in CD.

**Planned clinical trials**

S1P1 modulators have demonstrated clinical efficacy in a number of Th1-related immune diseases including multiple sclerosis, psoriasis and IBD. We chose to focus our initial development resources on IBD, where we believe CBP-307 has the highest potential to demonstrate superior clinical response and safety as compared to existing products. If we observe clinical activity in IBD, we will consider investigating the potential of CBP-307 in other immune diseases such as AD.

**CBP-174, a Histamine Receptor 3 Antagonist**

We are developing CBP-174 as a rapid acting therapy for the alleviation of pruritus in AD. CBP-174 is an antagonist of histamine receptor 3, or H3R, that was observed to reduce scratching after injection in a mouse model of pruritus. It was designed not to penetrate the blood brain barrier and has been well-tolerated in multiple preclinical studies. We obtained global rights to CBP-174 from Arena. We expect to initiate a Phase 1 trial with CBP-174 in the first quarter of 2021.

**Chronic inflammatory pruritus overview**

AD is often accompanied by chronic inflammatory pruritus, or an unpleasant and often persistent itch that can last over six weeks in duration and is often caused by inflamed skin lesions. Due to the significant impact chronic inflammatory pruritus has on AD patients' quality of life, AD severity is often measured by patients based on intensity of pruritus rather than skin lesions themselves. The effect on patients experiencing this symptom contributes to additional comorbidities in some, such as hyperactivity, generalized anxiety and major depressive disorders. Of those with AD, prevalence of chronic pruritus was estimated to range from 58 to 91% in 2015. Despite

currently available treatments for AD, an estimated 40 to 50% of AD patients have inadequate relief of their pruritus and are in need of new, efficacious pruritus therapies.

***The role of histamine receptors in pruritus***

Histamine is a small molecule that is released by inflammatory immune cells leading to multiple effects including dilation of local blood vessels and the facilitation of immune cells to leave the bloodstream and migrate to areas of tissue damage or infection. In diseases such as AD, this can lead to exacerbation of inflammatory conditions such as pruritus. Histamine and acetylcholine provoke itch by direct binding to 'itch receptors' and several mediators such as neuropeptides, proteases or cytokines indirectly via histamine release. The direct role of histamines in inducing pruritus has been demonstrated in mice, where injections of histamines or other agonists of histamine receptors induced strong itch.

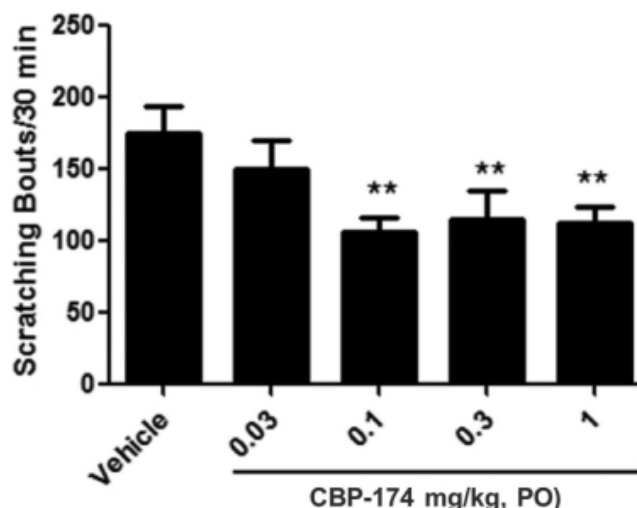
There are four types of histamine receptors, H1R, H2R, H3R, and H4R. H2R is involved in gastric acid secretion and is the target of drugs such as famotidine and ranitidine which are used to treat conditions such as peptic ulcers and gastroesophageal reflux. H3R is highly expressed in the central nervous system where it has been targeted by a number of product candidates intended to treat cognitive disorders such as Alzheimer's and Parkinson's diseases. H3R is also expressed in the peripheral tissues, including nerve cells.

Common antihistamine drugs, or molecules that block histamine receptors, primarily target the histamine 1 receptor, or H1R, and lead to alleviation of itch in part by blocking H1R on peripheral nerves. Antihistamines are commonly used in clinical practice and as over-the-counter therapies for the alleviation of histamine-driven allergic reactions. However, many types of chronic itch cannot be relieved by current antihistamine treatments that target H1R. Many of these antihistamines have significant activity in the central nervous system leading to undesirable side effects such as drowsiness, rapid heart rate, and dizziness. In our preclinical research we observed that inhibition of H3R significantly reduced itch in a mouse model of allergen-induced chronic skin inflammation, indicating inhibition of pruritus in skin inflammation by an H3R antagonist is not limited to acute itch induced by direct pruritogen injection.

***Our solution, CBP-174, a peripherally acting H3R antagonist***

We are developing CBP-174, a peripherally acting H3R antagonist, for oral administration to treat chronic pruritus associated with skin inflammation. We believe that the ability to quickly alleviate itch in the setting of AD has the potential to complement the anti-pruritic effect of disease-modifying IL-4Ra antagonists such as our CBP-201 product candidate or dupilumab. In clinical trials, these currently approved IL-4Ra targeted products required weeks of treatment for many AD patients to obtain significant relief of pruritus.

In a preclinical model of histamine-induced pruritus in mice, CBP-174 at an oral dose of 0.1 mg/kg led to significant reductions in scratching. We observed that CBP-174 had a strong anti-itch effect in mice with a rapid onset of action, within the first 30 minutes of dosing.



**Figure 20. CBP-174 reduced scratching in a histamine-induced pruritus mouse model at doses of 0.1 mg/kg, 0.3 mg/kg and 1 mg/kg**

We have developed a topical 0.01% ointment formulation of CBP-174 that led to similar reductions in scratching frequency in these mice. We observed that the slow release of CBP-174 from the topical ointment led to prolonged exposure while simultaneously increasing the local concentration of drug at skin lesions.

Administration of CBP-174 orally was well-tolerated with no clinical signs of toxicity in a 28-day multiple-dose study of up to 5 mg/kg in rats. Single doses of up to 3 mg/kg were well-tolerated in dogs with no toxicologically significant changes in heart rate or hematology. In mice, brain exposure of CBP-174 was between three and five percent of levels in plasma. These preclinical data supported advancing CBP-174 into clinical studies.

We expect to initiate a Phase 1 trial of CBP-174 in the first quarter of 2021. This will be a single ascending dose double-blind trial of CBP-174 in a total of 48 healthy adults. We intend to enroll six cohorts of eight volunteers with six in each cohort receiving CBP-174 and two placebo. Volunteers in individual cohorts will receive one of six oral doses of CBP-174. The primary endpoints of this trial will be safety and tolerability as well as pharmacokinetics changes. We believe that the oral formulation would work best for pruritus caused by chronic inflammatory diseases, such as AD, due to the large body surfaces that can be affected.

#### **Our Preclinical Programs**

We are building a rich pipeline of internally designed, wholly owned small molecules and antibodies leveraging our expertise in T cell biology and sophisticated functional assays. Consistent with our clinical-stage candidates, our preclinical programs are focused on targets, both novel and clinically validated, with strong biological rationale in immunology indications with high unmet medical need and sizable commercial potential. CBP-233 represents the most advanced antibody candidate in our preclinical portfolio and continues to evidence our ability to generate highly potent and specific T cell modulators.

#### **CBP-233, a Humanized Antibody Against IL-33**

CBP-233 is a highly potent, humanized antibody against IL-33, a cytokine involved in Th2 inflammation. We discovered CBP-233 by using a cell proliferation assay to screen for the most potent functional antibodies. We found that the functional potency of IL-33 antibodies, such as CBP-233, had poor correlation with antigen potency as measured by a standard enzyme-linked immunosorbent assay, thereby validating our approach of focusing on T cell modulation early in the discovery process.



IL-33 is a pro-inflammatory cytokine that is a central mediator of various immune responses leading to Th2-type inflammatory disorders, including asthma, food allergies and AD. IL-33 is highly expressed in lung epithelial cells and is rapidly released in response to pathogens, viruses, toxins or allergens. IL-33 is up-regulated in patients with allergic inflammatory diseases such as asthma and AD compared to healthy individuals. IL-33 initiates a diverse array of cellular immune responses, including the activation of mast cells, basophils and eosinophils, and the production of downstream inflammatory cytokines, such as IL-4, IL-5, IL-13, interferon gamma and TNF $\alpha$ .

Preliminary evidence of the therapeutic potential of an anti-IL-33 antibody has been reported in several indications including asthma, AD, and food allergy. We are currently conducting preclinical studies to support a future IND submission of CBP-233 with the FDA.

### **Commercialization**

Given the stage of development of our lead product candidates, we have not yet invested in a commercial infrastructure or distribution capabilities. While we currently plan to establish our own commercial organization in the United States, China and potentially in other selected markets, we continue to consider and evaluate in each market the potential advantages and enhancements of our commercial capabilities that may be realized as a result of a collaboration between us and a pharmaceutical or other company.

### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical, biopharmaceutical, therapeutics and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective or more convenient or have fewer or less severe side effects than any products that we may develop. Our competitors also may obtain FDA, NMPA or other regulatory approval for their products more rapidly than we do. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, cost, market access and reimbursement by payors, level of promotional activity devoted to them and intellectual property protection.

We expect to face competition from existing products and products in development for each of our product candidates. In addition to those described below, there may be other earlier stage clinical programs that, if approved, would compete with our product candidates. Many of our competitors have substantially greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

We expect CBP-201, if approved, to primarily compete across several targeted indications with dupilumab, marketed as Dupixent<sup>®</sup> by Sanofi and Regeneron, and another IL-4Ra antibody currently in development for moderate-to-severe AD by Sunshine Guojian Pharmaceutical, a subsidiary of 3SBio Inc., which recently announced approval of an IND application in June 2020.

If approved for the treatment of moderate-to-severe AD, CBP-201 would also compete directly with a number of other approved systemically administered products, such as baricitinib marketed as Olumiant<sup>®</sup> by Eli Lilly, a JAK inhibitor. Other systemic product candidates in clinical development with which CBP-201 could compete in the treatment of moderate-to-severe AD include tralokinumab (anti-IL-13 neutralizing monoclonal antibody, or mAb; Leo Pharmaceuticals), lebrikizumab (anti-IL-13 neutralizing mAb; Eli Lilly and Almirall S.A.), risankizumab (anti-IL-23 mAb; Abbvie), GBR 830 (anti-OX40 mAb; Glenmark Pharmaceuticals), KHK4083 (anti-OX40 mAb; Kyowa Kirin), upadacitinib (JAK1 inhibitor; Abbvie), abrocitinib (JAK1 inhibitor; Pfizer), etrasimod (S1P1, S1P4 and S1P5 modulator; Arena), and RPT193 (C-C chemokine receptor type 4, or CCR4, antagonist; RAPT Therapeutics).

If approved for the treatment of moderate-to-severe asthma, CBP-201 would compete directly with a number of approved antibodies, including dupilumab, as well as omalizumab marketed as Xolair® by Genentech/Roche and Novartis, an anti-IgE mAb, benralizumab marketed as Fasenra® by AstraZeneca, an anti-IL-5 mAb, mepolizumab marketed as Nucala® by GlaxoSmithKline, an anti-IL-5 mAb, and resalizumab, marketed as Cinqair® by Teva Pharmaceuticals, an anti-IL-5 mAb. CBP-201 would also face competition from RPT193 in the treatment of asthma.

We would expect to face similar competition if CBP-201 was approved for the treatment of CRSwNP. The majority of products or product candidates currently marketed for asthma with a type 2 inflammatory phenotype are also the agents either currently approved (dupilumab and omalizumab) or in clinical development (mepolizumab and benralizumab) for CRSwNP.

If approved for the treatment of UC and CD, we would expect CBP-307 to compete with a number of systemically administered antibodies and oral immunotherapies approved for the treatment of UC, including infliximab marketed as Remicade® by Janssen Pharmaceuticals, an anti-TNF $\alpha$  neutralizing mAb, adalimumab marketed as Humira® by Abbvie, an anti-TNF $\alpha$  neutralizing mAb, golimumab marketed as Simponi® by Janssen Pharmaceuticals, an anti-TNF $\alpha$  neutralizing mAb, vedolizumab marketed as Entyvio® by Takeda Pharmaceuticals, an anti- $\alpha$ 4 $\beta$ 7 integrin mAb, and ustekinumab marketed as Stelara® by Janssen Pharmaceuticals, an anti-IL-12/23 mAb. We would also expect CBP-307 to compete with certolizumab marketed as Cimzia® by UCB S.A., an anti-TNF $\alpha$  neutralizing mAb Fab fragment approved for the treatment of CD and tofacitinib marketed as Xeljanz® by Pfizer, an oral reversible JAK1 and JAK3 inhibitor, currently marketed for the treatment of UC. Other product candidates in clinical development with which CBP-307 could compete in the treatment of UC and CD include risankizumab (anti-IL-23 mAb; Abbvie), guselkumab (anti-IL-23 mAb; Janssen Pharmaceuticals), brazikumab (anti-IL-23 mAb; AstraZeneca), mirikizumab (anti-IL-23 mAb; Eli Lilly), filgotinib (reversible JAK1 inhibitor; Gilead Sciences), upadacitinib (reversible JAK1 inhibitor; Abbvie), etrasimod (S1P1, S1P4 and S1P5 modulator; Arena), and ozanimod (S1P1, S1P4 and S1P5 modulator; Bristol Myers Squibb).

If approved for treatment of chronic pruritus associated with inflammatory skin disease, CBP-174 could compete with current treatment options available for the treatment of acute pruritus of non-inflammatory origin, including topical and oral anti-histamines and would also face competition from other therapies in development for chronic inflammatory pruritus.

### **Intellectual Property**

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our current and future product candidates and novel discoveries, product development technologies, and know-how. In general, to protect our product candidates and related technologies, we seek patent protection by licensing relevant patent rights from third parties or by filing Patent Cooperation Treaty, or PCT, applications and national stage patent applications throughout the world, including in China, the United States, Europe and other major markets, in each case on subject matter relating to our technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on know-how, confidential methodologies and processes and continuing technological innovation to develop and maintain our proprietary positions, in addition to trademarks, copyrights and trade secret laws, and employee disclosure and invention assignment agreements. Our commercial success also depends in part on our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary rights.

As of December 31, 2020, we own or exclusively license three issued U.S. patents, one pending U.S. non-provisional patent application, 24 issued foreign patents and 33 pending foreign patent applications (including two pending PCT applications). This includes issued patents and pending patent applications in multiple jurisdictions worldwide, including in the United States, the United Kingdom, France, Germany, Switzerland, the Netherlands, Sweden, Spain, Belgium, Italy, Australia, Japan, China and Hong Kong, among other jurisdictions. The issued patents and the patents that may issue from the pending applications, if any, will have nominal expiration dates ranging from 2033 to 2040, without accounting for any available patent term adjustments or extensions

These issued patents and patent applications include:

- With respect to the composition of matter of CBP-201, one issued U.S. patent, one pending U.S. non-provisional patent application, and 21 pending foreign patent applications, including in the European Patent Office, or EPO, China, Japan, South Korea, Canada, Australia, South Africa, Brazil, Mexico and India, among other jurisdictions, with such issued patent and the patents that may issue from such patent applications, if any, expected to expire in 2037, without accounting for any available patent term adjustments or extensions. We also have two other patent families that relate to our CBP-201 program, which comprise of one pending PCT application, one pending patent application in Taiwan, and two pending patent applications in China, with the patents that may issue from such patent applications, if any, expected to expire between 2039 and 2040, without accounting for any available patent term adjustments or extensions.
- With respect to the composition of matter of CBP-307, one issued U.S. patent, 13 issued foreign patents, including in China, Japan, Australia, the United Kingdom, Germany, France, Switzerland, Italy, Sweden, Netherlands, and Belgium, and four pending foreign patent applications in South Korea, Canada, India and New Zealand, with such issued patents and the patents that may issue from such patent applications, if any, expected to expire between 2033 and 2034, without accounting for any available patent term adjustments or extensions. We further have one pending patent application in China and one pending PCT application related to additional salts and crystal forms of CBP-307, with the patents that may issue from such patent applications, if any, expected to expire in 2037, without accounting for any available patent term adjustments or extensions.
- With respect to CBP-174, we acquired an exclusive license from Arena under patents and know-how related to the composition of matter of CBP-174 and methods of making and using the same. Specifically, this includes one issued U.S. patent and 11 issued foreign patents in the United Kingdom, Germany, France, Spain, Switzerland, Italy, Sweden, Netherlands, Belgium, Japan, and Hong Kong and two pending foreign patent applications in the EPO and Hong Kong, with such issued patents and the patents that may issue from such patent applications, if any, expected to expire in 2034, without accounting for any available patent term adjustments or extensions. For more information regarding this license agreement, see the section titled “Business—Licensing Agreements.”

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug—and only those claims covering the approved drug, a method for using it, or a method for manufacturing it—may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval or applicable approval in other jurisdictions, we expect to apply for patent term extensions on issued patents covering those products in the United States and other jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. We also 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.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The relevant patent laws and their interpretation, both inside and outside of the United States, is also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that

infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block—in some cases—potential competitors from practicing the claimed inventions of the issued patents.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidate and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

We also rely on protections under trade secret laws, and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our trade secrets include, for example, certain program specific synthesis, formulations, patient selection strategies and certain aspects of our research. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements are intended to provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements would also provide that all inventions to which the individual contributed as an inventor shall be assigned to us, and as such, will become our property. There can be no assurance, however, that these agreements and our policies will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information. We also may be unsuccessful in executing such agreements with each party who, in fact, conceives or develops intellectual property that we regard as our own or receives access to our confidential information. The assignment of intellectual property rights may not be self-executing, or the agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. Further, we have filed for and are pursuing trademark protection for our company name "Connect Biopharmaceuticals" in the PRC. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks related to intellectual property."

### **Licensing Agreement**

On June 19, 2012, we and Arena entered into an exclusive license agreement, or the Arena Agreement. Pursuant to the Arena Agreement, as subsequently amended in October 2015, February 2018 and November 2020, Arena granted us an exclusive (even as to Arena, except for internal research purposes), worldwide, royalty-bearing, sublicensable (subject to certain conditions) license to identify, research, develop, make, have made, use, sell, offer for sale, have sold and import products under certain patents and know how relating to H3R antagonists and methods of making and using such H3R antagonists.

Under the Arena Agreement, we are obligated to use commercially reasonable efforts to conduct and complete clinical trials, other development work and commercialization activities in order to achieve the goal of commercialization of the licensed products worldwide. In the event that we desire to sublicense or otherwise transfer any rights under the Arena Agreement to a third party or otherwise enter into a commercialization agreement with a third party with respect to selling a licensed product in a specific country, Arena has the right to first negotiation with respect to such transaction pursuant to which we must negotiate in good faith for a certain specified period to reach an agreement with Arena before we are able to enter into such an agreement with a third party.

Pursuant to the Arena Agreement, we are obligated to pay Arena royalties of a high single-digit percentage on net sales of all licensed products sold by us anywhere in the world. If we grant any third party a sublicense to market, distribute, or otherwise commercialize a licensed product, we are obligated to pay Arena royalties of the greater of (a) low double-digit percentage of all royalty payments, on a licensed product-by-licensed product and country-by-country basis, received from such sublicensee based on the sales of all licensed products sold by such sublicensees anywhere in the world, and (b) a royalty of a mid-single-digit percentage on the net sales of all licensed products sold anywhere in the world by such sublicensee, provided that, in the latter case, to the extent such sublicense is granted by us after a licensed product is launched for commercial sale in a particular country, the applicable rate for the royalty based on net sales of all licensed products sold in such country by such sublicensee will be reduced. After our aggregate royalty payments based on the foregoing reach a certain low single-digit million threshold, the royalty rate with respect to licensed products sold by us for end use in the People's Republic of China shall reduce to a mid-single-digit percentage, while the same high single-digit percentage royalty rate will continue to apply to licensed products sold by us for end use in the rest of the world. In addition, we are obligated to pay Arena sublicense fees of a low double-digit percentage on our sublicense revenues. Similarly, if we sell or otherwise grant any rights with respect to marketing, distribution or other commercialization of any licensed products to any third party (including by sale of all or substantially all of our assets or of our assets that relate to the Arena Agreement), we are obligated to pay Arena a low double-digit percentage of all consideration received by us pursuant to such transaction (even consideration that is attributed to assets other than a licensed product or the Arena Agreement). Lastly, we are required to pay Arena an annual license maintenance fee in the low five-figures. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis from the first commercial sale of such licensed product in such country, until the later of (x) 12 years following such first commercial sale in such country, or (y) the expiration of the last to expire licensed patent in such country covering such licensed product or its manufacture or use.

Subject to the exclusive license granted to us, any intellectual property rights relating to the applicable H3R antagonists and the methods of making and using thereof discovered, developed or created during the term of the Arena Agreement or during the one-year period thereafter shall be owned solely by Arena. We have the sole responsibility to file, prosecute and maintain patents licensed under the Arena Agreement and the first right to enforce any such patents.

The Arena Agreement will continue until the expiration of our obligation to pay royalties in all countries of the world. We and Arena may each terminate the Arena Agreement upon a material breach by the other party that is not cured within 60 days after receiving written notice of breach. We may terminate the Arena Agreement without cause upon 60 days' prior written notice. Arena may terminate the Arena Agreement upon our bankruptcy or other insolvency-related events.

#### **Government Regulation and Product Approval**

Among others, the FDA, the EMA, U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare and Medicaid Services, or CMS, and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

### **U.S. Regulation of Drugs and Biologics**

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA and the Public Health Service Act, or PHSA, and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical studies may begin and must be updated annually;
- approval by an independent IRB or ethics committee representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with Good Clinical Practice, or GCP, requirements to establish the safety and efficacy, or with respect to biologics, the safety, purity and potency of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application, or NDA, or biologics license application, or BLA, after completion of all pivotal clinical studies;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product drug substance is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and audits of selected clinical trial sites to ensure compliance with GCP; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls, or CMC, information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. 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.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which includes the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides 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 it determines that there is an unacceptable safety risk for

subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency.

#### ***NDA and BLA Review Process***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act, or PREA, a NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any drug or biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews the submitted BLA or NDA to determine if the application is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. Once an NDA or

BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. When reviewing an NDA or BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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

#### ***Expedited Development and Review Programs***

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product candidate may also be eligible for rolling review,



where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

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

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

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

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

#### ***Orphan Drug Designation***

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to

the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug or biologic was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

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

#### **Post-Approval Requirements**

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

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and

criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

#### ***Drug Product Marketing Exclusivity***

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. For example, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

#### ***Biosimilars and Reference Product Exclusivity***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product

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

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, 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.

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

#### **PRC Regulation**

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business and operations.

#### **Regulations on Company Establishment and Foreign Investment**

The establishment, operation and management of corporate entities in China are governed by the Company Law of PRC, or the PRC Company Law, which was promulgated by the Standing Committee of the National People's Congress, or the NPC, in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013 and October 2018, respectively. According to the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. According to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

Investment activities in the PRC by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council in February 2002 and came into effect in April 2002, and the Special Administrative Measures for the Access of Foreign Investment (Negative List), or the Negative List, which was promulgated by MOFCOM and the National Development and Reform Commission in June 2020 and came into effect in July 2020. The Negative List sets out the restrictive measures in a unified manner, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited from receiving foreign investment. The Negative List covers 12 industries, and any field not falling under the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the PRC, or the Foreign Investment Law, was promulgated by the NPC in March 2019 and came into effect in January 2020. When the Foreign Investment Law came into effect, the Law on Wholly Foreign-owned Enterprises of the PRC, the Law on Sino-foreign Equity Joint Ventures of the PRC and the Law on Sino-foreign Cooperative Joint Ventures of the PRC were repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (collectively, the "foreign investors") directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law. Such activities include: (1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; (2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; (3) investing by foreign investors in new projects in China alone or jointly with other investors; and (4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC, which came into effect in January 2020. When the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise

Law of the PRC, Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise, the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law of the PRC and the Regulations on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC were repealed simultaneously.

In December 2019, the MOFCOM and the State Administration for Market Regulation, or the SAMR promulgated the Measures on Reporting of Foreign Investment Information, which came into effect in January 2020. When the Measures on Reporting of Foreign Investment Information came into effect, the Interim Measures for the Administration of Filing for Establishment and Changes in Foreign Investment Enterprises were repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the Measure on Reporting of Foreign Investment Information.

#### **Regulation on Pharmaceutical Product Development, Approval and Registration**

##### *Drug Regulatory Regime*

The Drug Administration Law of the PRC, or the Drug Administration Law, was promulgated by the Standing Committee of the NPC, in September 1984. The two latest amendments to the Drug Administration Law were the amendment promulgated in April 2015 and in August 2019. The Regulations for the Implementation of the Drug Administration Law were promulgated by the State Council in August 2002, and were last amended in March 2019. The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law 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. It regulates and provides for 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 Regulations for the Implementation of the Drug Administration Law, at the same time, provide the detailed implementation regulations for the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of the China Communist Party jointly issued Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices, or the Innovation Opinions. The expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug manufacturers to seek marketing approval in China first for the development of drugs in highly prioritized therapeutic areas, such as oncology or rare diseases.

To implement the regulatory reform introduced by the Innovation Opinions, the Standing Committee of the NPC, the National Medical Products Administration, or the NMPA, a newly formed government authority as well as other authorities, are currently responsible for revising the laws, regulations and rules governing the pharmaceutical products and the industry.

In August 2019, the Standing Committee of the NPC promulgated the new Drug Administration Law, or the 2019 Amendment, which came into effect in December 2019. The 2019 Amendment contains many of the major reform initiatives implemented by the Chinese government since 2015, including but not limited to the Marketing Authorization Holder, or the MAH, system, conditional approvals of drugs, traceability system of drugs, and the cancellation of relevant certification according to Good Manufacturing Practice and Good Supply Practice.

##### *Regulatory Authorities*

Pharmaceutical products in China are monitored and supervised on a national scale by the NMPA. The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The NMPA was newly formed under the SAMR. The NMPA's predecessor, the State Drug Administration was replaced by the State Food and Drug Administration, or the SFDA, which was later reorganized into the China Food and Drug Administration, or the CFDA, as part of the institutional reforms implemented by the State Council.

The primary responsibilities of the NMPA include:

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment as well as cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of pharmaceutical, medical devices, and cosmetics industry;
- evaluating, registering and approving new drugs, generic drugs, imported drugs and traditional Chinese medicine;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products, medical appliances and equipment;
- approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products;
- examining and evaluating the safety of pharmaceutical products, medical devices, and cosmetics; and
- managing significant accidents involving pharmaceutical products, medical devices and cosmetics.

In 2013, the Ministry of Health, or the MOH, and the National Population and Family Planning Commission were integrated into the National Health and Family Planning Commission of the PRC, or the NHFPC. In March 2018, the First Session of the Thirteenth NPC approved the State Council Institutional Reform Proposal, according to which, NHFPC and certain other governmental authorities were consolidated into the National Health Commission, or the NHC. The responsibilities of the NHC include coordinating the formulation of national drug policies, the national essential medicine system and the National Essential Medicines List and drafting the administrative rules for the procurement, distribution and use of national essential medicines.

According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs, which was promulgated by the CFDA in March 2017 and came into effect in May 2017, an IND approval should be issued by the Center for Drug Evaluation, or the CDE, on behalf of the CFDA.

### **Regulations on Clinical Trials and Registration of Drugs**

#### *Administrative Measures for Drug Registration*

In July 2007, the SFDA promulgated the amended version of the Administrative Measures for Drug Registration, or the Registration Measures, which became effective in October 2007. The Registration Measures mainly cover: (1) definitions of drug registration applications and regulatory responsibilities of drug administration; (2) general requirements for drug registration, including application for registration of new drugs, generic drugs, imported drugs and supplemental application, as well as application for re-registration; (3) clinical trials; (4) application, examination and approval of new drugs, generic drugs and imported drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) re-examination; and (10) liabilities and other supplementary provisions.

According to the Registration Measures, drug registration applications are divided into three different types, namely Domestic New Drug Application, Domestic Generic Drug Application and Imported Drug Application. Drugs which fall into one of three general types are divided according to the drug's working mechanism, namely whether the drug is classified as a chemical medicine, a biological product, a traditional Chinese medicine or a natural medicine. A Domestic New Drug Application, or Domestic NDA, refers to an application for registration of a drug that has not yet been marketed for sale in China. In addition, the registration of drugs that change the dosage form of the marketed drugs, change the route of administration and increase the new indications shall be reported in accordance with the application procedures for new drugs. Under the Registration Measures, a Category 1 drug refers to a new drug that has never been marketed in any country, and such drug is eligible for special review or fast track approval by the NMPA.

In January 2020, the SAMR released the amended Administrative Measures for Drug Registration, or the Amended Registration Measures, which came into effect in July 2020. The Amended Registration Measures provide detailed procedural and substantive requirements for the key regulatory concepts established by the Drug Administration Law, and confirms a number of reform actions that have been taken in the past years, including but not limited to: (i) the full implementation of the MAH system and implied approval of the commencement of clinical trial; (ii) the

implementation of associated review of drugs, excipients and packaging materials; and (iii) the introduction of four procedures for expedited registration of drugs, which are procedures for ground-breaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval. Detailed implementation rules for drug classification and requirements for corresponding application materials will be promulgated by the NMPA.

In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine, which outlined the reclassifications of drug applications under the Registration Measures. According to the Reform Plan for Registration Category of Chemical Medicine, Category 1 drugs refer to innovative new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2 drugs. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed abroad but not yet in China, can be classified as Category 3 drugs. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4 drugs. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic New Drug Application and the Imported Drug Application Procedures under the Registration Measures, respectively.

The SFDA promulgated the Administrative Provisions on Special Examination and Approval of Registration of New Drugs in January 2009, according to which, the SFDA conducts special examination and approval for new drug registration applications when: (1) the effective constituent of drug extracted from plants, animals, minerals, etc., as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing at home and abroad; (3) the new drugs have obvious clinical treatment advantages for such diseases as AIDS, malignant tumors and orphan diseases, etc. or (4) the new drugs treat diseases currently with no effective methods of treatment.

The Special Examination and Approval of Registration of New Drugs provides that the applicant may file for special examination and approval at the clinical trial application stage if the product candidate falls within items (1) or (2). The provisions provide that for product candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

#### *Accelerated Approval for Clinical Trial and Registration*

The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Innovation Opinions enhanced the standard of approval for drug registration and accelerated the evaluation and approval process for innovative drugs as well as drug clinical trials.

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval in November 2015, which further clarified the measures and policies for simplifying and accelerating the approval process of clinical trials, including:

- a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug's clinical trials, replacing the current phase-by-phase application and approval procedure; and
- a fast track drug registration or clinical trial approval pathway for the following applications: (1) registration of innovative new drugs for treating HIV, cancer, serious infectious diseases and orphan diseases, etc.; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating PRC-prevalent diseases in elders; (4) registration of drugs listed in national major science and technology projects or national key research and development plan; (5) registration of clinical urgently needed drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the United States or EU or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or EU and are manufactured using the same production line in China; and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

The NMPA released the Circular on Adjusting Evaluation and Approval procedures for Clinical Trials for Drugs in July 2018, according to which, within 60 days after the acceptance of and the fees paid for the IND application, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE. Such approval process has been further enacted into the 2019 Amendment.

*Trial Exemptions and Acceptance of Foreign Data*

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct Domestic NDAs. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug registration in China, provided that the sponsors must ensure the authenticity, completeness, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or the ICH. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug registrations in China using foreign clinical trial data.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, the NMPA and the NHC released the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs in October 2018, permitting drugs that have been approved within the last ten years in the United States, the EU 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 will be 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.

*Clinical Trial Process and Good Clinical Practices*

According to the Registration Measures, a clinical trial consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a product candidate's therapeutic effectiveness and safety for particular indications in patients, to provide evidence and support for the design of Phase III clinical trials and to settle the administrative dose regimen. Phase III refers clinical trials undertaken to confirm the therapeutic effectiveness and safety on patients with target indications, to evaluate the overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate the overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose.

To improve the quality of clinical trials, the SFDA promulgated the Good Clinical Trial Practice for Drugs in August 2003, or the GCP Rules, which was replaced by the revised Good Clinical Trial Practice for Drugs, or the Revised GCP Rules, promulgated by the NMPA and the NHC in April 2020 and coming into effect in July 2020. According to the Administration of Quality of Drug Clinical Practice, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the function, adverse reactions and/or absorption, distribution, metabolism and excretion of the drug being investigated. The purpose of a clinical trial is to determine the therapeutic efficacy and safety of the drug. The Revised GCP Rules provide comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the Revised GCP Rules enhance the protection for study subjects and tighten the control over bio-samples collected under clinical trials.

The Revised GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial, who must: (i) have professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and be able to provide the latest resume and relevant qualification documents per request; (ii) be familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) be familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keep a copy of the authorization form on work allocation signed by investigators; (v) accept supervision and inspection organized by the applicant and inspection by



the drug regulatory authorities; and (vi) in the case of investigators and clinical trial centers authorizing other individuals or institutions to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individuals or institutions are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

*Communication with the CDE*

According to the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, where the application for clinical trial of a new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to the CDE to discuss the key technical questions including the design of Phase III clinical trial protocol. Within 60 days after the acceptance of and the fees paid for the IND application, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

The NMPA promulgated the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs in September 2018, according to which, during the research and development periods and in the registration applications of, among others, innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. 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 IND application, meetings upon the completion of Phase II trials and before the commencement of Phase III trials, meetings before submitting a marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to meetings not classified as Type I or Type II.

*Drug Clinical Trial Registration*

According to the Registration Measures, upon obtaining the approval of its IND applications and before conducting a clinical trial, an applicant shall file a registration form with the SFDA containing various details, including the clinical trial protocol, the name of the principal researcher of the leading institution, the names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the informed consent form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. The CFDA released the Announcement on Drug Clinical Trial Information Platform in September 2013, according to which, instead of the aforementioned registration filed with the CFDA, all clinical trials approved by the CFDA and conducted in China shall complete a clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial approval in order to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval of the IND applications, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the IND applications shall automatically expire.

*New Drug Application*

According to the Registration Measures, drug registration applications include Domestic NDAs, domestic generic drug application and imported drug application. Drugs are classified into chemical drugs, biological products and traditional Chinese medicine or natural drugs. When Phases I, II and III clinical trials have been completed, the applicant may apply to the SFDA for approval of a Domestic NDA. The SFDA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE.

*Pilot Plan for the MAH System*

The Innovation Opinions provide a pilot plan for the MAH system.

Under the authorization of the Standing Committee of the NPC, the General Office of the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism in May 2016, which provides a detailed pilot plan for the MAH system in ten Chinese provinces. Under the MAH system, domestic drug research and development institutions and individuals in the pilot regions are eligible to be holders of drug registrations without having to become drug manufacturers. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and located within the pilot regions. Drugs

that qualify for the MAH system are: (1) new drugs (including but not limited to drugs under category I to category IV of chemical drugs, and targeted preparation, sustained release preparation, controlled release preparation under category V of chemical drugs, biological products approved as category I and VII drugs and biosimilars under the Registration Measures) approved after the implementation of the MAH system; (2) generic drugs approved as category III or IV drugs under the Reform Plan for Registration Category of Chemical Medicine; (3) previously approved generics that have passed equivalence assessments against original drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the pilot regions, but which have moved out of the pilot regions due to corporate mergers or other reasons.

The CFDA promulgated the Circular on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System in August 2017. It clarified the legal liability of the MAH, who is responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and legally liable for preclinical drug study, clinical trials, manufacturing, marketing, distribution and adverse drug reaction monitoring. According to the Circular on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System, the MAH shall submit a report of drug manufacturing, marketing, prescription, techniques, pharmacovigilance, quality control measures and other situations to the CFDA within 20 working days after the end of each year.

According to the Pilot Plan for the Drug Marketing Authorization Holder Mechanism, the pilot plan was originally set for a three-year period and was scheduled to expire in November 2018. The Standing Committee of the NPC promulgated the Decision of Extending the Pilot Period of Authorizing the State Council to Carry Out the Pilot Plan for the Drug Marketing Authorization Holder Mechanism in Certain Places in October 2018, which extended the term of the MAH system to November 4, 2019.

According to the 2019 Amendment, which came into effect on December 1, 2019, the MAH system will be applicable throughout the country and the legal representative and the key person-in-charge of a drug MAH shall be fully responsible for the quality of drugs.

#### *International Multi-Center Clinical Trials*

The International Multi-Center Clinical Trial Guidelines (Trial), or the Multi-Center Clinical Trial Guidelines, which was promulgated by the CFDA in January 2015 and came into effect in March 2015, provided guidance on the implementation of Multi-Regional Clinical Trials, or the MRCT, in China. According to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Implementing Regulations of the Drug Administration Law and the Registration Measures, execute the GCP Rules, make reference to universal international principles such as the ICH-GCP and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines, Registration Measures and other related laws and regulations.

In April 2020, the NMPA and the NHC promulgated the Revised GCP Rules, which came into effect in July 2020. The Revised GCP Rules summarize the requirements for initiating an MRCT, that is, before initiating an MRCT: (i) the applicant shall ensure that all the centers participating in the clinical trial comply with the trial protocol; (ii) the applicant shall provide each center with the same trial protocol, and each center shall comply with the same unified evaluation criterion for clinical trial and laboratory data and the same guidance for case report form; (iii) each center shall use the same case report form to record the data of each human subject obtained during the trial; (iv) before initiating a clinical trial, a written document is required to specify the responsibilities of the investigators of each center; and (v) the applicant shall ensure the communication among the investigators of each center.

Data derived from international multi-center clinical trials can be used for the new drug applications with the NMPA. When using international multi-center clinical trial data to support new drug applications in China, applicants shall

submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with the content and format requirements under the International Conference on Harmonization-Common Technical Document; subgroup research results summary and comparative analysis shall also be conducted concurrently. Leveraging the clinical trial data derived from international multi-center clinical trials conducted by our partners, we may avoid unnecessarily repetitive clinical trials and thus further accelerate the Domestic NDA process.

The CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration in October 2017, which includes the following key points:

- If the International Multicenter Clinical Trial, or the IMCCT, of a drug is conducted in China, Phase I clinical trial of the drug is allowed simultaneously. The IMCCT drug does not need to be approved or to enter into either a Phase II or III clinical trial in a foreign country, except for preventive biological products;
- If the IMCCT is conducted in China, the application for drug marketing authorization can be submitted directly after the completion of the IMCCT. The Registration Measures and relevant laws and regulations shall be complied with for registration application;
- With respect to applications for clinical trial and marketing of the imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required; and
- With respect to drug applications that have been accepted before the release of the Decision on Adjusting Items concerning the Administration of Imported Drug Registration, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from the IMCCT.

#### ***Approval of Human Genetic Resources***

The Interim Administrative Measures on Human Genetic Resources, promulgated by the Ministry of Science and Technology and the MOH in June 1998, aimed at protecting and fairly utilizing human genetic resources in the PRC. The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating Chinese organization shall apply for approval of the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology further promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources in October 2017, which became effective in December 2017 and simplified the approval of sampling and collecting human genetic resources for listing a drug in the PRC.

The Regulations of the PRC on the Administration of Human Genetic Resources, which was promulgated by the State Council in May 2019 and came into effect in July 2019, further stipulates that, in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resource to be used shall be filed with the administrative department of science and technology under the State Council before clinical trials.

#### ***Regulations on Drug Manufacturing and Distribution***

##### ***Drug Manufacturing***

According to the Drug Administration Law and the Implementing Regulations of the Drug Administration Law, a drug manufacturing enterprise is required to obtain a drug manufacturing license from the relevant provincial drug administration authority of the PRC. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Implementing Regulations of the Drug Administration Law and the Measures on the Supervision and Administration of the Manufacture of Drugs, which was promulgated in August 2004, amended in November 2017 and January 2020 and came into effect in July 2020, the drug manufacturing license is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. In addition, the name, legal representative, registered address

and type of the enterprise specified in the drug manufacturing certificate shall be identical to that set forth in the business license as approved and issued by the industrial and commercial administrative department. To the extent the MAH does not manufacture the drug internally but through a contract manufacturing organization, the MAH shall apply for drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

The Good Manufacturing Practice for Drugs was promulgated in March 1988 and was amended in December 1992 and June 1999 and January 2011. The latest amendment was in June 2020 and came into effect in October 2020. The Good Manufacturing Practice for Drugs comprises a set of detailed standard guidelines governing the manufacture of drugs, which include institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records, management of customer complaints and adverse event reports.

#### *Drug Distribution*

According to the Drug Administration Law, its implementing regulations and the Measures for the Supervision and Administration of Circulation of Pharmaceuticals, which was promulgated by the SFDA in January 2007 and came into effect in May 2007, pharmaceutical enterprises shall be responsible for the quality of the pharmaceuticals that they manufacture, operate, use, purchase, sell, transport, or store.

According to the Measures for the Administration of Pharmaceutical Operation Certificate, which was promulgated in February 2004 and amended in November 2017 by the CFDA, a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit six months prior to expiration. The establishment of a wholesale pharmaceutical distribution company requires the approval of provincial medicine administrative authorities. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the wholesale pharmaceutical product distribution company. The establishment of a retail pharmacy store requires the approval of the local medicine administrative authorities at or above the county level. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the retail pharmacy store.

### **Other PRC Government Regulations**

#### ***Regulations on Intellectual Property Rights***

In terms of international conventions, China has entered into (including but not limited to) the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Paris Convention for the Protection of Industrial Property, the Madrid Agreement Concerning the International Registration of Marks and the Patent Cooperation Treaty.

#### *Patents*

According to the Patent Law of the PRC, which was promulgated by the Standing Committee of the NPC in March 1984, amended in September 1992, August 2000 and December 2008, and came into effect in October 2009, and the Implementation Rules of the Patent Law of the PRC, which was promulgated by the State Council in June 2001 and amended in December 2002 and January 2010, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period is 20 years for an invention patent and 10 years for a utility model patent and a design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activities that infringe a patent without prior authorization of the patent holder shall pay compensation to the patent holder and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law. According to the Patent Law of the PRC, any organization or individual that applies for a patent in a foreign country for an invention or utility model patent established in China is required to report to the NIPA for confidentiality examination.

#### *Trade Secrets*

According to the PRC Anti-Unfair Competition Law, which was promulgated by the Standing Committee of the NPC in September 1993 and amended in November 2017 and April 2019, respectively, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets

obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate a confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

#### **Trademarks**

According to the Trademark Law of the PRC promulgated by the Standing Committee of the NPC in August 1982, and amended in February 1993, October 2001, August 2013 and April 2019, respectively, the period of validity for a registered trademark is ten years, commencing on the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years, commencing on the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be cancelled. Industrial and commercial administrative authorities have the authority to investigate any behavior that infringes the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

#### **Domain Names**

Domain names are protected under the Administrative Measures on the Internet Domain Names, which was promulgated by the Ministry of Industry and Information Technology in August 2017, and the Implementing Rules on Registration of National Top-level Domain Names, which was promulgated by China Internet Network Information Center in and came into effect in June 2019. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

#### **Regulations on Product Liability**

In addition to the strict new drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC laws, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. According to the General Principles of the Civil Law of the PRC promulgated in April 1986 and amended in August 2009 and General Rules of the Civil Law of the People's Republic of China promulgated and amended in October 2017, collectively, the PRC Civil Law, the manufacturer or vendor of a defective product which causes property damage or physical injury to any person may be subject to civil liability for such damage or injury.

In February 1993, the Product Quality Law of the PRC, or the Product Quality Law, was promulgated to supplement the PRC Civil Law, aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was last revised in December 2018. According to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

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

#### **Regulations on Tort**

According to the Tort Law of the PRC promulgated by the Standing Committee of the NPC in December 2009, if damages to other persons are caused by defective products due to the fault of third parties, such as the parties

providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of a warning, recall of products, etc., in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

***Regulations on Environment Protection***

Pursuant to the Environmental Protection Law of the PRC promulgated by the Standing Committee of the NPC, in December 1989, amended in April 2014 and effective in January 2015, any entity which discharges or will discharge pollutants during its course of operations or other activities must implement effective environmental protection safeguards and procedures to control and properly treat waste gas, waste water, waste residue, dust, malodorous gases, radioactive substances, noise vibrations, electromagnetic radiation and other hazards produced during such activities. According to the provisions of the Environmental Protection Law, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts take charge of administering and supervising said environmental protection matters.

Pursuant to the Environmental Protection Law, the environmental impact statement on any construction project must assess the pollution that the project is likely to produce and its impact on the environment, and stipulate preventive and curative measures; the statement shall be submitted to the competent administrative department of environmental protection for approval. Installations for the prevention and control of pollution in construction projects must be designed, built and commissioned together with the principal part of the project.

Pursuant to the Law of the People's Republic of China on Environment Impact Assessment, which was promulgated in October 2002 and most recently amended in December 2018, the government of the PRC implements a classification-based management on the environmental impact assessment of construction projects according to the impact of the construction projects on the environment. Construction units shall prepare an Environmental Impact Report or an Environmental Impact Statement, or fill out the Environmental Impact Registration Form.

Pursuant to the Regulations on Urban Drainage and Sewage Disposal, which was promulgated in October 2013 and came into effect in January 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network, which was promulgated in January 2015 and came into effect in March 2015, drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant government regulations. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

***Regulations on Fire Protection***

The Fire Prevention Law of the PRC, or the Fire Prevention Law, was adopted in April 1998 and last amended in April 2019. The Fire Prevention Law provides that fire control design and construction of a construction project shall comply with PRC's fire control technical standards. Developers, designers, builders and project supervisors shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. Development project fire safety design examinations and acceptance systems shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards.

According to the Eight Measures for the Public Security Fire Department to Deepen Reform and Serve Economic and Social Development promulgated by the Ministry of Public Security of the PRC in August 2015, the fire protection design and completion acceptance fire protection record of construction projects with an investment of less than RMB300,000 or a building area of less than 300 square meters (or below the limit set by the housing and urban construction department of the provincial people's government) was no longer required.

***Regulations on Foreign Exchange and Dividend Distribution***

***Foreign Exchange Control***

According to the PRC Regulation for the Foreign Exchange promulgated by the State Council in January 1996, which was amended in January 1997 and August 2008, and the Regulation on the Administration of the Foreign Exchange

Settlement, Sales and Payment promulgated by the People's Bank of China in June 1996, foreign exchanges required for distribution of profits and payment of dividends may be purchased from designated foreign exchange banks in the PRC upon presentation of a board resolution authorizing distribution of profits or payment of dividends.

According to the Circular of the State Administration of Foreign Exchange, or the SAFE, on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment and its appendix promulgated in November 2012 and amended in May 2015, October 2018 and December 2019 by the SAFE, (1) the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE; (2) reinvestment with legal income of foreign investors in China is no longer subject to approval by SAFE; (3) the procedures for capital verification and confirmation that foreign-funded enterprises need to go through are simplified; (4) purchase and external payment of foreign exchange under direct investment accounts are no longer subject to approval by SAFE; (5) domestic transfer of foreign exchange under direct investment account is no longer subject to approval by SAFE; and (6) the administration over the conversion of foreign exchange capital of foreign-invested enterprises is improved. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment in February 2015, which was further amended in December 2019 and prescribed that the bank instead of the SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while the SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

The Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors, which were promulgated by the SAFE in May 2013 and amended in October 2018 and December 2019, regulate and clarify the administration over foreign exchange administration in foreign direct investments.

According to the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises promulgated by the SAFE in March 2015 and amended in December 2019, and the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects promulgated by the SAFE in June 2016, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, the settlement of foreign exchange shall only be used for their own operational purposes within the business scope of the foreign invested enterprises and follow the principles of authenticity.

#### *Dividend Distribution*

The SAFE promulgated the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control in January 2017, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

#### *Foreign Exchange Registration of Offshore Investment by PRC Residents*

The SAFE promulgated the SAFE Circular 37 in July 2014. The SAFE Circular 37 requires PRC residents (including PRC institutions and individuals) to register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or the SPV, directly established or indirectly controlled by PRC residents for offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such PRC residents are also required to amend their registrations with the SAFE when there is a change to the basic information of the SPV, such as changes of a PRC resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV.

The Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment, which was promulgated in February 2015 and effective in June 2015 and further amended in December 2019, provides that PRC residents may register with qualified banks instead of the SAFE in connection with their establishment or control of an offshore entity established for the purpose of overseas direct investment. The SAFE

and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

### **Regulations on Labor**

#### ***Labor Law and Labor Contract Law***

According to the PRC Labor Law, which was promulgated by the Standing Committee of the NPC in July 1994 and amended in August 2009 and December 2018, respectively, the PRC Labor Contract Law, which was promulgated by the Standing Committee of the NPC in June 2007 and amended in December 2012 and came into effect July 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC, which was promulgated by the State Council in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than the local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by PRC rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with PRC rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

#### ***Social Insurance and Housing Provident Funds***

According to the Social Insurance Law of PRC, which was promulgated by the Standing Committee of the NPC in October 2010 and came into effect in July 2011, and further amended in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds, which was promulgated by the State Council in January 1999 and amended in March 2019, and the Regulations on the Administration of Housing Provident Funds, which was promulgated by the State Council in April 1999 and amended in March 2002 and March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

### **Regulations on Taxation**

#### ***Enterprise Income Tax***

According to the Enterprise Income Tax Law promulgated by the NPC in March 2007 and amended in February 2017 and December 2018, and the Implementation Rules of the Enterprise Income Tax Law of the PRC promulgated by the State Council in December 2007 and amended in April 2019, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either "resident enterprises" or "non-resident enterprises". Besides enterprises established within the PRC, enterprises established outside China whose "de facto management bodies" are located in China are considered "resident enterprises" and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. An income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

According to the Notice on Promoting the Implementation of Corporate Income Tax Policies for Advanced Technology Service Enterprises Nationwide, or the Notice, effective in January 2017, an enterprise which is recognized as an "Advanced Technology Service Enterprises" under the Notice enjoys a reduced enterprise income tax rate of 15%.

According to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income, or the Double



Tax Avoidance Arrangement, which was promulgated and came into effect in August 2006, and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5%. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties which was promulgated by the State Administration of Taxation, or the STA, in February 2009, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. Based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties, which was promulgated by the STA in February 2018 and came into effect in April 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

**Value Added Tax**

According to the Provisional Regulations of the PRC on Value-Added Tax, effective in January 1994 and further amended in November 2008, February 2016, and November 2017, and its implementation rules effected in January 1994 and amended in December 2008 and October 2011, except stipulated otherwise, taxpayers who sell goods, labor services or tangible personal property leasing services or import goods shall be subject to a 17% tax rate; taxpayers who sell transport services, postal services, basic telecommunications services, construction services, or real property leasing services, sell real property, transfer the land use right shall be subject to an 11% tax rate, and taxpayers who sell services or intangible assets shall be subject to a 6% tax rate.

According to the Circular of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates adopted in April 2018, as of May 2018, where a taxpayer engages in a taxable sales activity for the value-added tax purpose or imports goods, the previous applicable 17% and 11% rates are adjusted to 16% and 10%.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform, effective in April 2019, the 16% VAT tax rate, which applies to the sales or imported goods of a VAT general taxpayer, will be lowered to 13%; and the 10% VAT tax rate will be lowered to 9%.

According to the Measures for the Exemption of Value-Added Tax from Cross-Border Taxable Activities in the Collection of Value-Added Tax in Lieu of Business Tax (for Trial Implementation) revised in June 2018, if domestic enterprises provide cross-border taxable activities such as professional technical services, technology transfer, software services, the above-mentioned cross-border taxable activities are exempt from VAT.

**Foreign Government Regulation**

Our product candidates will be subject to similar laws and regulations imposed by jurisdictions outside of the United States, and, in particular, Europe, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

In order to market our future product candidates in the European Economic Area (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), or the EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the “Community MA,” which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Product candidates for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of product candidates, such as biotechnology medicinal product candidates, orphan medicinal product candidates and medicinal product candidates indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for product candidates containing a new active substance not yet authorized in the EEA, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and

- “National MAs,” which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for product candidates not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

*Data and marketing exclusivity.* In the EEA, new product candidates authorized for marketing, or reference product candidates, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

*Pediatric investigation plan.* In the EEA, marketing authorization applications for new medicinal product candidates not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. 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 PDCO can grant a deferral 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. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for a six-month supplementary protection certificate extension or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

*Orphan drug designation.* In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically-debilitating condition affecting not more than five in 10,000 persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the EU 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 EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the competent authorities of the Member States, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP.

This period of orphan market exclusivity 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 which it received orphan drug destination, i.e. the

prevalence of the condition has increased above the threshold or it is judged that the product is sufficiently profitable not to justify maintenance of market exclusivity. Granting of an authorization for another similar orphan medicinal product where another product has market exclusivity can happen only in selected cases, such as, for example, demonstration of "clinical superiority" by a similar medicinal product, inability of a manufacturer to supply sufficient quantities of the first product or where the manufacturer itself gives consent. A company may voluntarily remove a product from the orphan register. Medicinal products or medicinal product candidates designated as orphan are eligible for incentives made available by the EU and its Member States to support research into, development and availability of orphan medicinal products. In March 2016, we obtained orphan drug designation for setrusumab for the treatment of OI in the EU. We intend to pursue orphan designation for alvelestat and for future, eligible rare disease programs.

**Adaptive pathways.** The EMA has an adaptive pathways program which allows for early and progressive patient access to a medicine. The adaptive pathways concept is an approach to medicines approval that aims to improve patients' access to medicines in cases of high unmet medical need. To achieve this goal, several approaches are envisaged: identifying small populations with severe disease where a medicine's benefit-risk balance could be favorable; making more use of real-world data where appropriate to support clinical trial data; and involving health technology assessment bodies early in development to increase the chance that medicines will be recommended for payment and ultimately covered by national healthcare systems. The adaptive pathways concept applies primarily to treatments in areas of high medical need where it is difficult to collect data via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach builds on regulatory processes already in place within the existing EU legal framework. These include: scientific advice; compassionate use; the conditional approval mechanism (for medicines addressing life-threatening conditions); patient registries and other pharmacovigilance tools that allow collection of real-life data and development of a risk-management plan for each medicine.

The adaptive pathways program does not change the standards for the evaluation of benefits and risks or the requirement to demonstrate a positive benefit-risk balance to obtain marketing authorization. In February 2017, setrusumab was accepted into the adaptive pathways program.

**PRIME scheme.** In July 2016, the EMA launched the PRIME scheme. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation includes the appointment of a rapporteur from the Committee for Medicinal Product candidates for Human Use before submission of a Marketing Authorisation Application, early dialogue and scientific advice at key development milestones, and the potential to qualify product candidates for accelerated review earlier in the application process. In November 2017, the EMA granted PRIME designation for setrusumab for the treatment of OI.

#### **Other U.S. Healthcare Laws**

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and transparency laws and regulations, as well as similar foreign laws in the jurisdictions outside the United States, including but not limited to those discussed below.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

The federal civil monetary penalties and false claims laws, including the civil False Claims Act, or FCA, prohibit individuals or entities from, among other things: knowingly presenting, or causing to be presented, to the federal

government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Physician Payments Sunshine Act imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and “transfers of value” provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers including physician assistants and nurse practitioners.

Moreover, analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, many of which differ from each other in significant ways, are often not pre-empted, thus further complicating compliance efforts; and restrict marketing practices or require disclosure of marketing expenditures and pricing information.

Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if a manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

**Coverage and Reimbursement**

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufactures to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage

and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Third-party payors are also increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are more and more challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

#### **Healthcare Reform**

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the constitutionality of the ACA. It is unclear how the Supreme Court will rule, or the impact of any other efforts to challenge, repeal or replace the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2030 absent additional congressional action, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical

products. In addition, individual states in the United States have also become increasingly active in implementing 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, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

#### **Data Privacy and Security Laws**

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act of 1914, or FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information, which could apply to our operations or the operations of our partners. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA, as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state and non-U.S. laws, such as the GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. In addition, on November 3, 2020, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. Additionally, other states are considering the enactment of similar laws.

In Europe, we are subject to laws relating to our and our suppliers', vendors', partners' and subcontractors' collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, where we offer goods or services to EU and EEA residents and where we monitor the behavior of individuals in the EU and the EEA (i.e., undertaking clinical trials). We and our suppliers, partners and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the GDPR, the e-Privacy Directive and the e-Privacy Regulation (once in force) and the national laws and regulations implementing or supplementing each of them.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner consistent with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the EEA (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, requires the appointment of a data protection officer where sensitive personal data (*i.e.*, health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with service providers.

In addition, to the extent a company processes, controls or otherwise uses “special category” personal data (including patients’ health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. Finally, the GDPR provides a broad right for EU and EEA member states to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition.

We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. It is our policy to enter into contractual arrangements with each such provider to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EU, we do so in compliance with the relevant data export requirements from time to time. We take our data protection obligations seriously, as any improper, unlawful or accidental disclosure, loss, alteration or access to, personal data, particularly sensitive personal data (*i.e.*, special category), could negatively impact our business and/or our reputation.

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer adequate protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States: on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. GDPR increases financial penalties for noncompliance (including possible fines of up to four percent of global annual revenue for the preceding financial year or €20 million (whichever is higher) for the most serious violations). Relatedly, following the departure of the United Kingdom from the EU after the expiry of the transition period on January 1, 2021, the United Kingdom operates a separate but similar regime to the EU and allows for fines of up to £17.5 million or 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher).

## **Employees**

As of December 31, 2020, we had 53 full-time employees, including 7 employees with M.D. or Ph.D. degrees. Of these full-time employees, 38 employees are engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

**Facilities**

Our principal executive office is located in Taicang, Jiangsu Province, China, where we lease approximately 24,682 square feet of office and laboratory space under leases that expire on February 28, 2022 and July 31, 2023. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

**Legal Proceedings**

We are not subject to any material legal proceedings.



## MANAGEMENT

### Executive Officers and Directors

The following table presents information about our executive officers and directors, including their ages as of the date of this prospectus:

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<u>NAME</u>	<u>AGE</u>	<u>POSITION</u>
<b>Executive Officers</b>		
Zheng Wei, Ph.D.	57	Chief Executive Officer and Director
Wubin (Bill) Pan, Ph.D.	56	President and Chairman of the Board of Directors
Selwyn Ho, MB BS	50	Chief Business Officer
Eric Hall	66	Interim Chief Financial Officer
Lei Sun, Ph.D.	57	Vice President of Biologics and Head of CMC
Lan Xie	47	Vice President of Finance
<b>Non-Executive Directors</b>		
Derek DiRocco, Ph.D.	40	Director
Kan Chen, Ph.D.	38	Director
Jinghua (Jennifer) Jin	49	Director
Karen J. Wilson	57	Director
Kleanthis G. Xanthopoulos, Ph.D.	62	Director

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(1) Audit committee member

(2) Compensation committee member

(3) Nominating and Corporate Governance committee member

The current business addresses for our executive officers and board of directors is c/o Connect Biopharma Holdings Limited, Science and Technology Park, East R&D Building, 3rd Floor 6 Beijing West Road, Taicang, Jiangsu Province, China.

The following are brief biographies of our executive officers and directors:

### Executive Officers

**Zheng Wei, Ph.D.** Dr. Wei has served as our Chief Executive Officer and a member of our board of directors since our inception in 2012. Prior to that, Dr. Wei was Director of Immunology at Arena Pharmaceuticals, Inc. from December 2007 to March 2011, where he oversaw its immunology discovery programs. Prior to this role, Dr. Wei was a scientist and program leader at ChemoCentryx, Inc. from April 1998 to September 2007. Prior to this role, Dr. Wei was a scientist at Glycomed, Inc. (acquired by Ligand Pharmaceuticals Incorporated) from September 1992 to November 1995. Before joining Glycomed, Inc., Dr. Wei also conducted immunology research at Stanford University School of Medicine. Dr. Wei received his Ph.D. in Biochemistry and Molecular Biology from the University of California at Davis and his Bachelor's degree in Biology from South China Normal University. We believe that Dr. Wei is qualified to serve as a member of our board of directors based on his deep knowledge of our business and his extensive development, commercial and executive management experience.

**Wubin (Bill) Pan, Ph.D.** Dr. Pan is a co-founder of the company and has served as our President and Chairman of our board of directors since May 2012. Previously, Dr. Pan co-founded and led Crown Bioscience Inc., a venture-backed contract research organization, from June 2006 to October 2011. During this tenure, he served in various executive leadership positions at the company, including China President, Chief Operation Officer and Executive Vice President. Prior to this role, Dr. Pan was the Vice President at TsingHuaYuanXing Biopharmaceutical Co. Ltd. from November 2000 to May 2006. Prior to that, Dr. Pan worked as a research scientist with TerraGen Discovery Inc. (acquired by Cubist Pharmaceuticals) from October 1996 to October 2000. Dr. Pan obtained his Ph.D. in Biology from University of Sussex and completed postdoctoral training at the University of California at Berkeley. He holds an M.B.A. from Tsing-Hua University and an M.S. in Pharmacology and a B.S. in Zoology, both from Sun Yat-sen

University. We believe that Dr. Pan is qualified to serve as Chairman of our board of directors based on his extensive knowledge of our business and his senior executive and board-level experience at biopharmaceutical companies.

**Selwyn Ho, MB BS.** Dr. Ho has served as our Chief Business Officer since January 2021 and previously as an adviser to our company since May 2019 in his capacity as Consultant and Managing Director of Artemis Catalyst Ltd., a U.K.-based management consulting firm. Dr. Ho has served in this role at Artemis Catalyst Ltd. since he founded the company in October 2017. In his capacity as a consultant, Dr. Ho has served as an advisor to several biopharmaceutical companies and private capital markets firms including: Boehringer Ingelheim, from October 2020 to January 2021; Oculis S.A., from February 2020 to October 2020; New Rhein Healthcare Investors, from December 2019 to December 2020; Pharming NV, from February 2020 to April 2020; Argenx S.A., from May 2019 to November 2019; Dermira Inc., a biopharmaceutical company acquired by Eli Lilly in Jan 2020, from February 2019 to April 2019; UCB S.A., from October 2018 to March 2020; Kala Pharmaceuticals, from December 2017 to February 2018; and Oxular Ltd., from October 2017 to May 2019. Dr. Ho has been an Executive-In-Residence at New Rhein Healthcare Investors, a venture capital and growth stage fund manager focused on healthcare therapeutics and medical devices since July 2020. Prior to his consulting work, Dr. Ho held several leadership positions at biopharmaceutical companies. He was Vice President, Head of Market Access and Vice President, Head of Strategic Marketing, at Dermira Inc. from September 2016 to September 2017. Prior to this role, Dr. Ho served as Vice President, Head of International Markets, from March 2015 to September 2016, and Vice President, Global Missions Lead, Cimzia, from March 2013 to March 2015, at UCB S.A. Dr. Ho has been a qualified Medical Doctor since 1994. He obtained his Bachelor of Medicine and Bachelor of Surgery (MB BS) and his BSc in Pharmacology with Basic Medical Sciences from Imperial College of Science, Technology & Medicine, University of London.

**Eric Hall.** Mr. Hall has served as our interim Chief Financial Officer since August 2020 through his capacity as a partner at FLG Partners, LLC, or FLG Partners, a Silicon Valley chief financial officer services firm. Mr. Hall has served as a partner at FLG Partners since 2004. In his capacity as a partner at FLG Partners, Mr. Hall has served as advisor to Erisyon, a medical device company, since May 2020. He served as advisor of RTI, Inc. an IIoT software company, since July 2020. He served as advisor to the Managing Member at Foresite Labs, a venture capital life sciences incubator, from November 2019 to August 2020. He served as interim Chief Financial Officer at ALX Oncology Inc., a biotechnology company from October 2018 to December 2019, and at 4Info, Inc., an advertising company, from April 2018 to November 2019. He served as interim Chief Financial Officer at uBiome, Inc., or uBiome, a biotechnology company, from September 2018 to December 2018. Prior to uBiome, Mr. Hall served as interim Chief Financial Officer at Peninsula Clean Energy from August 2018 to October 2018. He served as interim Chief Financial Officer at Lightning Bolt Solutions, Inc., a software company, from May 2018 to January 2019. He served as interim Chief Financial Officer at E2 Consulting Engineers, Inc., an engineering services company, from August 2017 to March 2018. Mr. Hall served as interim Chief Financial Officer at Singulex, Inc., a medical equipment company, from February 2016 to December 2017. He served as interim Chief Financial Officer at Xambala Inc., or Xambala, a financial technology company, from June 2015 to November 2015. Prior to Xambala, he served as interim Chief Financial Officer at Visionnaire Ventures, LLC, an investment firm, from March 2014 to August 2015. Mr. Hall has been a Chartered Financial Analyst charterholder since 1990. Mr. Hall obtained an M.B.A. in Finance from Vanderbilt University and an A.B. in Economics from the University of California, Davis.

**Lei Sun, Ph.D.** Dr. Sun has served as our Vice President of Biologics and Head of CMC since January 2020. Previously, Dr. Sun served as Chief Technology Officer and Vice President of Manufacturing at AutekBio, Inc. from January 2008 to May 2019. Prior to this role, Dr. Sun supported drug development at PERCIVIA from January 2005 to December 2007, Shire Plc from January 2003 to December 2004 and UCB S.A. from January 2001 to December 2002. Dr. Sun was a founding member of PERCIVIA a joint venture between Royal DSM N.V. and Crucell N.V. Dr. Sun completed his postdoctoral training in molecular immunology at Harvard Medical School, obtained his Ph.D. in Molecular Biology and Biochemistry from the University of Minnesota and received his B.S. in Biochemistry from Nankai University.

**Lan Xie.** Ms. Xie has served as our Vice President of Finance since October 2020. Prior to that, she was Vice President of Finance at 3SBio Inc., a Hong Kong-listed pharmaceutical company, from April 2019 to July 2020. From October 2018 to March 2019, Ms. Xie was Chief Financial Officer of China Rapid Finance Ltd., a fintech company. From August 2012 to October 2018, she was VP Finance and China Chief Financial Officer at SciClone Pharmaceuticals, Inc., a pharmaceutical company. Ms. Xie is a Certified Public Accountant (inactive) in the

Commonwealth of Massachusetts. She received her M.B.A. from INSEAD and a B.S. in Business Administration from Boston University.

#### **Non-Executive Directors**

**Derek DiRocco, Ph.D.** Dr. DiRocco has served as a member of our board of directors since August 2020. Dr. DiRocco has been a principal at RA Capital Management since December 2017 and was previously an analyst from June 2015 to December 2017 and an associate from July 2013 to June 2015. Dr. DiRocco has served on the boards of directors of iTeos Therapeutics, Inc., CANbridge Pharmaceuticals Inc., Achilles Therapeutics Ltd. and 89bio, Inc. since March 2020, February 2020, September 2019 and May 2018, respectively. Dr. DiRocco holds a B.A. in Biology from College of the Holy Cross and a Ph.D. in Pharmacology from the University of Washington. We believe that Dr. DiRocco is qualified to serve as a member of our board of directors because of his experience as an investor in biopharmaceutical companies and his roles in early-stage companies.

**Kan Chen, Ph.D.** Dr. Chen has served as a member of our board of directors since December 2020. Dr. Chen is a principal at Qiming Weichuang Venture Capital Management (Shanghai) Co. Ltd., where he has served with a focus on healthcare investment since February 2016. Dr. Chen has also served on the boards of directors of Zion Pharma Limited, Kira Pharmaceuticals and Abbisko Therapeutics since August 2020, April 2020 and February 2020, respectively. From October 2014 to January 2016, Dr. Chen was a senior scientist at Johnson & Johnson, where he focused on cancer medicine. Prior to that, Dr. Chen was a group leader at Jiangsu Hengrui Medicine, where he specialized in cancer immunotherapies. Dr. Chen completed his postdoctoral training in immunology at Harvard Medical School, earned his Ph.D. in Cell Biology from Case Western Reserve University and earned his B.S. in Biological Sciences from Fudan University. We believe that Dr. Chen is qualified to serve as a member of our board of directors because of his experience as an investor in biopharmaceutical companies and his expertise in immunology and drug discovery.

**Jinghua (Jennifer) Jin.** Ms. Jin has served as a member of our board of directors since December 2018. Ms. Jin has also served as partner at Advantech Capital since July 2017. Prior to this role, Ms. Jin was an executive director at Advantech Capital from January 2016 to June 2017. Previously, Ms. Jin was an executive director at New Horizon Capital from September 2014 to December 2015. Ms. Jin earned her M.B.A. from Columbia University and her M.A. and B.A. in Economics from Peking University. We believe that Ms. Jin is qualified to serve as a member of our board of directors because of her experience as an investor in healthcare companies.

**Karen J. Wilson.** Ms. Wilson has served as a member of our board of directors since December 2020. Ms. Wilson is also currently a member of the boards of directors of Angion Biomedica and Vaxart, Inc. Ms. Wilson served as Senior Vice President of Finance at Jazz Pharmaceuticals plc until September 2020 after serving as Vice President of Finance and Principal Accounting Officer. Prior to joining the Jazz Pharmaceuticals organization in February 2011, Ms. Wilson served as Vice President of Finance and Principal Accounting Officer at PDL BioPharma, Inc. from 2009 to January 2011. She also previously served as a Principal at the consulting firm of Wilson Crisler LLC, Chief Financial Officer of ViroLogic, Inc., Chief Financial Officer and Vice President of Operations for Novare Surgical Systems, Inc., and as a consultant and auditor for Deloitte & Touche LLP. Ms. Wilson is a Certified Public Accountant and received a B.S. in Business from the University of California, Berkeley. We believe that Ms. Wilson is qualified to serve as a member of our board of directors because of her expertise in finance and accounting and her senior executive experience in the pharmaceutical industry.

**Kleanthis G. Xanthopoulos, Ph.D.** Dr. Xanthopoulos has served as a member of our board of directors since December 2020. Dr. Xanthopoulos is currently Chief Executive Officer of IRRAS AB, and Chairman of Stork Capital Life Sciences which focuses on building and investing in innovative biotechnology companies. Dr. Xanthopoulos was Managing General Partner at Cerus DMCC, from 2015 to 2020. Previously, he served as President and Chief Executive Officer of Regulus Therapeutics Inc. from the time of its formation in 2007 until June of 2015. Prior to that, he was a Managing Director of Enterprise Partners Venture Capital. Dr. Xanthopoulos co-founded and served as President and Chief Executive Officer of Anadys Pharmaceuticals, Inc. from its inception in 2000 to 2006 and remained a director until its acquisition by Roche in 2011. He was Vice President at Aurora Biosciences (acquired by Vertex Pharmaceuticals, Inc.) from 1997 to 2000. Dr. Xanthopoulos also co-founded and served as the first President and Chief Executive Officer of Sente Labs, and serves as Executive Chairman of Shoreline Biosciences, a cell therapy company. Dr. Xanthopoulos participated in The Human Genome Project as a Section Head of the National Human Genome Research Institute from 1995 to 1997. Prior to this,

## [Table of Contents](#)

he was an Associate Professor at the Karolinska Institute, Stockholm, Sweden after completing a Postdoctoral Research Fellowship at The Rockefeller University, New York. In addition to being a director at IRRAS AB, Dr. Xanthopoulos is also a member of the board of directors of Zosano Pharma, Inc. Dr. Xanthopoulos received his B.S. in Biology with honors from Aristotle University of Thessaloniki, Greece, and received both his M.Sc. in Microbiology and Ph.D. in Molecular Biology from the University of Stockholm, Sweden. Dr. Xanthopoulos has over 45 peer review publications and several issued patents. We believe that Dr. Xanthopoulos's senior executive experience managing and developing a major biotechnology company and his extensive industry knowledge and leadership experience in the life sciences industry qualify him to serve as a member of our board of directors.

### Family Relationships

There are no family relationships among any of our executive officers or directors.

### Board Composition

Under our amended and restated memorandum and articles of association, or articles of association, which will become effective immediately prior to completion of this offering, our board of directors must be composed of between                      and                      members. Our directors may be elected by a resolution of our board of directors, or by an ordinary resolution of our shareholders, which requires approval by                      of the votes which are cast at such meeting by those of our shareholders who, being entitled to do so, attend and vote at such meeting. Our post-offering amended and restated memorandum and articles also provide that our directors may be removed with or without cause by the affirmative vote of the holders of at least                      of the votes of the shareholders present, represented by a proxy or voting by mail at the relevant ordinary shareholders' meeting, and that any vacancy on our board resulting from the death or resignation of a director may be filled by vote of a majority of our directors then in office. Directors chosen or appointed to fill a vacancy shall be elected by the board for the remaining duration of the current term of the replaced director (if any).

We currently have seven directors. The following table sets forth the names of our directors and the years of their initial appointment as directors.

<u>NAME</u>	<u>CURRENT POSITION</u>	<u>YEAR OF APPOINTMENT</u>
Wubin (Bill) Pan, Ph.D.	Chairman	2015 (1)
Derek DiRocco, Ph.D.	Director	2020
Kan Chen, Ph.D.	Director	2018
Jinghua (Jennifer) Jin	Director	2018
Zheng Wei, Ph.D.	Director	2015 (1)
Karen J. Wilson	Director	2020
Kleanthis G. Xanthopoulos, Ph.D.	Director	2020

(1) Served as a director of Connect SZ since 2012 and continued to serve as a director of our Company following the Reorganization in 2015. See "Our History and Corporate Structure" beginning on page 96 of this prospectus for more information.

### Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except with respect to our audit committee, for which the Nasdaq listing requirements permit specified phase-in schedules.

Our board of directors has determined that, applying the applicable rules and regulations of the SEC and the Nasdaq listing standards, all of our directors, except Wubin (Bill) Pan, Ph.D. and Zheng Wei, Ph.D., qualify as "independent directors." In making such determination, our board considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities.

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

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

### **Corporate Governance Practices**

As a Cayman Islands exempted company incorporated with limited liability, we are subject to various corporate governance requirements under Cayman Islands law. In addition, as a foreign private issuer listed on Nasdaq, we will be subject to the Nasdaq corporate governance listing standards. However, Nasdaq's listing standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of the Nasdaq rules, with certain exceptions. Certain corporate governance practices in Cayman Islands may differ significantly from corporate governance listing standards. For example, neither the corporate laws of the Cayman Islands nor our post-offering amended and restated memorandum and articles require that (i) a majority of our directors be independent, (ii) our compensation committee include only independent directors, or (iii) our independent directors hold regularly scheduled meetings at which only independent directors are present. Other than as set forth below, we currently intend to comply with the corporate governance listing standards of Nasdaq to the extent possible under Cayman Islands law. However, we may choose to change such practices to follow home country practice in the future.

Although we are a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. Under Rule 10A-3, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders of the Company, the audit committee's responsibilities or powers with respect to such matter may instead be advisory.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least 33 1/3% of the outstanding shares of the company's common voting stock. As provided under our post-listing amended and restated memorandum and articles of association, and as permitted by Cayman Islands law, a quorum required for and throughout a meeting of shareholders consists of one or more shareholders entitled to vote and present in person or by proxy or (in the case of a shareholder being a corporation) by its duly authorized representative holding shares which carry in aggregate not less than one-third of all votes attaching to all of our shares in issue and entitled to vote. See the section of this prospectus titled "Description of Share Capital—Differences in Corporate Law."

Further, Nasdaq rules require that listed companies have a nominations committee comprised solely of independent directors. We intend to follow our Cayman Islands home country practice, as described under "—Board Composition," rather than complying with this Nasdaq rule.

## **Committees of our Board of Directors**

Our board of directors has the following standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee. We expect that, upon completion of this offering, the composition and functioning of all of our committees will comply with the Cayman Islands Companies Law, the Exchange Act, Nasdaq, and SEC rules and regulations

### ***Audit Committee of the Board***

The audit committee, which consists of \_\_\_\_\_ and \_\_\_\_\_, assists the board in overseeing our accounting and financial reporting processes and the audits of our consolidated financial statements. \_\_\_\_\_ serves as Chairman of the committee. The audit committee consists exclusively of members of our board who are financially literate, and \_\_\_\_\_ is considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The audit committee will be governed by a charter that complies with Nasdaq rules.

The audit committee's responsibilities will include:

- recommending the appointment of the independent auditor to the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board on at least an annual basis;
- reviewing and discussing with the executive officers, the board and the independent auditor our consolidated financial statements and our financial reporting process; and
- approving or ratifying any related person transaction (as defined in our related person transaction policy) in accordance with our related person transaction policy.

The audit committee will meet as often as one or more members of the audit committee deem necessary, but in any event will meet at least \_\_\_\_\_ times per year. The audit committee will meet at least once per year with our independent accountant, without our executive officers being present.

### ***Compensation Committee of the Board***

The compensation committee, which consists of \_\_\_\_\_ and \_\_\_\_\_, assists the board in determining executive officer compensation. \_\_\_\_\_ serves as Chairman of the committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard board member fees. Although foreign private issuers are not required to meet this heightened standard, all of our expected compensation committee members meet this heightened standard.

The compensation committee's responsibilities will include:

- identifying, reviewing and proposing policies relevant to executive officer compensation;
- evaluating each executive officer's performance in light of such policies and reporting to the board;
- analyzing the possible outcomes of the variable compensation components and how they may affect the compensation of the executive officers;
- recommending any equity long-term incentive component of each executive officer's compensation in line with the compensation policy and reviewing our executive officer compensation and benefits policies generally; and
- reviewing and assessing risks arising from our compensation policies and practices.

### **Nominating and Corporate Governance Committee of the Board**

The nominating and corporate governance committee, which consists of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, assists our board in identifying individuals qualified to become members of our board and executive officers consistent with criteria established by our board and in developing our corporate governance principles. \_\_\_\_\_ will serve as Chairman of the nominating and corporate governance committee.

The nominating and corporate governance committee's responsibilities will include:

- drawing up selection criteria and appointment procedures for board members;
- reviewing and evaluating the size and composition of our board and making a proposal for a composition profile of the board at least annually;
- recommending nominees for election to our board and its corresponding committees;
- assessing the functioning of individual members of board and executive officers and reporting the results of such assessment to the board; and
- developing and recommending to the board rules governing the board, reviewing and reassessing the adequacy of such rules governing the board and recommending any proposed changes to the board.

### **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 or her duties a greater degree of skill than may reasonably be expected from a person of his or her knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands. In fulfilling their duty of care to us, our directors must ensure compliance with our 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 a resolution of our board of directors, or by a \_\_\_\_\_ resolution of our shareholders. Our directors are not subject to a term of office and hold office until such time as they are removed from office by resolution of the shareholders. A director will cease to be a director if, among other things, the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found by our company to be or becomes of unsound mind, (iii) resigns his or her office by notice in writing to the company, or (iv) without special leave of absence from our board, is absent from three consecutive board meetings and our directors resolve that his or her office be vacated. Our officers are elected by and serve at the discretion of our board of directors. We have entered into employment agreements with certain of our executive officers.

### **Compensation of Directors and Executive Officers**

For the year ended December 31, 2019, we paid an aggregate of approximately RMB4.7M (USD0.7M) in cash to our executive officers and we did not pay any compensation to our non-executive directors. With the exception of our

obligations to Dr. Wei under the Connect Biopharm LLC Pension Plan, we have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. Dr. Wei is the only participant in the Connect Biopharm LLC Pension Plan, which was terminated in May 2020. The aggregate value of the benefits under this plan, which is fully funded, is \$460,390, which the Company rolled over into an individual retirement account for the benefit of Dr. Wei in 2020. The Company has no further obligations with respect to such plan. Our PRC 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.

#### **Employment Agreements with Executive Officers**

We have entered into employment agreements with each of our executive officers other than Mr. Hall, who serves as a consultant to our company. Under these agreements, certain of our executive officers are employed for specified time periods. We may terminate employment for cause, at any time, for certain acts of the executive officer.

Each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our business partners, or the confidential or proprietary information of any third party received by us and for which we have confidential obligations. 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.

#### **Employment Agreement with Wubin (Bill) Pan**

Effective January 1, 2021, Connect Biopharma Hong Kong Limited and its affiliates entered into an employment agreement with Dr. Wubin (Bill) Pan setting forth the terms of his employment as the President and Chairman of Connect Biopharma Hong Kong Limited and our company. Pursuant to the agreement, Dr. Pan is entitled to an annual base salary of \$495,000 USD, which amount is subject to annual review by and at the sole discretion of our board of directors or its designee. Dr. Pan's employment agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 50% of his annual base salary.

Pursuant to his employment agreement, if we terminate Dr. Pan's employment other than for cause or Dr. Pan terminates his employment for good reason (each as defined in his employment agreement), he is entitled to the following payments and benefits, subject (except for item (1) below) to his timely execution and non-revocation of a general release of claims in favor of the company: (1) his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, any annual bonus payable for any prior calendar year (to the extent not previously paid), plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 12 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; (3) a payment equal to his prorated target annual bonus for the calendar year in which the termination date occurs, payable in a lump sum payment 60 days following the termination; and (4) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 18 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment. In the event that such termination occurs during the period beginning two (2) months prior to and ending twelve (12) months following a change in control of our company (as defined in his employment agreement), in addition to the severance benefits provided above, all of Dr. Pan's equity awards will vest on an accelerated basis as of the later of the date of termination or the date of the change in control (provided that if any equity award is subject to more favorable vesting conditions, such more favorable provisions shall apply).

In the event we terminate Dr. Pan's employment for cause, he terminates his employment without good reason, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, any annual bonus



payable for any prior calendar year (to the extent not previously paid), plus all other amounts under any compensation plan or practice to which he is entitled.

Pursuant to his employment agreement, Dr. Pan is subject to a one-year post-termination non-solicitation of employees covenant and a perpetual non-disparagement covenant, in addition to a noncompetition covenant that applies during the employment term and his obligations under the Company's standard proprietary information and inventions assignment agreement.

#### ***Employment Agreement with Zheng Wei***

Effective January 1, 2021, Connect Biopharm LLC and its affiliates entered into an employment agreement with Dr. Zheng Wei setting forth the terms of his employment as the Chief Executive Officer of Connect Biopharm LLC and our company. Pursuant to the agreement, Dr. Wei is entitled to an annual base salary of \$495,000 USD, which amount is subject to annual review by and at the sole discretion of our board of directors or its designee. Dr. Wei's employment agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 50% of his annual base salary.

Pursuant to his employment agreement, if we terminate Dr. Wei's employment other than for cause or Dr. Wei terminates his employment for good reason (each as defined in his employment agreement), he is entitled to the following payments and benefits, subject (except for item (1) below) to his timely execution and non-revocation of a general release of claims in favor of the company: (1) his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, any annual bonus payable for any prior calendar year (to the extent not previously paid), plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 12 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; (3) a payment equal to his prorated target annual bonus for the calendar year in which the termination date occurs, payable in a lump sum payment 60 days following the termination date; and (4) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 18 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment. In the event that such termination occurs during the period beginning two (2) months prior to and ending twelve (12) months following a change in control of our company (as defined in his employment agreement), in addition to the severance benefits provided above, all of Dr. Wei's equity awards will vest on an accelerated basis as of the later of the date of termination or the date of the change in control (provided that if any equity award is subject to more favorable vesting conditions, such more favorable provisions shall apply).

In the event we terminate Dr. Wei's employment for cause, he terminates his employment without good reason, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, any annual bonus payable for any prior calendar year (to the extent not previously paid), plus all other amounts under any compensation plan or practice to which he is entitled.

Pursuant to his employment agreement, Dr. Wei is subject to a one-year post-termination non-solicitation of employees covenant and a perpetual non-disparagement covenant, in addition to a noncompetition covenant that applies during the employment term and his obligations under the Company's standard proprietary information and inventions assignment agreement.

#### ***Employment Arrangements with Selwyn Ho***

*US Employment Offer Letter.* On January 19, 2021, Connect Biopharm LLC entered into an offer letter with Mr. Selwyn Ho setting forth the terms of his employment as the Senior Vice President of Corporate Development and Chief Business Officer of Connect Biopharm LLC. Pursuant to the offer letter, prior to his relocation to the US, Mr. Ho will be employed full-time under a UK employment contract through Globalization Partners Limited for up to twelve months, on substantially the same financial terms as the offer letter. The terms of the UK employment contract are summarized below under the heading "UK Contract of Employment".

Pursuant to the offer letter, Mr. Ho will be entitled to an annual base salary of \$350,000 USD and an annual performance-based bonus with a target amount equal to 40% of his annual base salary. Mr. Ho's employment in the

US will be at-will. Mr. Ho will also be eligible to receive a relocation lump sum payment equal to \$100,000 USD and reimbursement of certain expenses in connection with his relocation to the US.

Pursuant to the offer letter, if Mr. Ho's employment (including under the UK contract) is terminated without cause, as a result of a change in control of our company, or as a result of a constructive termination (each as defined in his offer letter), he will be entitled to the following payments and benefits, subject to his execution of a general release of claims in favor of the company: (1) a payment equal to 9 months of his then-current base salary plus his prorated target annual bonus for the calendar year in which the termination date occurs, payable in a lump sum payment within 5 days following the expiration of the release revocation period (subject to Section 409A of the Code); and (2) payment of COBRA premiums until the earliest of (a) the expiration of 9 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment. In the event that Mr. Ho's employment (including under the UK contract) is terminated without cause during the period beginning two (2) months prior to and ending twelve (12) months following a change in control or corporate transaction of our company (as defined in his offer letter), subject to his execution of a release, all of Mr. Ho's outstanding equity awards will become fully vested. Any severance amounts payable under the offer letter will be reduced by the amount of any notice, severance, redundancy pay or payment in lieu of notice to which Mr. Ho is entitled under English employment law or other applicable law at the time of termination.

The employment agreement also includes a "best pay" provision under Section 280G of the Code, pursuant to which any "parachute payments" that become payable to Mr. Ho will either be paid in full or reduced so that such payments are not subject to the excise tax under Section 4999 of the Code, whichever results in the better after-tax treatment to Mr. Ho.

Mr. Ho was also required to execute the Company's confidential information and invention assignment agreement as a condition to his employment under the offer letter.

*UK Contract of Employment.* On January 20, 2021, Globalization Partners Limited (GPL) entered into a contract of employment with Mr. Ho, pursuant to which Mr. Ho will serve as Senior Vice President of Corporate Development and Chief Business Officer of Connect Biopharm LLC while based in the UK. Pursuant to the contract of employment, Mr. Ho is entitled to an annual base salary of £257,000 GBP, and is eligible to earn an annual bonus with a target amount equal to 40% of his annual base salary. Unless he opts out, Mr. Ho will be contractually enrolled in GPL's workplace pension scheme, under which GPL will make a pension contribution equal to 4% of his base salary and Mr. Ho must make a contribution equal to 5% of his base salary during each year of employment. Under the contract of employment, Mr. Ho's employment may be terminated by him or by GPL with one week's notice in writing (or, for GPL, payment in lieu of notice). Under the contract, Mr. Ho is subject to a three-month post-termination non-competition covenant applying to Connect Biopharm LLC, a twelve-month service provider non-solicitation covenant applying to both GPL and Connect Biopharm LLC, and a twelve-month customer non-solicitation covenant applying to Connect Biopharm LLC, in addition to an indefinite confidentiality provision and intellectual property rights and inventions provisions.

#### **Limitations on Liability and Indemnification Matters**

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our post-offering articles of association provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his or her 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 intend to enter into indemnification agreements with each of our directors and executive officers. Under these agreements, we may agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.

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.

### **2021 Stock Incentive Plan**

In connection with this offering, our board of directors will adopt, and we will ask our shareholders to approve our 2021 Stock Incentive Plan, or the 2021 Plan, to provide additional incentives to our employees, directors and consultants and to promote our business.

The following paragraphs describe the principal terms of the 2021 Plan.

**Shares Available for Issuance.** The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2021 Plan will be \_\_\_\_\_ ordinary shares, plus an annual increase on the first day of each of our fiscal years during the term of the 2021 Plan commencing with the fiscal year beginning January 1, 2022, by an amount equal to the least of (i) \_\_\_\_\_ % of the total number of ordinary shares issued and outstanding on the last day of the immediately preceding fiscal year; or (ii) such lesser number of shares as may be determined by our board of directors. In no event will more than \_\_\_\_\_ shares be issuable upon the exercise of incentive share options (within the meaning of Section 422 of the U.S. Internal Revenue Code) under the 2021 Plan.

As of the effective date of the 2021 Plan, no further grants will be made under the 2019 Plan. However, the 2019 Plan will continue to govern the terms and conditions of the outstanding awards granted under it.

**Types of Awards.** The 2021 Plan will permit the awards of options, share appreciation rights, restricted shares, restricted share units, dividend equivalent rights or other stock- or cash-based awards that the plan administrator determines to award under the 2021 Plan.

**Plan Administration.** Our board of directors or a committee designated by the board of directors will administer the 2021 Plan. The committee or the full board of directors, as applicable, will have the authority to (i) determine whether and the total number of awards to be granted in any fiscal year; (ii) determine the fair market value and exercise price set forth in the notice of stock option award and the award agreements; (iii) approve forms of award agreements for use under the 2021 Plan and amend terms of the award agreements, (iv) amend the terms of any outstanding awards granted under the 2021 Plan, provided that any amendment that would adversely affect a grantee's rights under an outstanding award in material aspects will not be made without the grantee's written consent, (v) construe and interpret the terms of the 2021 Plan and awards, including any notice of award or award agreement and (vi) exercise such other powers provided by the 2021 Plan, any award agreement or notice of award. In addition, our board of directors may authorize one or more officers or directors to grant awards under the 2021 Plan, and delegate authority under the 2021 Plan to such officers. We expect that our compensation committee will administer the 2021 Plan generally, other than awards to non-employee directors, which shall continue to be administered by our board of directors.

**Award Agreement.** Awards granted under the 2021 Plan will be evidenced by an award agreement that sets forth terms, conditions and limitations for each award, which may include the term of the award, the provisions applicable in the event of the grantee's employment or service terminates, and our authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind the award.

**Eligibility.** We may grant awards to employees, directors and consultants of our company and its related entities. However, we may grant options that are intended to qualify as incentive share options only to our employees and employees of our parent companies and subsidiaries.

**Vesting Schedule.** In general, the plan administrator will determine the vesting schedule, which will be specified in the relevant award agreement.

**Exercise of Awards.** The plan administrator will determine the exercise price or purchase price, as applicable, for each award, which will be stated in the award agreement. The vested portion of option will expire if not exercised prior to the time as the plan administrator determines at the time of its grant. However, the maximum exercisable term is ten years from the date of grant.

**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.

**Termination and Amendment of the 2021 Plan.** Unless terminated earlier, the 2021 Plan will have a term of ten years from the date of our board of directors' initial adoption of the 2021 Plan. Our board of directors or the compensation committee will have the authority to amend or terminate the plan, subject to shareholder approval to the extent necessary to comply with applicable law. However, no such action may adversely affect in any material way any awards previously granted unless agreed by the recipient.

## **2019 Stock Incentive Plan**

Our shareholders and our board of directors adopted our 2019 Stock Incentive Plan, or the 2019 Plan, in November 2019 to provide additional incentives to our employees, directors and consultants and to promote our business. As of the date of this prospectus, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2019 Plan is 4,473,305 ordinary shares.

The following paragraphs describe the principal terms of the 2019 Plan.

**Types of Awards.** The 2019 Plan permits the awards of options, share appreciation rights, restricted shares, restricted share units, dividend equivalent rights or any other type of awards that the plan administrator determines to award under the 2019 Plan.

**Plan Administration.** Our board of directors or a committee designated by the board of directors, which committee constituted of one or more members of the board of directors, administers the 2019 Plan. The committee or the full board of directors, as applicable, has the authority to (i) determine whether and the total number of awards to be granted in any fiscal year; (ii) determine the fair market value and exercise price set forth in the notice of stock option award and the award agreements; (iii) approve forms of award agreements for use under the 2019 Plan and amend terms of the award agreements, (iv) amend the terms of any outstanding awards granted under the 2019 Plan, provided that any amendment that would adversely affect a grantee's rights under an outstanding award in material aspects will not be made without the grantee's written consent, (v) construe and interpret the terms of the 2019 Plan and awards, including any notice of award or award agreement and (vi) exercise such other powers provided by the 2019 Plan, any award agreement or notice of award. In addition, our board of directors may authorize one or more officers of directors to grant awards under the 2019 Plan, and delegate authority under the 2019 Plan to such officers.

**Award Agreement.** Awards granted under the 2019 Plan are evidenced by an award agreement that sets forth terms, conditions and limitations for each award, which may include the term of the award, the provisions applicable in the event of the grantee's employment or service terminates, and our authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind the award.

**Eligibility.** We may grant awards to employees, directors and consultants of our company and its related entities. However, we may grant options that are intended to qualify as incentive share options only to our employees and employees of our parent companies and subsidiaries.

**Vesting Schedule.** In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

**Exercise of Awards.** The plan administrator determines the exercise price or purchase price, as applicable, for each award, which is stated in the award agreement. The vested portion of option will expire if not exercised prior to the time as the plan administrator determines at the time of its grant. However, the maximum exercisable term is ten years from the date of grant.

**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.

**Termination and Amendment of the 2019 Plan.** Unless terminated earlier, the 2019 Plan has a term of ten years from the date of our board of directors' initial adoption of the 2019 Plan. Our board of directors has the authority to amend or terminate the plan, subject to shareholder approval to the extent necessary to comply with applicable law. However, no such action may adversely affect in any material way any awards previously granted unless agreed by the recipient.

**ESOP Entity.** Due to regulatory and practical administration issues relating to equity awards in the PRC, we formed Connect Union as a means of facilitating the issuance and delivery of ordinary shares under the 2019 Plan to our employees in the PRC. In connection therewith, we have issued 4,473,305 ordinary shares to Connect Union, to hold for the 2019 Plan. Connect Union holds the ordinary shares issued by our company as a nominee structure, and the ordinary shares of our company to be obtained by employees, directors and consultants upon exercise of the options will come from the ordinary shares of our company held by Connect Union.

Connect Union has two classes of shares, the Class A ordinary shares, which have voting rights, and the Class B ordinary shares, which are non-voting. Wubin (Bill) Pan, Ph.D., our President and Chairman of our board of directors, is the sole director and owner of 100% of the outstanding Connect Union Class A ordinary shares. Connect Union remains the record holder of, and retains the voting rights with respect to, our ordinary shares held by Connect Union. Connect Union has agreed to transfer back to us our ordinary shares as necessary for us to settle in our ordinary shares those awards.

**Outstanding Awards.** As of December 31, 2020, share options to purchase a total of 2,812,342 ordinary shares have been granted to our employees, directors and consultants and were outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates.

The following table summarizes, as of December 31, 2020, the outstanding share options we have granted to our directors and executive officers under our 2019 Plan. Other individuals as a group were granted outstanding share options representing a total of 1,628,949 ordinary shares as of September 30, 2020. All of these outstanding share options will be settled by us upon exercise with our ordinary shares held by Connect Union.

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<b>NAME</b>	<b>NUMBER OF SHARES UNDERLYING OPTIONS</b>
Zheng Wei, Ph.D.	250,000
Eric J. Hall	—
Wubin (Bill) Pan, Ph.D.	250,000
Lei Sun, Ph.D.	127,055
Lan Xie	120,000
Derek DiRocco, Ph.D.	—
Kan Chen, Ph.D.	—
Jinghua (Jennifer) Jin	—
Karen J. Wilson	155,244
Kleanthis G. Xanthopoulos, Ph.D.	155,244

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#### **2021 Employee Share Purchase Plan**

Effective the day prior to the first public trading date of our ordinary shares, we intend to adopt and ask our shareholders to approve the 2021 Employee Share Purchase Plan, or the 2021 ESPP, the material terms of which are summarized below.

The 2021 ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the 2021 ESPP to U.S. and to non-U.S. employees. Specifically, the 2021 ESPP authorizes (1) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code (the "Section 423 Component") and (2) the grant of options that are not intended to be

tax-qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations (the “Non-Section 423 Component”). Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

**Shares Available for Awards; Administration.** A total of \_\_\_\_\_ ordinary shares will initially be reserved for issuance under the 2021 ESPP, plus an annual increase on January 1 of each calendar year beginning in 2022 and ending in and including 2031, by an amount equal to the lesser of (A) \_\_\_\_\_ % of the ordinary shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors, provided that no more than \_\_\_\_\_ ordinary shares may be issued under the Section 423 Component. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the 2021 ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2021 ESPP.

**Eligibility.** We expect that all of our employees will be eligible to participate in the 2021 ESPP. However, an employee may not be granted rights to purchase shares under our 2021 ESPP if the employee, immediately after the grant, would own (directly or through attribution) shares possessing 5% or more of the total combined voting power or value of all classes of our shares.

**Grant of Rights.** Shares will be offered under the 2021 ESPP during offering periods. The length of the offering periods under the 2021 ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2021 ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods. In non-U.S. jurisdictions where participation in the 2021 ESPP through payroll deductions is prohibited, the plan administrator may provide that an eligible employee may elect to participate through contributions to the participant’s account under the 2021 ESPP in a form acceptable to the 2021 ESPP administrator in lieu of or in addition to payroll deductions.

The 2021 ESPP permits participants to purchase ordinary shares through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period. In addition, no employee will be permitted to accrue the right to purchase shares under the Section 423 Component at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our ordinary shares as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase our ordinary shares. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our ordinary shares on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2021 ESPP at any time during a specified period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase ordinary shares. Participation ends automatically upon a participant’s termination of employment.

A participant may not transfer rights granted under the 2021 ESPP other than by will or the laws of descent and distribution, and are generally exercisable only by the participant.

**Certain Transactions.** In the event of certain non-reciprocal transactions or events affecting our ordinary shares, the plan administrator will make equitable adjustments to the 2021 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares subject to

outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase shares on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

**Plan Amendment.** The plan administrator may amend, suspend or terminate the 2021 ESPP at any time. However, shareholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2021 ESPP or changes the corporations or classes of corporations whose employees are eligible to participate in the 2021 ESPP.

#### **Code of Business Conduct and Ethics**

Upon the closing of this offering, we intend to adopt a Code of Business Conduct and Ethics that will be applicable to all of our employees, executive officers and directors. Following the completion of this offering, the Code of Conduct will be available under the "Corporate Governance" section of our website at [www.connectbiopharm.com](http://www.connectbiopharm.com). Our board of directors will be responsible for overseeing the Code of Conduct and will be required to approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of December 1, 2020 by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares; and
- each member of our board of directors and each of our executive officers.

The number of ordinary shares beneficially owned by each entity, person, board member or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of December 1, 2020 through the exercise of any option or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

The percentage of ordinary shares beneficially owned before the offering is computed on the basis of 77,254,917 ordinary shares outstanding as of December 1, 2020 on an as-converted basis, which has taken into consideration the automatic conversion of all of our outstanding convertible preferred shares to ordinary shares on a one to one basis. The percentage of ordinary shares beneficially owned after the offering is computed on the basis of ordinary shares, on an as-converted basis, including ordinary shares represented by ADSs to be issued and sold in connection with this offering, assuming no exercise of the underwriters' option to purchase additional ADSs in this offering. Ordinary shares that a person has the right to acquire within 60 days of December 1, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all board members and executive officers as a group. The percentages do not give effect to any ADSs that may be acquired by our shareholders, directors or officers pursuant to the directed share program or in this offering. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Connect Biopharma Holdings Limited, Science and Technology Park, East R&D Building, 3rd Floor, 6 Beijing West Road, Taicang, Jiangsu, China 215400.

NAME AND ADDRESS OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
<b>5% or Greater Shareholders:</b>			
BioFortune Inc. (1)	10,245,798	13.3%	
Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership) (2)	9,232,700	12.0%	
Entities affiliated with Qiming Venture Partners (3)	8,411,253	10.9%	
Advantech Capital II Connect Partnership L.P. (4)	8,286,202	10.7%	
Entities affiliated with RA Capital Management (5)	6,325,789	8.2%	
Connect Union Inc. (6)	4,473,305	5.8%	
<b>Executive Officers and Directors:</b>			
Zheng Wei, Ph.D.	10,245,798	13.3%	
Wubin (Bill) Pan, Ph.D. (1)(6)	14,719,103	19.1%	
Selwyn Ho, MB BS	—	*	
Eric Hall	—	*	
Lei Sun, Ph.D.	—	*	
Lan Xie	—	*	
Derek DiRocco, Ph.D.	—	*	
Kan Chen, Ph.D.	—	*	
Jinghua (Jennifer) Jin	—	*	
Karen J. Wilson	—	*	
Kleanthis G. Xanthopoulos, Ph.D.	—	*	
All directors and executive officers as a group (eleven (11) persons)	24,964,901	32.3%	



## Table of Contents

- \* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.
- (1) Includes 10,245,798 ordinary shares held by BioFortune Inc., a company limited by shares organized under the laws of the British Virgin Islands. Wubin (Bill) Pan, Ph.D., our President and Chairman of our board of directors, is the sole shareholder of BioFortune Inc. and may be deemed to have voting and investment power over such shares. Dr. Pan disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The registered address of BioFortune Inc. is Coastal Building, Wickham's Cay II, P. O. Box 2221, Road Town, Tortola, British Virgin Islands.
  - (2) Consists of 9,232,700 ordinary shares held by Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership), a limited partnership formed under the laws of the PRC. Suzhou Xiangtang Venture Investment Limited, a limited liability company organized under the laws of the PRC and the ultimate shareholders of which are Mr. Gu Zhenqi and Mr. Gu Jianping, is the general partner of Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership). The registered address of Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership) is 1/F, Block 1, No. 251, Yao Hua Road, Pilot Free Trade Zone, Shanghai, PRC.
  - (3) Represents (i) 167,504 ordinary shares held by Qiming Managing Directors Fund V, L.P., a Cayman Islands exempted limited partnership, (ii) 5,397,144 ordinary shares held by Qiming Venture Partners V, L.P., a Cayman Islands exempted limited partnership, (iii) 25,992 ordinary shares held by Qiming VII Strategic Investors Fund, L.P., a Cayman Islands exempted limited partnership, (iv) 2,820,613 ordinary shares held by Qiming Venture Partners VII, L.P., a Cayman Islands exempted limited partnership. The general partner of Qiming Venture Partners V, L.P. is Qiming GP V, L.P., whose general partner is Qiming Corporate GP V, Ltd., a Cayman Islands exempted company. Qiming Corporate GP V, Ltd. is also the general partner of Qiming Managing Directors Fund V, L.P. The voting and investment power of the shares held by Qiming Managing Directors Fund V, L.P. and Qiming Venture Partners V, L.P. in our company are exercised by Qiming Corporate GP V, Ltd., which is beneficially owned by Messrs. Duane Kuang, Gary Rieschel, and Nisa Leung. The general partner of Qiming Venture Partners VII, L.P. and Qiming VII Strategic Investors Fund, L.P. is Qiming GP VII, LLC, a Cayman Islands limited liability company. The voting and investment power of the shares held by Qiming Venture Partners VII, L.P. and Qiming VII Strategic Investors Fund, L.P. in our company are exercised by Qiming GP VII, LLC, which is beneficially owned by Messrs. Duane Kuang, Gary Rieschel, and Nisa Leung. Messrs. Duane Kuang, Gary Rieschel, and Nisa Leung disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The registered address of each of Qiming Managing Directors Fund V, L.P., Qiming Venture Partners V, L.P., Qiming Venture Partners VII, L.P. and Qiming VII Strategic Investors Fund, L.P. is P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.
  - (4) Consists of 8,286,202 ordinary shares held by Advantech Capital II Connect Partnership L.P., a Cayman Islands exempted limited partnership, or Advantech. Advantech Capital II Investment Partners Limited, an exempted company organized under the laws of the Cayman Islands, is the general partner of Advantech and may be deemed to beneficially own certain shares held by Advantech. Advantech Capital II Investment Partners Limited is beneficially owned and controlled by Advantech Capital Partners II Limited, which in turn is ultimately controlled by Hebert Pang Kee Chan. Mr. Chan disclaims beneficial ownership of the shares held by Advantech, except to the extent of any pecuniary interest therein. The registered address of Advantech is 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands.
  - (5) Consists of (i) 4,299,267 ordinary shares held by RA Capital Healthcare Fund, L.P., or RA Capital (ii) 1,581,447 ordinary shares held by RA Capital Nexus Fund, L.P., or Nexus Fund and (iii) 445,075 ordinary shares held by Blackwell Partners LLC—Series A, or Blackwell. RA Capital Management, L.P. is the investment manager for RA Capital, Nexus Fund and Blackwell. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the shares held by RA Capital, Nexus Fund and Blackwell. RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the RA Capital entities is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.
  - (6) Includes 4,473,305 ordinary shares held by Connect Union, a company limited by shares organized under the laws of the British Virgin Islands. The ordinary shares held by Connect Union were issued pursuant to the terms of our 2019 Plan established by us under which certain ordinary shares are held by Connect Union to be issued in satisfaction of awards issued under the 2019 Plan to employees, directors and consultants of our company. Wubin (Bill) Pan, Ph.D., our President and Chairman of our board of directors, is the sole director and owner of 100% of the outstanding voting shares of Connect Union Inc. and may be deemed to have voting and investment power over such shares. Dr. Pan disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The registered address of Connect Union Inc. is Coastal Building, Wickham's Cay II, P.O. Box 2221, Road Town, Tortola, British Virgin Islands.

**RELATED PARTY TRANSACTIONS**

The following is a description of material related party transactions we have entered into since January 1, 2018 with any members of our board of directors or executive officers and the holders of more than 5% of our ordinary shares.

**Preferred Share Private Placements**

See “Description of Share Capital—History of Securities Issuances.”

**Shareholders Agreement**

See “Description of Share Capital—Shareholders Agreement.”

**Arrangements with our Executive Officers & Directors****Agreements with Our Executive Officers & Directors**

We have entered into employment agreements with certain of our executive officers, a consulting agreement with Eric Hall, our interim Chief Financial Officer, and consulting agreements with our non-employee directors.

**Indemnification Agreements**

In connection with the completion of this offering, we will enter into indemnification agreements with each of our directors and executive officers. See “Management—Limitations on Liability and Indemnification Matters.”

**Directed Share Program**

At our request, the underwriters have reserved up to \_\_\_\_\_ ADSs, or \_\_\_\_\_ % of the ADSs to be offered hereby for sale, at the initial public offering price, through a directed share program.

**Contract Research Organization Services**

In the ordinary course of business, we have entered into transactions with the below entities, which are affiliated with Ye Linlu, who was a director of our company until November 2020, and Ye Xiaoping, who was a member of the board of directors of Connect SZ until February 2021. For the year ended December 31, 2019, the total amount of contract research organization services with the following related parties is equal to approximately RMB9.8 million.

	YEAR ENDED DECEMBER 31		
	2018	2019	2020
	RMB'000	RMB'000	RMB'000
<b>Purchase of CRO Services</b>			
Hangzhou Simo Company Limited	—	5,601	
Frontage Laboratories (Suzhou) Company Limited (Note)	—	2,346	
Shanghai Tigermed Consulting Company Limited	1,155	891	
Hangzhou Tigermed Consulting Company Limited	158	810	
Beijing Medical Development (Suzhou) Company Limited	—	186	
<b>Total:</b>	<b>1,313</b>	<b>9,834</b>	

**2019 Stock Incentive Plan**

See “Management—2019 Stock Incentive Plan.”

**Related Person Transaction Policy**

Prior to the completion of this offering, our board of directors intends to adopt a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover any transaction or proposed transactions between us and a related person that are material to us or the related person, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

## DESCRIPTION OF SHARE CAPITAL

### General

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our memorandum and articles of association, as amended from time to time, the Companies Law (2020 Revision) of the Cayman Islands, which we refer to as the Companies Law below and the common law of the Cayman Islands.

As of the date of this prospectus, our authorized share capital is \$50,000 consisting of 500,000,000 shares, par value \$0.0001 per share, of which: (i) 456,942,684 shares are designated as ordinary shares, par value \$0.0001 per share, or the Ordinary Shares, (ii) 3,109,000 shares are designated as Series Pre-A Preferred Shares, (iii) 8,471,200 shares are designated as Series A Preferred Shares, (iv) 10,127,579 shares are designated as Series B redeemable convertible preferred shares, par value \$0.0001 per share, or the Series B Preferred Shares, and (v) 21,349,537 shares are designated as Series C redeemable convertible preferred shares, par value \$0.0001 per share, or the Series C Preferred Shares. We refer to the Series Pre-A Preferred Shares, the Series A Preferred Shares, the Series B Preferred Shares and the Series C Preferred Shares in this prospectus collectively as the Preferred Shares. As of the date of this prospectus, 34,197,601 Ordinary Shares, 3,109,000 Series Pre-A Preferred Shares, 8,471,200 Series A Preferred Shares, 10,127,579 Series B Preferred Shares and 21,349,537 Series C Preferred Shares are issued and outstanding. The total number of ordinary shares outstanding as of the date of this prospectus includes 4,473,305 ordinary shares issued to Connect Union as nominee for purposes of implementation of awards issued or to be issued to employees, directors and consultants of our company pursuant to the 2019 Plan (see "Management—2019 Stock Incentive Plan"). All of our issued and outstanding ordinary and convertible preferred shares are fully paid.

Immediately prior to the completion of this offering, our authorized share capital will be changed into \$ divided into shares comprised of (i) ordinary shares, par value \$0.0001 per share, and (ii) preference shares, par value \$0.0001 per share, of such class or classes (however designated) as the board of directors may determine in accordance with our post-offering amended and restated memorandum and articles of association. Immediately prior to the completion of this offering, all of our issued and outstanding convertible preferred shares will be converted into as ordinary shares on a one-for-one basis. Following such conversion, we will have ordinary shares issued and outstanding immediately prior to the completion of this offering. All of our shares issued and outstanding prior to the completion of the offering will be fully paid, and all of our shares to be issued in the offering will be issued as fully paid.

### Our Post-Offering Amended and Restated Memorandum and Articles of Association

Our shareholders will adopt the amended and restated memorandum and articles of association, which will become effective and replace our current fourth amended and restated memorandum and articles of association in its entirety conditional and immediately prior to the completion of this offering. The following are summaries of certain material provisions of the post-offering amended and restated memorandum and articles of association that will become effective immediately prior to completion of this offering, and of the Companies Law, insofar as they relate to the material terms of our ordinary shares.

*Objects of Our Company.* Under our post-offering amended and restated 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 law of the Cayman Islands.

*Ordinary Shares.* Our ordinary shares are issued in registered form and are issued when registered in our register of members (shareholders). We may not issue shares to bearer. Our shareholders who are nonresidents of the Cayman Islands may freely hold and vote their shares. Each ordinary share shall entitle the holder thereof to one vote on all matters subject to vote at our general meetings.

*Dividends.* The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our post-offering amended memorandum and restated articles of

association provide that our directors may, before recommending or declaring any dividend, set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall, in the absolute discretion of the directors, be applicable for meeting contingencies or for equalizing dividends or for any other purpose to which those funds may be properly applied. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or our share premium account, provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

*Voting Rights.* Each ordinary share shall be entitled to one vote on all matters subject to a vote at general meetings of our company. Voting at any shareholders' meeting is by show of hands unless a poll is demanded (before or on the declaration of the result of the show of hands). A poll may be demanded by the chairman of such meeting or by any one or more shareholders who together hold not less than 10% of the votes attaching to the total ordinary shares which are 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 attaching to the ordinary shares which are cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes attaching to the ordinary shares which are cast at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our post-offering amended and restated memorandum and articles of association. Our company may, among other things, divide or combine our ordinary shares, by an ordinary resolution of our shareholders.

*General Meetings of Shareholders.* As a Cayman Islands exempted company, we are not obliged by the Companies Law to call shareholders' annual general meetings. Our post-offering amended and restated memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by a majority of our board of directors. Advance notice of at least ten 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 shareholders present in person or by proxy, holding shares which carry in aggregate not less than one-third of all votes attaching to all of our shares in issue and entitled to vote.

The Companies Law 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 amended and restated memorandum and articles of association provide that upon the requisition of shareholders holding shares which carry in aggregate not less than one-third of the votes attaching to the issued and outstanding shares of our company entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, our post-offering amended and restated 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;

## Table of Contents

- 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 the Nasdaq Global Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within three 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 Global 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 shall 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 shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall 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 the whole of the share capital, the assets will be distributed so that 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 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 by our board of directors. Our company may also 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 Law, the redemption or repurchase of any share may be paid out of our 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 Law 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 our company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

*Variations of Rights of Shares.* If at any time, our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound-up, may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

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

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

- the designation of the series;
- the number of shares of the series;

## [Table of Contents](#)

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

Our board of directors may issue preference 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 (except for the memorandum and articles of association, special resolutions which have been passed by our shareholders, our register of mortgages and charges and a list of our current directors). However, we will provide our shareholders with annual audited consolidated financial statements. See “Where You Can Find Additional Information.”

*Anti-Takeover Provisions.* Some provisions of our post-offering amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference 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 amended and restated 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.

*Exempted Company.* We are an exempted company with limited liability under the Companies Law. The Companies Law 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;
- the statutory provisions as to the required majority vote have been met;
- 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 Law 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 Law and the current Companies Act of England. In addition, the Companies Law 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 Law applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

*Mergers and Similar Arrangements.* The Companies Law 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 the merger or consolidation, provide the dissenting shareholder complies strictly with the procedures set out in the Companies Law. 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 Law 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 Law.

The Companies Law also contains a statutory power of compulsory acquisition which may facilitate the "squeeze out" of dissentient minority shareholders upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares affected 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, 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 officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our post-offering amended and restated memorandum and articles of association provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his or her 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 certain 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 or she reasonably believes to be in the best interests of the corporation. He or she must not use their corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a



breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he or she owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his or her position as director (unless the company permits them to do so), a duty not to put himself or herself in a position where the interests of the company conflict with his or 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 company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be expected from a person of his 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 Resolution.* Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Cayman Islands law and our post-offering amended and restated articles of association provide that our shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

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

The Companies Law 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 amended and restated articles of association allow our shareholders holding shares which carry in aggregate not less than one-third of all votes attaching to the issued and outstanding shares of our company 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 amended and restated articles of association do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As an exempted Cayman Islands company, we may but 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 amended and restated articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

*Removal of Directors.* Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our post-offering amended and restated articles of association, directors may be removed with or without cause, by an ordinary resolution of our shareholders. In addition, a director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his or her office by notice in writing to the company; (iv) without special leave of absence from our board of directors, is absent from three consecutive meetings of the board and the board resolves that his or her office be vacated; or (v) is removed from office pursuant to any other provisions of our post-offering amended and restated 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 share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

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

*Dissolution; Winding up.* Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so.

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

*Amendment of Governing Documents.* Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under the Companies Law and our post-offering amended and restated 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 amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

## **History of Securities Issuances**

The following is a summary of our securities issuances in the past three years.

### **Ordinary Shares**

On November 20, 2015, we issued (i) one ordinary share to N.D. Nominees Ltd., which was immediately transferred to BioFortune Inc. (ii) 4,999 ordinary shares to BioFortune Inc., and (iii) 5,000 ordinary shares to Zheng Wei, Ph.D. On October 30, 2018, each of BioFortune Inc. and Zheng Wei, Ph.D. surrendered 4,000 Ordinary Shares.

## Table of Contents

On October 30, 2018, in connection with the Restructuring, we issued 92,327 ordinary shares to Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership), which was later sub-divided into 9,232,700 ordinary shares on December 20, 2018.

On April 14, 2020, we issued 245,798 ordinary shares to each of BioFortune Inc. and Zheng Wei, Ph.D.

As further described in the section titled “Management–2019 Stock Incentive Plan,” from December 2018 through December 2020, we issued 4,473,305 ordinary shares to Connect Union as nominee for purposes of the implementation of awards issue or to be issued to employees, directors and consultants of our company pursuant to the 2019 Plan.

### **Preferred Shares**

**Series Pre-A Preferred Shares Financing.** In connection with the Restructuring, on October 30, 2018, we issued and sold to existing shareholders of Connect SZ an aggregate of 31,090 Series Pre-A Preferred Shares (which were split into 3,109,000 Series Pre-A Preferred Shares in December 2018) as consideration and in exchange for the same equity interests they held in Connect SZ. The equity interest held in Connect SZ was originally purchased for aggregate consideration of approximately USD6 million.

**Series A Preferred Shares Financing.** In connection with the Restructuring, on October 30, 2018, we issued and sold to existing shareholders of Connect SZ an aggregate of 84,712 Series A Preferred Shares (which were split into 8,471,200 Series A Preferred Shares in December 2018) as consideration and in exchange for the same equity interests they held in Connect SZ. The equity interest held in Connect SZ was originally purchased for aggregate consideration of approximately USD20 million.

**Series B Preferred Shares Financing.** On December 20, 2018, we issued and sold to investors in private placements an aggregate of 10,127,579 Series B Preferred Shares at a subscription price of \$5.4307 per share, for aggregate consideration of approximately \$55 million.

**Series C Preferred Shares Financing.** On August 21, 2020, we issued and sold to investors in private placements an aggregate of 16,605,196 Series C Preferred Shares at a subscription price of \$6.3233 per share, for aggregate consideration of approximately \$105 million. On December 1, 2020, we issued and sold to investors in private placements an aggregate of 4,744,341 Series C Preferred Shares at a subscription price of \$6.3233 per share, for aggregate consideration of approximately \$30 million.

The following table sets forth the aggregate number of our ordinary shares and Preferred Shares acquired by holders of more than 5% of our ordinary shares in the financing transactions described above. Each Preferred Share identified in the following table is convertible at the option of the holder into one ordinary share.

<b>PARTICIPANTS</b>	<b>ORDINARY SHARES</b>	<b>SERIES A PREFERRED SHARES</b>	<b>SERIES B PREFERRED SHARES</b>	<b>SERIES C PREFERRED SHARES</b>
<b>5% or Greater Shareholders (1)</b>				
Entities affiliated with Qiming Venture Partners (2)	—	4,235,600	1,012,758	3,162,895
Advantech Capital II Connect Partnership L.P.	—	—	8,286,202	—
Entities affiliated with RA Capital Management (3)	—	—	—	6,325,789
Shanghai Minhui Enterprise Management Consulting Partnership (Limited Partnership)	9,232,700	—	—	—

(1) Additional details regarding these shareholders and their equity holdings are provided in this prospectus under the caption “Principal Shareholders.”

## [Table of Contents](#)

- (2) Represents shares acquired by Qiming Managing Directors Fund V, L.P., Qiming Venture Partners V, L.P., Qiming VII Strategic Investors Fund, L.P. and Qiming Venture Partners VII, L.P.
- (3) Represents shares acquired by RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC—Series A.

Some of our directors are associated with our principal shareholders as indicated in the table below:

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<b>DIRECTOR</b>	<b>PRINCIPAL SHAREHOLDER</b>
Derek DiRocco, Ph.D.	Entities affiliated with RA Capital Management
Kan Chen, Ph.D.	Entities affiliated with Qiming Venture Partners
Jinghua (Jennifer) Jin	Advantech Capital II Connect Partnership L.P.

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### **Shareholders Agreement**

We entered into a Second Amended and Restated Shareholders Agreement, or Shareholders Agreement, on December 1, 2020, by and among us and certain of our shareholders, including each of the holders of more than 5% of our ordinary shares identified above. The Shareholders Agreement, as amended, imposes certain affirmative obligations on us and also grants certain rights to holders, including certain registration rights with respect to the securities held by them, certain preemptive rights, certain co-sale and drag-along rights and certain information and inspection rights. Pursuant to the Shareholders Agreement, we have agreed to issue ordinary shares to our founders upon the completion of this offering.

Each of our current directors was designated to serve on our board of directors under the Shareholders Agreement. Dr. Wei, Dr. Pan, Ms. Wilson and Dr. Xanthopoulos were designated by our founders to serve on our board of directors as their representatives. Dr. DiRocco, designated by RA Capital Management, was selected to serve on our board of directors as a representative of our Series C Preferred Shares. Ms. Jin, designated by Advantech Capital, was selected to serve on our board of directors as a representative of our Series B Preferred Shares. Dr. Chen, designated by Qiming, was selected to serve on our board of directors as a representative of our Series A Preferred Shares.

The rights of our shareholders under the Shareholders Agreement, except the registration rights discussed below (see “Description of Share Capital—Registration Rights”), will terminate immediately prior to the completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our ordinary shares. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition.”

### **Registration Rights**

Pursuant to the Shareholders Agreement, we have granted certain registration rights to our shareholders. Set forth below is a description of the registration rights granted under the agreement.

**Demand Registration Rights.** At any time after the earlier of (i) December 31, 2024 or (ii) 180 days following the effectiveness of a registration statement for a qualified initial public offering, holders of at least 10% of the registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$10 million) have the right to demand that we file a registration statement on Form F-1 or Form S-1 covering all registrable securities that the holders request to be registered and included in such registration by written notice. A qualified initial public offering of ADSs means an initial public offering or a backdoor listing on the Nasdaq or the New York Stock Exchange approved by (i) the holders of at least a majority of the voting power of our issued and outstanding ordinary shares and (ii) the holders of at least two-thirds of the voting power of our issued and outstanding preferred shares (calculated on a fully diluted and as-converted basis). We shall effect the registration of the securities on Form F-1 or Form S-1 as soon as practicable, except in certain circumstances. We have the right to defer filing a registration statement for a period of not more than 90 days after the receipt of the request of the initiating holders if our board of directors determines in its good faith judgment that it would be materially detrimental to us and our shareholders for such registration statement to be filed at such time because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving us; (ii) require premature disclosure of material information that we have a bona fide business purpose for preserving as confidential; or (iii) render us unable to comply with requirements under the

## [Table of Contents](#)

Securities Act or Exchange Act. We may not exercise our right to defer filing a registration statement more than once in any 12 month period, and, subject to certain exceptions, we may not register any equity securities for our own account or that of any other shareholder during such 90 day period. We are obligated to effect no more than three (3) demand registrations on Form F-1 or Form S-1, and we need not effect the registration of securities on Form F-1 or Form S-1 if such securities may be immediately registered on Form F-3 or Form S-3 as provided below.

*Registration on Form F-3 or Form S-3.* If we qualify for registration on Form F-3 or Form S-3, the holders of at least 10% of the registrable securities then outstanding are entitled to request us to file a registration statement on Form F-3 or Form S-3 with respect to outstanding registrable securities of such holders having an anticipated aggregate offering price, net of selling expenses, of at least \$2 million. We shall effect the registration of the securities on Form F-3 or Form S-3 as soon as practicable, except in certain circumstances. We have the right to defer filing a registration statement for a period of not more than 90 days after the receipt of the request of the initiating holders if our board of directors determines in its good faith judgment that it would be materially detrimental to us and our shareholders for such registration statement to be filed at such time because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving us; (ii) require premature disclosure of material information that we have a bona fide business purpose for preserving as confidential; or (iii) render us unable to comply with requirements under the Securities Act or Exchange Act. We may not exercise our right to defer filing a registration statement more than once in any 12 month period, and, subject to certain exceptions, we may not register any equity securities for our own account or that of any other shareholder during such 90 day period. We are obligated to effect no more than two (2) demand registrations on Form F-3 or Form S-3.

*Piggyback Registration Rights—Demand Registration.* If the initiating holders of a demand registration intend to distribute the registrable securities covered by their request by means of an underwriting, we must offer shareholders an opportunity to include in the registration all or any part of the registrable securities held by such holders. If the managing underwriter(s) of any underwritten offering advises the initiating holders in writing that marketing factors require a limitation of the number of shares to be underwritten, then the number of shares that may be included in the registration and the underwriting shall be allocated among the holders requesting inclusion of their registrable securities in such registration statement, including the initiating holders, in proportion (as nearly as practicable) to the number of registrable securities requested by each holder to be included in the registration.

*Piggyback Registration Rights—Company Registration.* If we propose to file a registration statement for a public offering of our securities, we must offer shareholders an opportunity to include in the registration all or any part of the registrable securities held by such holders. If the managing underwriter(s) of any underwritten offering determine(s) in good faith that marketing factors require a limitation of the number of shares to be underwritten, then the number of shares that may be included in the registration and the underwriting shall be allocated (i) first, to us, (ii) second, to each of the holders requesting inclusion of their registrable securities in such registration statement in proportion (as nearly as practicable) to the number of registrable securities requested by each holder to be included in the registration. However, except in our initial public offering, the number of registrable securities included in any offering may not be reduced below 30% of the total number of securities included in the such offering.

*Expenses of Registration.* We will bear all registration expenses, other than underwriting discounts and selling commissions. *Termination of Registration Rights.* Our shareholders' registration rights will terminate upon the earlier of (i) the fifth anniversary of a qualified initial public offering, (ii) as to any shareholder when the shareholder together with its affiliates can sell all of its shares subject to registration rights in reliance on Rule 144 without transfer restrictions, and (iii) after the consummation of any liquidation, dissolution or winding up of us.

### **Listing**

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

**Transfer agent and registrar**

Upon the closing of this offering, the depositary for the ADSs will be . Our ordinary share register is maintained by . The share register reflects only record owners of our ordinary shares. Holders of our ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see “Description of American Depositary Shares” in this prospectus.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

### American Depositary Shares

, as the Depositary, has agreed to act as the depositary for the ADSs. The Depositary's depositary offices are located at . ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is located at .

We have appointed the Depositary as depositary pursuant to a deposit agreement. A copy of the deposit agreement will be on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website ([www.sec.gov](http://www.sec.gov)). Please refer to registration number 333- when retrieving such copy.

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

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, ordinary shares that are on deposit with the depositary and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-ordinary share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder

rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system, or DRS).

The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

### **Dividends and Other Distributions**

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction the applicable fees, taxes and expenses.

#### ***Distributions of Cash***

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of the Cayman Islands.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

#### ***Distributions of Shares***

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.



The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

***Distributions of Rights***

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depositary will *not* distribute the rights to you if:

- we do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

***Elective Distributions***

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

***Other Distributions***

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depository may sell all or a portion of the property received.

The depository will *not* distribute the property to you and will sell the property if:

- we do not request that the property be distributed to you or if we ask that the property not be distributed to you; or
- we do not deliver satisfactory documents to the depository; or
- the depository determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

#### **Redemption**

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depository in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depository will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depository will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depository. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depository may determine.

#### **Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depository may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable registration statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depository may not lawfully distribute such property to you, the depository may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

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

Upon completion of this offering, the ordinary shares being offered pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depository will issue ADSs to the underwriters named in this prospectus. After the completion of this offering, the ordinary shares that are being offered for sale pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depository will issue ADSs to the underwriters named in this prospectus.

After the closing of this offer, the depository may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depository will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depository or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depository will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary. As such, you will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised;
- you are duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement); and
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

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

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

#### **Withdrawal of Ordinary Shares Upon Cancellation of ADSs**

As a holder, you will be entitled to present your ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except as a result of:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges; and/or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

## Voting Rights

As a holder, you generally have the right under the deposit agreement to instruct the depository to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in “Description of Share Capital—Our Post-Offering Amended and Restated Memorandum and Articles of Association—Voting Rights” in this prospectus.

At our request, the depository will distribute to you any notice of shareholders’ meeting received from us together with information explaining how to instruct the depository to exercise the voting rights of the securities represented by ADSs.

If the depository timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder’s ADSs as follows:

- *In the event of voting by show of hands*, the depository will vote (or cause the custodian to vote) all ordinary 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.
- *In the event of voting by poll*, the depository will vote (or cause the custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated herein). Please note that the ability of the depository to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depository in a timely manner.

## Fees and Charges

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

SERVICE	FEE	
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio), excluding ADS issuances as a result of distributions of ordinary shares	Up to \$	per ADS issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio)	Up to \$	per ADS cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to \$	per ADS held
Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to \$	per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to \$	per ADS held
ADS Services	Up to \$	per ADS held on the applicable record date(s) established by the depository

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depository or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;

- the expenses and charges incurred by the depositary in the conversion of foreign currency;
- the fees and expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary fees, the depositary 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. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

### **Amendments and Termination**

We may agree with the depositary to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

### **Termination**

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale,

the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with the termination of the deposit agreement, the depositary may, independently and without the need for any action by us, make available to holders a means to withdraw the ordinary shares and other deposited securities represented by their ADSs and to direct the deposit of such ordinary shares and other deposited securities into an unsponsored American depositary shares program established by the depositary, upon such terms and conditions as the depositary may deem reasonably appropriate, subject however, in each case, to satisfaction of the applicable registration requirements by the unsponsored American depositary shares program under the Securities Act, and to receipt by the depositary of payment of the applicable fees and charges of, and reimbursement of the applicable expenses incurred by, the depositary.

### **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 ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

### **Transmission of Notices, Reports and Proxy Soliciting Material**

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. Subject to the terms of the deposit agreement, the depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to.

### **Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles of association or in any provisions of or governing the securities on deposit.

- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

#### **Pre-Release Transactions**

Subject to the terms and conditions of the deposit agreement, the depositary may issue to broker/dealers ADSs before receiving a deposit of ordinary shares or release ordinary shares to broker/dealers before receiving ADSs for cancellation. These transactions are commonly referred to as "pre-release transactions," and are entered into between the depositary and the applicable broker/dealer. The deposit agreement limits the aggregate size of pre-release transactions (not to exceed 30% of the ordinary shares on deposit in the aggregate) and imposes a number of conditions on such transactions (e.g., the need to receive collateral, the type of collateral required, the representations required from brokers, etc.). The depositary may retain the compensation received from the pre-release transactions.

#### **Taxes**

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

#### **Foreign Currency Conversion**

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

**Governing Law/Waiver of Jury Trial**

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of the Cayman Islands.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU WAIVE YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY.



## ORDINARY SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our ADSs. Upon completion of this offering, we will have ADSs outstanding, representing of our ordinary shares. Some of our ADSs and ordinary shares are subject to contractual and legal restrictions on resale as described below. There may be sales of substantial amounts of our ADSs in the public market after such restrictions lapse, which could adversely affect prevailing market prices of our ADSs.

Based on the number of ordinary shares outstanding on , 2021, upon the closing of this offering, we will have ADSs outstanding, representing ordinary shares, and ordinary shares outstanding (including ordinary shares in the form of ADSs), or, if the underwriters exercise in full their option to purchase an additional ADSs in this offering, representing ordinary shares, ordinary shares (including ordinary shares in the form of ADSs). The ADSs sold in this offering will be freely transferable without restriction, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. We expect ordinary shares outstanding after this offering will be subject to the contractual 180-day lock-up period described below.

Following this offering, ordinary shares may be eligible to be exchanged for ADSs. In addition, ordinary shares that we may issue following this offering may be eligible to be exchanged for ADSs.

### Rule 144

In general, a person who has beneficially owned our ordinary shares for at least six months would be entitled to sell such ordinary shares, including in the form of ADSs, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our ordinary shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our ordinary shares then outstanding, in the form of ADSs or otherwise, which will equal approximately ordinary shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional ADSs; or
- the average weekly trading volume of our ordinary shares in the form of ADSs on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

### Rule 701

In general, under Rule 701, any of our employees, board members, executive officers, consultants or advisors who purchases ordinary shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of the offering is entitled to resell such shares 90 days after the effective date of the offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the lock-up restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates," as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

**Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

**Lock-up Agreements**

All of our board members and executive officers and holders of substantially all of our outstanding ordinary shares and other securities have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, 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 or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our ADSs or ordinary shares or such other securities for a period of 180 days after the date of this prospectus, without the prior written consent of the representatives of the underwriters. See “Underwriting—No Sales of Similar Securities.”

## TAXATION

*The following summary of Cayman Islands, PRC and U.S. federal income tax consequences 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 prospectus, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in the ADSs or ordinary shares, such as the tax consequences under state, local and other tax laws, or tax laws of jurisdictions other than the Cayman Islands, the PRC 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 counsel as to Cayman Islands law, to the extent that the discussion relates to matters of PRC tax law, it represents the opinion of Han Kun Law Offices, our counsel as to PRC law, and to the extent that the discussion relates to matters of U.S. federal income tax law, and subject to the qualifications herein, it represents the opinion of Latham & Watkins LLP, our counsel as to U.S. federal income tax law.*

### **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, after execution, brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our ordinary shares or ADSs will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend 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.

### **People's Republic of China Taxation**

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside China with "de facto management body" within China is considered as a Tax Resident Enterprise for PRC enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its worldwide income. The implementation rules of the PRC Enterprise Income Tax Law define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In April 2009, the SAT issued Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel located in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in China.

We believe that we should not be considered as a PRC resident enterprise for PRC tax purposes as (i) we are incorporated outside of China and not controlled by a PRC enterprise or PRC enterprise group; and (ii) we do not meet all of the conditions above. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." There can be no assurance that PRC tax authorities will ultimately not take a different view.

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident

enterprise holders of our ordinary shares or ADSs may be treated as income derived from sources within China and therefore, subject to a 10% withholding tax (or 20% in the case of non-resident individual holders) unless an applicable income tax treaty provides otherwise. In addition, capital gains realized by non-resident enterprise shareholders (including our ADS holders) upon the disposition of our ordinary shares or ADSs may be treated as income derived from sources within PRC and therefore, subject to 10% income tax (or 20% in the case of non-resident individual shareholders or ADS holders) unless an applicable income tax treaty provides otherwise. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. See "Risk Factors—Risks Related to Doing Business in the PRC—We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income."

#### **United States Federal Income Taxation Considerations**

The following discussion describes certain material United States federal income tax consequences to U.S. Holders (defined below) of an investment in the ADSs or ordinary shares. This summary applies only to investors that hold the ADSs or ordinary shares as capital assets (generally, property held for investment) and that have the U.S. dollar as their functional currency. This discussion is based on the United States Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, as in effect on the date of this prospectus and on United States Treasury regulations in effect or, in some cases, proposed, as of the date of this prospectus, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. The summary below does not discuss certain United States federal tax consequences that may be relevant to a particular U.S. Holder's particular circumstances, such as consequences relating to the Medicare contribution tax on net investment income or the alternative minimum tax.

The following discussion neither deals with the tax consequences to any particular investor nor describes all of the tax consequences applicable to persons in special tax situations such as:

- banks;
- certain financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- broker dealers;
- United States expatriates;
- traders that elect to use the mark-to-market method of accounting;
- tax-exempt entities;
- persons holding an ADS or ordinary share as part of a straddle, hedging, conversion or integrated transaction;
- persons that actually or constructively own 10% or more of our stock, by total combined voting power or by value;
- persons who acquired ADSs or ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation; or
- persons holding ADSs or ordinary shares through partnerships or other pass-through entities.

#### **INVESTORS SHOULD CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE UNITED STATES FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE AND LOCAL, FOREIGN AND OTHER TAX CONSEQUENCES TO THEM OF THE OWNERSHIP AND DISPOSITION OF ADSs OR ORDINARY SHARES.**

The discussion below of the United States federal income tax consequences to "U.S. Holders" will apply to you if you are a beneficial owner of ADSs or ordinary shares and you are, for United States federal income tax purposes,

- an individual who is a citizen or resident of the United States;

- a corporation (or other entity taxable as a corporation for United States federal income tax purposes) created or organized in the United States 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 United States federal income taxation regardless of its source; or
- a trust (a) that is subject to the supervision of a court within the United States and the control of one or more United States persons as described in Internal Revenue Code Section 7701(a)(30), or (b) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person.

If an entity or arrangement treated as a partnership for United States federal income tax purposes holds ADSs or ordinary shares, the tax treatment of a partner will generally depend upon the status and the activities of the partnership. A U.S. Holder that is a partner in a partnership holding ADSs or ordinary shares is urged to consult its tax advisor.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Based on such assumptions, if you hold ADSs, you should generally be treated as the holder of the underlying ordinary shares represented by those ADSs for United States federal income tax purposes.

The United States Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the underlying ordinary shares may be taking actions that are inconsistent with the beneficial ownership of the underlying ordinary shares. Accordingly, the creditability of foreign tax credits by U.S. Holders of ADSs or the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders could be affected by actions taken by intermediaries in the chain of ownership between the holder of an ADS and the Company.

#### ***Taxation of Dividends and Other Distributions on the ADSs or Ordinary Shares***

Subject to the PFIC rules discussed below, the gross amount of any distributions we make to you with respect to the ADSs or ordinary shares (without reduction for any amounts withheld) generally will be includible in your gross income as foreign source dividend income on the date of receipt by the depository, in the case of ADSs, or by you, in the case of ordinary shares, but only to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under United States federal income tax principles). Any such dividends will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from other United States corporations. To the extent that the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under United States federal income tax principles), such excess amount will be treated first as a tax-free return of your tax basis in your ADSs or ordinary shares, and then, to the extent such excess amount exceeds your tax basis in your ADSs or ordinary shares, as capital gain. However, we currently do not, and we do not intend to calculate our earnings and profits under United States federal income tax principles. Therefore, a U.S. Holder should expect that any distribution will generally be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gains rate applicable to "qualified dividend income", provided that (1) the ADSs or ordinary shares, as applicable, are readily tradable on an established securities market in the United States or we are eligible for the benefits of a qualifying income tax treaty with the United States, (2) we are neither a PFIC nor treated as such with respect to you (as discussed below) for the taxable year in which the dividend is paid or the preceding taxable year, and (3) the ADSs or ordinary shares are held for a holding period of more than 60 days during the 121-day period beginning 60 days before the ex-dividend date. Ordinary shares or ADSs will generally be considered for the purpose of clause (1) above to be readily tradable on an established securities market in the United States if they are listed on Nasdaq, as our ADSs are expected to be. If we are treated as a "resident enterprise" for PRC tax purposes (see "Taxation—People's Republic of China Taxation"), we may be eligible for the benefits of the income tax treaty between the United States and the PRC, or the Treaty. You should consult your tax advisors regarding the availability of the lower capital gains rate applicable to qualified dividend income for any dividends paid with respect to our ADSs or ordinary shares.

Any non-U.S. withholding tax (including any PRC withholding tax (see “Taxation—People’s Republic of China Taxation”)) paid (or deemed paid) by a U.S. Holder at the rate applicable to such Holder may be eligible for foreign tax credits (or deduction in lieu of such credits) for U.S. federal income tax purposes, subject to applicable limitations. Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, any dividends distributed by us with respect to ADSs or ordinary shares will generally constitute “passive category income.”

The rules relating to the determination of the foreign tax credit are complex and U.S. Holders should consult their tax advisors to determine whether and to what extent a credit would be available in their particular circumstances, including the effects of any applicable income tax treaties.

***Taxation of a Disposition of ADSs or Ordinary shares***

Subject to the PFIC rules discussed below, upon a sale or other disposition of ADSs or ordinary shares, a U.S. Holder will generally recognize a capital gain or loss for United States federal income tax purposes in an amount equal to the difference between the amount realized for the ADS or ordinary share and such U.S. Holder’s tax basis in such ADSs and ordinary shares. Any such gain or loss will be treated as long-term capital gain or loss if the U.S. Holder’s holding period in the ADSs and ordinary shares at the time of the disposition exceeds one year. Long-term capital gain of individual U.S. Holders generally will be subject to United States federal income tax at reduced tax rates. The deductibility of capital losses is subject to limitations.

Any such gain or loss that you recognize generally will be treated as United States source income or loss for foreign tax credit limitation purposes. However, if we are treated as a “resident enterprise” for PRC tax purposes, we may be eligible for the benefits of the Treaty. In such event, if PRC tax were to be imposed on any gain from the disposition of the ADSs or ordinary shares, a U.S. Holder that is eligible for the benefits of the Treaty may elect to treat the gain as PRC source income for foreign tax credit purposes. U.S. Holders should consult their tax advisors regarding the proper treatment of gain or loss in their particular circumstances, including the effects of any applicable income tax treaties.

***Passive Foreign Investment Company***

A non-United States corporation will be a PFIC for United States federal income tax purposes for any taxable year if, after applying certain look-through rules, either:

- at least 75% of its gross income for such taxable year is passive income (the income test), or
- at least 50% of the total value of its assets (generally based on an average of the quarterly values of the assets during such year) is attributable to assets, including cash, that produce passive income or are held for the production of passive income (the asset test).

For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% (by value) of the stock.

Based on the expected market price of our ordinary shares and ADSs following this offering and the composition of our income and assets, including goodwill, although not clear, we do not expect to be treated as a PFIC for U.S. federal income tax purposes for the current taxable year or in the foreseeable future. However, this is a factual determination that must be made annually after the close of each taxable year, and the application of the PFIC rules is subject to uncertainty in several respects. Moreover, the value of our assets for purposes of the PFIC determination will generally be determined by reference to the market price of our ordinary shares and ADSs, which could fluctuate significantly. Therefore, there can be no assurance that we are not a PFIC for the current taxable year, or will not be classified as a PFIC in the future.

If we are a PFIC for any taxable year during which you hold ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold our ordinary shares or ADSs, unless we cease to be a PFIC and you make a “deemed sale” election with respect to the ordinary shares or ADSs. If

such election is timely made, you will be deemed to have sold the ADSs and ordinary shares you hold at their fair market value on the last day of the last taxable year in which we were as a PFIC and any gain from such deemed sale would be subject to the consequences described in the following two paragraphs. In addition, a new holding period would be deemed to begin for the ordinary shares and ADSs for purposes of the PFIC rules. After the deemed sale election, your ordinary shares or ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year that we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any “excess distribution” that you receive and any gain you recognize from a sale or other disposition (including a deemed sale discussed in the preceding paragraph and a pledge) of the ADSs or ordinary shares, unless you make a “mark-to-market” election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs or ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year, and any taxable year in your holding period prior to the first taxable year in which we were a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

In addition, non-corporate U.S. Holders will not be eligible for reduced rates of taxation on any dividends received from us (as described above under “—Taxation of Dividends and Other Distributions on the ADSs or Ordinary Shares”) if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

The tax liability for amounts allocated to taxable years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale or other disposition of the ADSs or ordinary shares cannot be treated as capital, even if you hold the ADSs or ordinary shares as capital assets.

If we are treated as PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs or we make direct or indirect equity investments in other entities that are PFICs, you may be deemed to own shares in such lower-tier PFICs that are directly or indirectly owned by us in that proportion which the value of the ADSs and ordinary shares you own bears to the value of all of the ADSs and ordinary shares, and you may be subject to the adverse tax consequences described in the preceding paragraphs with respect to the shares of such lower-tier PFICs that you would be deemed to own. You should consult your tax advisor regarding the applicability of the PFIC rules to any of our subsidiaries.

A U.S. Holder of “marketable stock” (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the PFIC rules described above regarding excess distributions and recognized gains. If you make a valid mark-to-market election for the ADSs or ordinary shares, you will include in income for each year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs or ordinary shares as of the close of your taxable year over your adjusted basis in such ADSs or ordinary shares. You will be allowed a deduction for the excess, if any, of the adjusted basis of the ADSs or ordinary shares 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 or ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs or ordinary shares will be treated as ordinary income. Ordinary loss treatment will also apply to the deductible portion of any mark-to-market loss on the ADSs or ordinary shares, as well as to any loss realized on the actual sale or other disposition of the ADSs or ordinary shares, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ADSs or ordinary shares. Your basis in the ADSs or ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a mark-to-market election, any distributions that we make would generally be subject to the tax rules discussed above under “—Taxation of Dividends and Other Distributions

on the ADSs or Ordinary Shares,” except that the lower rate applicable to qualified dividend income (discussed above) would not apply.

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 (“regularly traded”) on a qualified exchange or other market, as defined in the applicable United States Treasury regulations. Nasdaq is a qualified exchange. Our ADSs will be listed on Nasdaq and, consequently, if you are a holder of ADSs and the ADSs are regularly traded, the mark-to-market election might be available to you if we become a PFIC. Because a mark-to-market election may not be made for equity interests in any lower-tier PFICs we own, a U.S. Holder may continue to be subject to the PFIC rules with respect to its indirect interest in any investments held by us that are treated as an equity interest in a PFIC for United States federal income tax purposes. You should consult your tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Alternatively, if a non-United States corporation is a PFIC, a holder of shares in that corporation may avoid taxation under the PFIC rules described above regarding excess distributions and recognized gains by making a “qualified electing fund” election (a “QEF Election”) to include in income its share of the corporation’s income on a current basis. However, you may make a qualified electing fund election with respect to our ADSs or ordinary shares only if we agree to furnish you annually with certain tax information. If we determine we are a PFIC for any taxable year, we intend to provide the information necessary for you to make a QEF Election with respect to us and intend to cause each lower-tier PFIC which we control to provide such information with respect to such lower-tier PFIC.

A U.S. Holder of a PFIC is generally required to file an annual report with the U.S. Internal Revenue Service. If we are or become a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you.

You should consult your tax advisor regarding the application of the PFIC rules to your investment in ADSs or ordinary shares.

**Information Reporting and Backup Withholding**

Any dividend payments with respect to ADSs or ordinary shares and proceeds from the sale, exchange, redemption or other disposition of ADSs or ordinary shares may be subject to information reporting to the U.S. Internal Revenue Service and possible United States backup withholding. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. U.S. Holders who are required to establish their exempt status generally must provide such certification on Internal Revenue Service Form W-9. U.S. Holders should consult their tax advisors regarding the application of the United States information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your United States federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the U.S. Internal Revenue Service and furnishing any required information.

**Additional Reporting Requirements**

Certain U.S. Holders who are individuals (and certain entities) are required to report information relating to an interest in our ADSs or ordinary shares, subject to certain exceptions (including an exception for ADSs and ordinary shares held in accounts maintained by certain financial institutions). U.S. Holders should consult their tax advisors regarding the effect, if any, of these rules on the ownership and disposition of our ADSs or ordinary shares.



## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated \_\_\_\_\_, 2021, among us and Jefferies LLC, SVB Leerink LLC, Piper Sandler & Co. and China International Capital Corporation Hong Kong Securities Limited, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us the respective number of ADSs shown opposite its name below:

<b>UNDERWRITER</b>	<b>NUMBER OF ADSs</b>
Jefferies LLC	
SVB Leerink LLC	
Piper Sandler & Co.	
China International Capital Corporation Hong Kong Securities Limited	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the ADSs if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the ADSs as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ADSs, that you will be able to sell any of the ADSs held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Certain of the underwriters are expected to make offers and sales both inside and outside the United States through their respective selling agents. Any offers or sales in the United States will be conducted by broker-dealers registered with the SEC. China International Capital Corporation Hong Kong Securities Limited is not a broker-dealer registered with the SEC and, to the extent that its conduct may be deemed to involve participation in offers or sales of ADSs in the United States, those offers or sales will be made through one or more SEC-registered broker-dealers in compliance with applicable laws and regulations.

### Commission and Expenses

The underwriters have advised us that they propose to offer the ADSs to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ \_\_\_\_\_ per ADS. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ \_\_\_\_\_ per ADS to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

## [Table of Contents](#)

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	PER ADS		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL ADSs	WITH OPTION TO PURCHASE ADDITIONAL ADSs	WITHOUT OPTION TO PURCHASE ADDITIONAL ADSs	WITH OPTION TO PURCHASE ADDITIONAL ADSs
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$ . We have agreed to reimburse the underwriters for expenses of \$ relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc., or FINRA.

### **Determination of Offering Price**

Prior to this offering, there has not been a public market for our ADSs. Consequently, the initial public offering price for our ADSs will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the ADSs will trade in the public market subsequent to the offering or that an active trading market for the ADSs will develop and continue after the offering.

### **Listing**

We have applied to have our ADSs listed on the Nasdaq Global Market under the trading symbol "CNTB".

### **Stamp Taxes**

If you purchase ADSs offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### **Option to Purchase Additional ADSs**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of ADSs from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional ADSs proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more ADSs than the total number set forth on the cover page of this prospectus.

### **No Sales of Similar Securities**

We, our officers, directors and holders of substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or otherwise dispose

of any ordinary shares, ADSs, options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs currently or hereafter owned either of record or beneficially, or

- enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of our ordinary shares or ADSs, or of options or warrants or other rights to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, or
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any ordinary shares or ADSs, or of options or warrants or other rights to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of the representatives.

This restriction terminates after the close of trading of the ADSs on and including the 180th day after the date of this prospectus.

With respect to the lock-up agreements that have been entered into by our officers, directors and holders of substantially all our outstanding capital stock and other securities, the foregoing restrictions do not apply to:

- (i) the transfer of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, by gift, including, without limitation, to a charitable organization, or by will or intestate succession to the legal representative, heir, beneficiary or any family member or to a trust whose beneficiaries consist exclusively of one or more of the lock-up signatory and/or a family member;
- (ii) the transfer or disposal of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, acquired in this offering or on the open market following this offering, provided that no public disclosure or filing under the Exchange Act (other than filings under Section 13 of the Exchange Act) by any party to the transfer shall be required, or made voluntarily, during the lock-up period;
- (iii) transfers or dispositions of the lock-up signatory's ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which, in each case, are held by the lock-up signatory or any family member;
- (iv) the transfer of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, by operation of law, including pursuant to a domestic order or divorce settlement;
- (v) if the lock-up signatory is a corporation, partnership, limited liability company, trust or other business entity, the transfer of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, to (x) another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act) of the lock-up signatory, (y) any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up signatory or affiliates of the lock-up signatory, or (z) limited partners, general partners, members, managers, managing members, directors, officers, employees, shareholders or other equity holders of the lock-up signatory or of the entities described in the preceding clauses (x) and (y);
- (vi) the exercise of share options granted under any equity incentive plans described in the final prospectus relating to this offering by the lock-up signatory, and the receipt by the lock-up signatory from us of ordinary shares or ADSs upon such exercise, insofar as such option is outstanding as of the date of this prospectus, provided that the underlying ordinary shares or ADSs shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement, and provided further, if required, any public report or filing shall clearly indicate in the footnotes thereto that the filing relates to the exercise of a stock option and that no ordinary shares or ADSs were sold by the reporting person;

- (vii) transfers of ADSs, ordinary shares to us as forfeitures (x) to satisfy tax withholding and remittance obligations of the lock-up signatory in connection with the vesting or exercise of equity awards granted pursuant to our equity incentive plans or (y) pursuant to a net exercise or cashless exercise by the shareholder of outstanding equity awards pursuant to our equity incentive plans, provided that any ordinary shares or ADSs received as a result of such exercise, vesting or settlement shall remain subject to the terms of the lock-up agreement, and provided further, if required, any public report or filing shall clearly indicate in the footnotes thereto that such transfer is being made pursuant to the circumstances described in this clause (vii);
- (viii) the transfer of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, pursuant to a change of control of us after this offering that has been approved by the independent members of our board of directors, provided, that in the event that such change of control is not completed, the ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, owned by the lock-up signatory shall remain subject to the terms of the lock-up agreement;
- (ix) the transfer of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, to us in connection with the repurchase of such ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, upon the termination of the lock-up signatory's employment with us pursuant to a contractual agreement between the lock-up signatory and us as in effect as of the date of this prospectus; or
- (x) establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of ADSs or ordinary shares, provided that such plan does not provide for any transfers of ADSs or ordinary shares during the lock-up period and the entry into such plan is not publicly disclosed, including in any filing under the Exchange Act, during the lock-up period.

*Provided* that in any such case as provided in clauses (i), (iii), (iv) and (v) above, it shall be a condition to such transfer that (a) each transferee executes and delivers to the representatives a lock-up agreement in form and substance satisfactory to the representatives, and (b) prior to the expiration of the lock-up period, no public disclosure or filing under the Exchange Act by any party to the transfer (donor, donee, transferor or transferee) shall be required, or made voluntarily, reporting a reduction in beneficial ownership of ordinary shares, ADSs or options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs in connection with such transfer.

The representatives may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of ordinary shares or ADSs prior to the expiration of the lock-up period.

#### **Stabilization**

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ADSs at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our ADSs in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional ADSs or purchasing our ADSs in the open market. In determining the source of ADSs to close out the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the option to purchase additional ADSs.

"Naked" short sales are sales in excess of the option to purchase additional ADSs. The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created

if the underwriters are concerned that there may be downward pressure on the price of our ADSs in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of ADSs on behalf of the underwriters for the purpose of fixing or maintaining the price of the ADSs. A syndicate covering transaction is the bid for or the purchase of ADSs on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our ADSs or preventing or retarding a decline in the market price of our ADSs. As a result, the price of our ADSs may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ADSs originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ADSs. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our ADSs on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of our ADSs in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

### **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of ADSs for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### **Other Activities and Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the ADSs offered hereby. Any such short positions could adversely affect future trading prices of the ADSs offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in

respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **Directed Share Program**

At our request, the underwriters have reserved up to \_\_\_\_\_ ADSs, or \_\_\_\_\_ % of the ADSs to be offered hereby for sale, at the initial public offering price, for our directors, officers, employees, business associates and related persons through a directed share program. ADSs purchased through the directed share program will not be subject to a lock-up restriction, except in the case of ADSs purchased by any of our directors or officers. We do not know if any of these potential investors will choose to purchase all or any portion of the allocated shares, but the number of ADSs available for sale to the general public will be reduced to the extent these individuals or entities purchase such reserved common shares. Any reserved ADSs that are not so purchased will be offered by the underwriters to the general public on the same basis as the other ADSs offered by this prospectus. The underwriters will receive the same discount from such reserved ADSs as they will from other ADSs sold to the public in this offering. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the reserved ADSs.

### **Selling Restrictions**

#### **General**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### **Notice to prospective investors in the European Economic Area and the United Kingdom**

In relation to each Member State of the European Economic Area and the United Kingdom, each a Relevant State, no ADSs have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the 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 underwriters have 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.

***Notice to prospective investors in the United Kingdom***

In addition, in the United Kingdom, this prospectus is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the ADSs in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this prospectus or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this prospectus relates to may be made or taken exclusively by relevant persons.

***Notice to prospective investors in Australia***

This prospectus:

- does not constitute a product 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 under Chapter 6D.2 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, or Exempt Investors, available under section 708 of the Corporations Act.

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 prospectus 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.

***Notice to prospective investors in 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.

***Notice to prospective investors in the Cayman Islands***

No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

***Notice to prospective investors in the Dubai International Financial Center, or DIFC***

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This prospectus 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 prospectus. The securities to which this prospectus 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 prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus 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.

***Notice to prospective investors in 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.

***Notice to prospective investors in Indonesia***

This prospectus does not, and is not intended to, constitute a public offering in Indonesia under Law Number 8 of 1995 regarding Capital Market. This prospectus may not be distributed in the Republic of Indonesia and the ADSs may not be offered or sold in the Republic of Indonesia or to Indonesian citizens wherever they are domiciled, or to Indonesia residents, in a manner which constitutes a public offering under the laws of the Republic of Indonesia.

***Notice to prospective investors in Israel***

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) 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, underwriters, 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 (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

***Notice to prospective investors in 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.

***Notice to prospective investors in 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.

***Notice to prospective investors in Kuwait***

Unless all necessary approvals from the Kuwait Capital Markets Authority pursuant to Law No. 7/2010, its Executive Regulations, and the various Resolutions and Announcements issued pursuant thereto or in connection therewith have been given in relation to the marketing of and sale of the ADSs, these may not be offered for sale, nor sold in the State of Kuwait, or Kuwait. Neither this prospectus nor any of the information contained herein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait. With regard to the contents of this prospectus we recommend that you consult a licensee as per the law and specialized in giving advice about the purchase of ADSs and other securities before making the subscription decision.

***Notice to prospective investors in 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 License; (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 License 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.

***Notice to Prospective Investors in 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.

***Notice to prospective investors in the Philippines***

**THE ADSS BEING OFFERED OR SOLD HAVE NOT BEEN AND WILL NOT BE REGISTERED WITH THE PHILIPPINE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES REGULATION CODE OF THE PHILIPPINES, OR THE SRC. ANY FUTURE OFFER OR SALE OF THE ADSS WITHIN THE PHILIPPINES IS SUBJECT TO THE REGISTRATION REQUIREMENTS UNDER THE SRC UNLESS SUCH OFFER OR SALE QUALIFIES AS A TRANSACTION EXEMPT FROM THE REGISTRATION UNDER THE SRC.**

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 in the Philippines, and the ADSs may not be offered or sold, or be made the subject of an invitation for subscription or purchase, to persons in the Philippines, other than (i) to qualified investors in transactions that are exempt from the registration requirements of the SRC; and (ii) by persons licensed to make such offers or sales in the Philippines.

***Notice to prospective investors in 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.

***Notice to prospective investors in Saudi Arabia***

This prospectus 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 prospectus and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. 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 prospectus, you should consult an authorized financial adviser.

***Notice to prospective investors in Singapore***

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of ADSs, the we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the ADSs are “prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has 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:

- 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;
- to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA and in accordance with the conditions specified in Section 275 of the SFA; or
- 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 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
- 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:

- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

***Notice to prospective investors in 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 prospectus 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 prospectus 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 prospectus nor any other offering or marketing material relating to the offering, us or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority, or 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.

***Notice to prospective investors in 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.

***Notice of prospective investors in Thailand***

This prospectus does not, and is not intended to, constitute a public offering in Thailand. The ADSs may not be offered or sold to persons in Thailand, unless such offering is made under the exemptions from approval and filing requirements under applicable laws, or under circumstances which do not constitute an offer for sale of the ADSs to the public for the purposes of the Securities and Exchange Act of 1992 of Thailand, nor require approval from the Office of the Securities and Exchange Commission of Thailand.

***Notice to prospective investors in the 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 Center) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Center) 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.

***Notice to prospective investors in Vietnam***

This offering of ADSs has not been and will not be registered with the State Securities Commission of Vietnam under the Law on Securities of Vietnam and its guiding decrees and circulars. The ADSs will not be offered or sold in Vietnam through a public offering and will not be offered or sold to Vietnamese persons other than those who are licensed to invest in offshore securities under the Law on Investment of Vietnam.

**EXPENSES OF THE OFFERING**

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

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<u>EXPENSES</u>	<u>AMOUNT</u>
Securities and Exchange Commission registration fee	*
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	*

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\* To be filed by amendment

All amounts in the table are estimates except the SEC registration fee, the Nasdaq listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

**LEGAL MATTERS**

Latham & Watkins LLP is representing us with respect to certain legal matters as to United States federal securities and New York State law. The underwriters are being represented by Davis Polk & Wardwell LLP with respect to certain legal matters as to United States federal securities and New York State law. The validity of our ordinary shares represented by the ADSs and certain other matters of Cayman Islands law will be passed upon for us by Maples and Calder (Hong Kong) LLP. Certain legal matters as to PRC law will be passed upon for us by Han Kun Law Offices and for the underwriters by Global Law Office. Latham & Watkins LLP may rely upon Maples and Calder (Hong Kong) LLP with respect to matters governed by Cayman Islands law and Han Kun Law Offices with respect to matters governed by PRC law. Davis Polk & Wardwell LLP may rely upon Global Law Office with respect to matters governed by PRC law.

**EXPERTS**

The financial statements as of December 31, 2019 and 2018 and January 1, 2018 and for each of the two years in the period ended December 31, 2019 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers Zhong Tian LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## ENFORCEMENT 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 exchange control or currency restrictions; and
- the availability of professional and support services.

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

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

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

A substantial part of our operations are conducted in China, and substantially all of our operational assets are located in China. 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.

We have appointed \_\_\_\_\_, as our agent upon whom process may be served in any action brought against us under the securities laws of the United States. We have been informed by Maples and Calder (Hong Kong) LLP, our counsel as to Cayman Islands law, that the United States and the Cayman Islands do not have a treaty providing for reciprocal recognition and enforcement of judgments of U.S. courts in civil and commercial matters and that there is uncertainty as to whether the courts of the Cayman Islands would (i) recognize or enforce judgments of U.S. courts obtained against us or our directors or officers, predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (ii) entertain original actions brought in the Cayman Islands against us or our directors or officers, predicated upon the securities laws of the United States or any state in the United States. We have also been advised by Maples and Calder (Hong Kong) LLP that a judgment obtained in any federal or state court in the United States will be recognized and enforced in the courts of the Cayman Islands at common law, without any re-examination of the merits of the underlying dispute, by an action commenced on the foreign judgment debt in the Grand Court of the Cayman Islands, provided such judgment (i) is given by a foreign court of competent jurisdiction, (ii) imposes on the judgment debtor a liability to pay a liquidated sum for which the judgment has been given, (iii) is final, (iv) is not in respect of taxes, a fine or a penalty, and (v) was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

However, the Cayman Islands courts are unlikely to enforce a judgment obtained from the United States courts under the civil liability provisions of the securities laws if such judgment is determined by the courts of the Cayman Islands to give rise to obligations to make payments that are penal or punitive in nature. Because the courts of the Cayman Islands have yet to rule on whether such judgments are penal or punitive in nature, it is uncertain whether such civil liability judgments from U.S. courts would be enforceable in the Cayman Islands.

Han Kun Law Offices, our counsel as to PRC law, has advised us that there is uncertainty as to whether the courts of China would:

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



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

Han Kun Law Offices has further advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law and other applicable laws and regulations based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in the PRC will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign shareholders may originate actions based on PRC law against a company in China for disputes if they can establish sufficient nexus to the PRC for a PRC court to have jurisdiction, and meet other procedural requirements, including, among others, the plaintiff must have a direct interest in the case, and there must be a concrete claim, a factual basis and a cause for the suit. It will be, however, difficult for U.S. shareholders to originate actions against us in the PRC in accordance with PRC laws because we are incorporated under the laws of the Cayman Islands and it will be difficult for U.S. shareholders, by virtue only of holding the ADSs or ordinary shares, to establish a connection to the PRC for a PRC court to have jurisdiction as required under the PRC Civil Procedures Law.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. We have also filed a related registration statement on Form F-6 with the SEC to register the ADSs. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our board members, executive officers, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and consolidated financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send our transfer agent a copy of all notices of our general meetings of shareholders and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

CONNECT BIOPHARMA HOLDINGS LIMITED

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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	<u>PAGE</u>
<b>Audited consolidated financial statements:</b>	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Statements of Loss for the Years Ended December 31, 2018 and 2019</a>	F-3
<a href="#">Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2018 and 2019</a>	F-4
<a href="#">Consolidated Balance Sheets as of January 1, 2018, December 31, 2018 and 2019</a>	F-5
<a href="#">Consolidated Statements of Changes in Shareholders' Deficit for the Years Ended December 31, 2018 and 2019</a>	F-6
<a href="#">Consolidated Statements of Cash Flows for the Years Ended December 31, 2018 and 2019</a>	F-8
<a href="#">Notes to Consolidated Financial Statements</a>	F-9

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of Connect Biopharma Holdings Limited

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Connect Biopharma Holdings Limited and its subsidiaries (the "Company") as of December 31, 2019 and 2018 and January 1, 2018, and the related consolidated statements of loss, comprehensive loss, changes in shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2019, including 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, 2019 and 2018 and January 1, 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

***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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers Zhong Tian LLP  
Beijing, the People's Republic of China  
December 17, 2020

We have served as the Company's auditor since 2020.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Statements of Loss**

	NOTES	YEAR ENDED DECEMBER 31,		
		2018	2019	2019
		RMB'000	RMB'000	USD'000
Research and development expenses	5	(59,275)	(106,414)	(15,254)
Administrative expenses	5	(7,175)	(9,713)	(1,392)
Other income	7	433	2,836	407
Other gains—net	8	3,802	3,050	437
<b>Operating loss</b>		<b>(62,215)</b>	<b>(110,241)</b>	<b>(15,802)</b>
Finance income	9	1,255	1,066	153
Finance cost	9	(9,905)	(53)	(8)
Finance (cost)/ income—net	9	(8,650)	1,013	145
Fair value loss of financial instruments with preferred rights	24	(23,012)	(59,397)	(8,514)
<b>Loss before income tax</b>		<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
Income tax expense	10	—	—	—
<b>Loss for the year</b>		<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss attributable to:</b>				
Owners of the Company		(76,965)	(168,625)	(24,171)
Non-controlling interests		(16,912)	—	—
		<b>(93,877)</b>	<b>(168,625)</b>	<b>(24,171)</b>
<b>Loss per share</b>				
Basic and diluted	11	RMB (3.58)	RMB (5.74)	USD (0.82)

The accompanying notes are an integral part of these consolidated financial statements.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Statements of Comprehensive Loss**

	NOTES	YEAR ENDED DECEMBER 31,		
		2018	2019	2019
		RMB'000	RMB'000	USD'000 Note 2.5(d)
<b>Loss for the year</b>		<b><u>(93,877)</u></b>	<b><u>(168,625)</u></b>	<b><u>(24,171)</u></b>
Other comprehensive income/(loss)				
<i>Items that may be reclassified to profit or loss</i>				
Exchange differences on translation of foreign operations		3,388	(6,027)	(864)
<i>Items that will not be reclassified to profit or loss</i>				
Exchange differences on translation of foreign operations		(120)	(466)	(67)
<b>Other comprehensive income/(loss) for the year, net of tax</b>		<b><u>3,268</u></b>	<b><u>(6,493)</u></b>	<b><u>(931)</u></b>
<b>Total comprehensive loss for the year</b>		<b><u>(90,609)</u></b>	<b><u>(175,118)</u></b>	<b><u>(25,102)</u></b>
<b>Total comprehensive loss attributable to:</b>				
Owners of the Company		(73,697)	(175,118)	(25,102)
Non-controlling interests		(16,912)	—	—
		<b><u>(90,609)</u></b>	<b><u>(175,118)</u></b>	<b><u>(25,102)</u></b>

The accompanying notes are an integral part of these consolidated financial statements.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Balance Sheets**

	NOTES	AS OF	AS OF DECEMBER 31,		
		JANUARY 1, 2018	2018	2019	2019
		RMB'000	RMB'000	RMB'000	USD'000
					Note 2.5(d)
<b>ASSETS</b>					
<b>Non-current assets</b>					
Property, plant and equipment	13	1,019	1,850	2,539	364
Right-of-use assets		—	1,290	883	127
Other non-current assets	14	1,876	4,751	6,354	912
<b>Total non-current assets</b>		<b>2,895</b>	<b>7,891</b>	<b>9,776</b>	<b>1,403</b>
<b>Current assets</b>					
Other receivables and prepayments	16	10,638	16,563	23,208	3,327
Financial assets at fair value through profit or loss	17	27,276	27,565	30,632	4,391
Term deposits		59,007	—	—	—
Cash and cash equivalents	18	40,933	401,597	308,972	44,289
<b>Total current assets</b>		<b>137,854</b>	<b>445,725</b>	<b>362,812</b>	<b>52,007</b>
<b>Total assets</b>		<b>140,749</b>	<b>453,616</b>	<b>372,588</b>	<b>53,410</b>
<b>LIABILITIES</b>					
<b>Non-current liabilities</b>					
Lease liabilities		—	882	470	67
Financial instruments with preferred rights	24	175,693	573,499	643,008	92,172
<b>Total non-current liabilities</b>		<b>175,693</b>	<b>574,381</b>	<b>643,478</b>	<b>92,239</b>
<b>Current liabilities</b>					
Trade payables		915	3,437	22,788	3,267
Other payables and accruals	23	1,209	2,499	4,197	602
Lease liabilities		—	392	412	59
<b>Total current liabilities</b>		<b>2,124</b>	<b>6,328</b>	<b>27,397</b>	<b>3,928</b>
<b>Total liabilities</b>		<b>177,817</b>	<b>580,709</b>	<b>670,875</b>	<b>96,167</b>
<b>Net liabilities</b>		<b>(37,068)</b>	<b>(127,093)</b>	<b>(298,287)</b>	<b>(42,757)</b>
<b>SHAREHOLDERS' DEFICIT</b>					
Share capital	19	64	21	21	3
Share premium	19	(64)	38,074	38,123	5,465
Treasury shares	20	—	(1)	(1)	—
Share-based compensation reserves	21(a)	—	584	4,411	632
Other reserves	21(b)	(602)	(42,280)	(48,725)	(6,984)
Accumulated losses		(46,526)	(123,491)	(292,116)	(41,873)
<b>Total deficit attributable to owners of the Company</b>		<b>(47,128)</b>	<b>(127,093)</b>	<b>(298,287)</b>	<b>(42,757)</b>
Non-controlling interests	12	10,060	—	—	—
<b>Total shareholders' deficit</b>		<b>(37,068)</b>	<b>(127,093)</b>	<b>(298,287)</b>	<b>(42,757)</b>

The accompanying notes are an integral part of these consolidated financial statements.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Statements of Changes in Shareholders' Deficit**

	NOTES	ATTRIBUTABLE TO OWNERS OF THE COMPANY						TOTAL	NON-CONTROLLING INTERESTS	TOTAL SHAREHOLDERS' DEFICIT
		SHARE CAPITAL	SHARE PREMIUM	TREASURY SHARES	SHARE-BASED COMPENSATION RESERVES	OTHER RESERVES	ACCUMULATED LOSSES			
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
<b>Balance at January 1, 2018</b>		64	(64)	—	—	(602)	(46,526)	(47,128)	10,060	(37,068)
<b>Comprehensive income/(loss)</b>										
Loss for the year		—	—	—	—	—	(76,965)	(76,965)	(16,912)	(93,877)
Exchange differences		—	—	—	—	3,268	—	3,268	—	3,268
		—	—	—	—	3,268	(76,965)	(73,697)	(16,912)	(90,601)
<b>Transactions with owners</b>										
Share-based compensations	22	—	—	—	584	—	—	584	—	584
Issuance of ordinary shares	19	70	(70)	—	—	—	—	—	—	—
Cancellation of ordinary shares	19	(134)	134	—	—	—	—	—	—	—
Issuance of treasury shares	20	1	—	(1)	—	—	—	—	—	—
Reissuance of ordinary shares	19	14	(14)	—	—	—	—	—	—	—
Transaction with non-controlling interests	12	6	38,088	—	—	(44,946)	—	(6,852)	6,852	—
		(43)	38,138	(1)	584	(44,946)	—	(6,268)	6,852	—
<b>Balance at December 31, 2018</b>		<b>21</b>	<b>38,074</b>	<b>(1)</b>	<b>584</b>	<b>(42,280)</b>	<b>(123,491)</b>	<b>(127,093)</b>	<b>—</b>	<b>(127,093)</b>

The accompanying notes are an integral part of these consolidated financial statements.



**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Statements of Changes in Shareholders' Deficit**

	NOTES	ATTRIBUTABLE TO OWNERS OF THE COMPANY							NON-CONTROLLING INTERESTS	TOTAL SHAREHOLDERS' DEFICIT
		SHARE CAPITAL	SHARE PREMIUM	TREASURY SHARES	SHARE-BASED COMPENSATION RESERVES	OTHER RESERVES	ACCUMULATED LOSSES	TOTAL		
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
<b>Balance at January 1, 2019</b>		21	38,074	(1)	584	(42,280)	(123,491)	(127,093)	—	(127,093)
<b>Comprehensive loss</b>										
Loss for the year		—	—	—	—	—	(168,625)	(168,625)	—	(168,625)
Exchange differences		—	—	—	—	(6,493)	—	(6,493)	—	(6,493)
		—	—	—	—	(6,493)	(168,625)	(175,118)	—	(175,118)
<b>Transactions with owners</b>										
Exercise of share option	22	—	49	—	(48)	48	—	49	—	49
Share-based compensation	22	—	—	—	3,875	—	—	3,875	—	3,875
		—	49	—	3,827	48	—	3,924	—	3,924
<b>Balance at December 31, 2019</b>		<u>21</u>	<u>38,123</u>	<u>(1)</u>	<u>4,411</u>	<u>(48,725)</u>	<u>(292,116)</u>	<u>(298,287)</u>	<u>—</u>	<u>(298,287)</u>

The accompanying notes are an integral part of these consolidated financial statements.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Consolidated Statements of Cash Flows**

	NOTES	YEAR ENDED DECEMBER 31,		
		2018	2019	2019
		RMB'000	RMB'000	USD'000
<b>Cash flows from operating activities</b>				
Cash used in operations	25(a)	(69,032)	(90,256)	(12,938)
<b>Net cash used in operating activities</b>		<b>(69,032)</b>	<b>(90,256)</b>	<b>(12,938)</b>
<b>Cash flows from investing activities</b>				
Purchase of property, plant and equipment		(1,190)	(1,072)	(154)
Purchase of financial assets at fair value through profit or loss		(106,700)	(163,000)	(23,365)
Proceeds from disposal of financial assets at fair value through profit or loss		106,958	160,731	23,040
Withdrawal of term deposits upon maturity		59,007	—	—
<b>Net cash generated from/ (used in) investing activities</b>		<b>58,075</b>	<b>(3,341)</b>	<b>(479)</b>
<b>Cash flows from financing activities</b>				
Proceeds from exercise of share options		—	49	7
Proceeds from issuance of financial instruments with preferred rights	24	379,148	—	—
Payment for lease liabilities	25(c)	(334)	(445)	(64)
Issuance cost of financial instruments with preferred rights		(9,859)	—	—
<b>Net cash generated from/ (used in) financing activities</b>		<b>368,955</b>	<b>(396)</b>	<b>(57)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>357,998</b>	<b>(93,993)</b>	<b>(13,474)</b>
Cash and cash equivalents at the beginning of year		40,933	401,597	57,567
Effects of exchange rate changes on cash and cash equivalents		2,666	1,368	196
<b>Cash and cash equivalents at end of year</b>		<b>401,597</b>	<b>308,972</b>	<b>44,289</b>

The accompanying notes are an integral part of these consolidated financial statements.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**1. General Information, reorganization and basis of presentation**

**1.1 General information**

Connect Biopharma Holdings Limited (“the Company”) was incorporated on November 23, 2015 in the Cayman Islands as an exempted company with limited liability. The address of the Company’s registered office is P.O. Box 613, Harbour Centre, George Town, Grand Cayman KY1-1107, Cayman Islands.

The Company and its subsidiaries (collectively the “Group”) is a clinical-stage Group focused on the discovery and development of next-generation immune modulators for the treatment of serious autoimmune diseases and inflammation. The Group has leveraged its expertise in the biology of T cell modulation to build a portfolio of drug candidates consisting of small molecules and antibodies targeting critical pathways of inflammation (“Listing Business”).

**1.2 Reorganization**

Prior to the incorporation of the Company and the completion of the reorganization as described below, the Group carried out its business through Suzhou Connect Biopharma Co., Ltd. (“Connect SZ”) and its subsidiaries, Connect Biopharm LLC. (“Connect US”) and Connect Biopharma Australia PTY LTD (“Connect AU”) (collectively the “Operating Companies”) since January 2012.

Dr. Zheng Wei and Dr. Pan Wubin are the founders of the Group (collectively the “Co-Founders”) and jointly controlled the Group pursuant to the act-in-concert agreements entered into among relevant shareholders since the inception of the Group until December 31, 2018.

In May 2012, Xiang Tang Group (“XT Group”) as the angel investor has invested RMB30 million for 30% equity interests of the Group.

*Incorporation of overseas companies and Reorganization*

In January 2016, the Group underwent a reorganization (the “Reorganization”) to establish the Company as the Group’s ultimate holding company. The Reorganization mainly involved the following:

- 1) The Company was incorporated on November 23, 2015 in the Cayman Islands with an authorized share capital of U.S. Dollar (“USD”) 50,000 divided into 50,000 ordinary shares with a par value of USD1 each;
- 2) Connect Biopharma Hong Kong Limited (“Connect HK”) was incorporated on December 1, 2015 in Hong Kong (“HK”) as a direct wholly owned subsidiary of the Company; and
- 3) In January 2016, the Company issued ordinary shares to the Co-Founders as consideration in exchange for the 70% equity interests they held in Connect SZ. Thereafter the Co-Founders held 70% of the equity interests of the Group through the Company and Connect HK and retained joint control over the Group, while XT Group held 30% of the equity interests in Connect SZ, which was considered as non-controlling interests (“NCI”) to the Group.

*Issuance of Series Pre-A preferred shares and Series A preferred shares*

In March 2016 and January 2017, Connect SZ has issued Series Pre-A preferred shares and Series A preferred shares to certain investors, respectively, the details of which are disclosed in Note 24.

*Transaction with NCI*

In October 2018, for the purpose of preparation for the public listing of the shares of the Company, the Group completed a series of restructuring steps as follows:

- 1) Transferred 100% of the outstanding shares of Connect US and Connect AU then held by Connect SZ to Connect HK. Accordingly, Connect US and Connect AU became the wholly-owned subsidiaries of Connect HK;

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**1. General Information, reorganization and basis of presentation (Continued)**

**1.2 Reorganization (Continued)**

- 2) The Company issued ordinary shares to XT Group as consideration in exchange for its 30% of the equity interests in Connect SZ; and
- 3) The Company issued Series Pre-A preferred shares and Series A preferred shares to the preferred shareholders of Connect SZ as consideration in exchange for the same equity interests they held in Connect SZ, respectively.

Upon completion of the restructuring, each of the equity holders of Connect SZ became the shareholders of the Company with the same shareholding percentages and rights in Connect SZ immediately before and after such transaction.

As of December 31, 2019, the Group had direct or indirect interests in the following principal subsidiaries:

COMPANY NAME	PRINCIPAL ACTIVITIES	PLACE AND DATE OF INCORPORATION	ATTRIBUTABLE EQUITY INTEREST TO THE GROUP
<b>Directly Held:</b>			
Connect HK	Investment holding	Hong Kong/December 1, 2015	100%
<b>Indirectly held:</b>			
Connect US	Pharmaceutical R&D	San Diego, United States of America/ January 24, 2012	100%
Connect SZ	Pharmaceutical R&D	Suzhou, PRC/May 2, 2012	100%
Connect AU	Pharmaceutical R&D	Prahran, Australia/July 18, 2014	100%
Connect Biopharma (Shanghai) Co., Ltd	Dormant	Shanghai, PRC/October 23, 2015	100%
Connect Union, Inc. (Note)	Employee share plan management	British Virgin Islands/November 23, 2018	100%
Connect Biopharma (Beijing) Co., Ltd	Dormant	Beijing, PRC/July 9, 2019	100%

Note: Connect Union, Inc. ("Connect Union") was established for the purpose of holding shares for the Group's share incentive plans. The Company consolidated Connect Union as the Group has power to govern the relevant activities of Connect Union and can derive benefits from the contribution of the eligible employees who are awarded with the options under such plans.

**1.3 Basis of presentation**

Immediately prior to and after the Reorganization, the Listing Business was operated by the Operating Companies. Pursuant to the Reorganization, the Listing Business was transferred to and held by the Company through the Operating Companies. The Company has not been involved in any other business prior to the Reorganization and does not meet the definition of a business. The Reorganization is merely a reorganization of the Listing Business with no change in management and control of such business. Accordingly, the Group resulting from the Reorganization is regarded as a recapitalization of the Listing Business under the Operating Companies for the purpose of this financial information. The financial information of the Group has been prepared on a consolidated basis as if the Reorganization had occurred since the earliest presented in these financial statements and is presented using the carrying values of the assets, liabilities and operating results of the Listing Business under the Operating Companies for all periods presented.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**1. General Information, reorganization and basis of presentation (Continued)**

**1.3 Basis of presentation (Continued)**

Since the Company retained control over the Operating Companies since its incorporation, the acquisition of the NCI in Connect SZ and changes in the Company's ownership interests arising from the restructuring in 2018 were accounted for as an equity transaction. Thus, no gain or loss was recognized in the consolidated statements of loss on selling Connect SZ's equity interests. Similarly, the Company did not record any additional goodwill to reflect its purchases of additional equity interests in Connect SZ. Instead, the carrying amount of NCI will be adjusted to nil to reflect the change in the ownership interest in Connect SZ. The difference between the amount of the adjustment to NCI and the fair value of the shares of the Company issued to the NCI is recognized in other reserve within equity attributable to owners of the Company.

**2. Summary of Significant Accounting Policies**

The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

**2.1 Basis of preparation**

*First time adoption of IFRS*

These financial statements are the first consolidated financial statements prepared by the Group in accordance with International Financial Reporting Standards ("IFRS") issued by the International Accounting Standards Board ("IASB"), with transition date being January 1, 2018. The financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through profit or loss and financial instruments with preferred rights.

No financial statements of the Group or the Company have previously been prepared under any other accounting standards.

IFRS 1 "First-time adoption of International Financial Reporting Standards" has been applied in preparing the consolidated financial statements for the years ended December 31, 2018 and 2019.

All effective standards, amendments to standards and interpretations, which are mandatory for the financial year ending December 31, 2019, are consistently applied to the Group throughout the years ended December 31, 2018 and 2019. In preparing these first consolidated financial statements, the Group has early adopted IFRS 9 Financial Instruments ("IFRS 9") and IFRS 16 Leases ("IFRS 16").

The financial statements for the years ended December 31, 2018 and 2019 were authorized for issue by the Company's board of directors (the "Board") on December 17, 2020.

*Liquidity*

As of December 31, 2019, the Group had net liabilities of RMB298,287,000, and accumulated losses of RMB292,116,000. For the year ended December 31, 2019, the Group had net operating loss of RMB110,241,000 and net operating cash outflow of RMB90,256,000. The principal sources of funding have historically been continuous cash contributions from equity holders and preferred shareholders amounted to approximately RMB581 million in totality up to December 31, 2019. In August 2020 and December 2020, the Company has completed two tranches Series C financing and received capital contribution from Series C preferred shareholders amounted to an aggregate of USD135 million (RMB926 million), respectively. The details are set out in Note 27. Taking this into consideration, the Board believes that the Group will have sufficient available financial resources generated by anticipated financing activities to meet its obligations falling due and working capital requirements in the next twelve months from the date of issuance of these financial statements. Accordingly, the Board considers that it is appropriate to prepare the consolidated financial information on a going concern basis.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)****2.2 New and amended standards and interpretations not yet adopted by the Group**

The Group has not applied the following new and revised IFRSs that have been issued but are not yet effective in the consolidated financial statements.

		<b>EFFECTIVE FOR ANNUAL PERIODS BEGINNING ON OR AFTER</b>
Amendments to IFRS 3	Definition of a Business	January 1, 2020
Amendments to IAS 1 and IAS 8	Definition of Material	January 1, 2020
Amendments to IFRS 9, IAS 39 and IFRS 7	Interest Rate Benchmarking	January 1, 2020
Amendments to IFRS 16	Covid-19—Related Rent Concessions	June 1, 2020
IFRS 17	Insurance Contracts	Originally January 1, 2021, but extended to January 1, 2023 by the IASB in March 2020
Amendments to IAS 1	Classification of Liabilities as Current or Non-current	January 1, 2022
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before intended use	January 1, 2022
Amendments to IFRS 3	Reference to the Conceptual Framework	January 1, 2022
Annual Improvements	Annual Improvements to IFRS Standards 2018–2020	January 1, 2022

The Group expects to adopt these standards, updates and interpretations when they become mandatory. These standards are not expected to have a significant impact on disclosures or amounts reported in the Group's consolidated financial statements in the period of initial application and future reporting periods.

**2.3 Principles of consolidation***(a) Subsidiaries*

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Intra-group transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. When necessary, amounts reported by subsidiaries have been adjusted to conform with the Group's accounting policies.

Non-controlling interests in the results and equity of subsidiaries are shown separately in the consolidated statements of loss, consolidated statements of comprehensive loss, consolidated statements of changes in shareholders' deficit and consolidated balance sheets, respectively.

*(b) Changes in ownership interests*

The Group treats transactions with non-controlling interests that do not result in a loss of control as transactions with equity owners of the Group. A change in ownership interest results in an adjustment between the carrying amounts of the controlling and non-controlling interests to reflect their relative interests in the subsidiary. Any difference between the amount of the adjustment to non-controlling interests and any consideration paid or received is recognized in a separate reserve within equity attributable to owners of the Group.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.4 Separate financial statements**

Investments in subsidiaries are accounted for at cost less impairment. Cost includes direct attributable costs of investment. The results of subsidiaries are accounted for by the Company on the basis of dividends received and receivable.

Impairment testing of the investments in subsidiaries is required upon receiving a dividend from these investments if the dividend exceeds the total comprehensive income of the subsidiary in the period the dividend is declared or if the carrying amount of the investment in the separate financial statements exceeds the carrying amount in the consolidated financial statements of the investee's net assets including goodwill.

**2.5 Foreign currency translation**

*(a) Functional and presentation currency*

Since the majority of the assets and operations of the Group are located in the People's Republic of China ("PRC"), the consolidated financial statements are presented in RMB, which is the functional currency of the subsidiaries carrying out the principal activities of the Group in the mainland of the PRC. The functional currency of the Company is USD.

*(b) Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions, and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are generally recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statements of loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statements of loss on a net basis within other gains- net.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at fair value through profit or loss are recognized in profit or loss as part of the fair value gain or loss and translation differences on non-monetary assets such as equities classified as at fair value through other comprehensive income are recognized in other comprehensive income.

*(c) Group companies*

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each statement of comprehensive income/(loss) are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions); and
- all resulting currency translation differences are recognized in other comprehensive income/(loss);

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)****2.5 Foreign currency translation (Continued)***(d) Convenience translation*

Translations of the consolidated balance sheets, the consolidated statements of loss, consolidated statements of comprehensive loss and consolidated statements of cash flows from RMB into USD as of and for the year ended December 31, 2019 are solely for the convenience of the readers and calculated at the rate of USD1.00=RMB 6.9762, representing the exchange rate as of December 31, 2019 set forth in the China Foreign Exchange Trade System. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into USD at that rate, or at any other rate, on December 31, 2019.

**2.6 Property, plant and equipment**

Property, plant and equipment are stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate the cost, net of their residual values, over their estimated useful lives or, in the case of leasehold improvements, the shorter lease term as follows:

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<b>ASSETS</b>	<b>USEFUL LIFE</b>
Laboratory equipment	5 years
Leasehold improvements	Shorter of lease term or 5 years
Office equipment and furniture	5 years

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The assets' residual values and useful lives are reviewed and adjusted if appropriate at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (Note 2.7).

Gains and losses on disposals are determined by comparing proceeds with carrying amount and are recognized within other gains—net in the statements of loss.

**2.7 Impairment of non-financial assets**

Non-financial assets other than goodwill and intangible assets that have an indefinite useful life are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.



**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.8 Investments and other financial assets**

*(a) Classification*

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income ("OCI") or through profit or loss), and
- those to be measured at amortized cost.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through OCI ("FVOCI").

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

*(b) Recognition and derecognition*

Regular way purchases and sales of financial assets are recognized on trade date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

*(c) Measurement*

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss ("FVPL"), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial asset carried at FVPL are expensed in profit or loss. Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

*(i) Debt instruments*

Subsequent measurement of debt instruments depends on the Group's business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- **Amortized cost:** Assets that are held for collection of contractual cash flows, where those cash flows represent solely payments of principal and interest, are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognized directly in profit or loss and presented in other gains/(losses), together with foreign exchange gains and losses. Impairment losses are presented as separate line item in the statements of loss.
- **FVOCI:** Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to profit or loss and recognized in other gains/(losses). Interest income from these financial assets is included in finance income using the effective interest rate method. Foreign exchange gains and losses are presented in other gains/(losses) and impairment expenses are presented as a separate line item in the statements of loss.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.8 Investments and other financial assets (Continued)**

*(c) Measurement (Continued)*

*(i) Debt instruments (Continued)*

- FVPL: Assets that do not meet the criteria for amortized cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognized in profit or loss and presented net within other gains/(losses) in the period in which it arises.

*(ii) Equity instruments*

The Group subsequently measures all equity investments at fair value. Where the Group's management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the Group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognized in other gains/(losses) in the statements of loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

There were no equity investments during the reporting periods.

*(d) Impairment*

The Group assesses on a forward-looking basis the expected credit loss associated with its debt instruments carried at amortized cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

**2.9 Other receivables**

Other receivables are recognized initially at the amount of consideration that is unconditional, unless they contain significant financing components when they are recognized at fair value. The Group holds the other receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method, less loss allowance. See Note 3.1(b) for a description of the Group's impairment policies.

**2.10 Cash and cash equivalents**

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

**2.11 Share capital**

Ordinary shares are classified as equity. Mandatorily redeemable preferred shares are classified as liabilities. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Where any Group company purchases the Company's equity instruments, for example as the result of a share buy-back or a share-based payment plan, the consideration paid, including any directly attributable incremental costs (net of income taxes), is deducted from equity attributable to the owners of the Group as treasury shares until the shares are cancelled or reissued. Where such ordinary shares are subsequently reissued, any consideration received, net of any directly attributable incremental transaction costs and the related income tax effects, is included in equity attributable to the owners of the Group.

Shares held by Connect Union, which was established for the purpose of holding shares for the share incentive plans are disclosed as treasury shares and deducted from contributed equity.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.12 Trade and other payables**

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

**2.13 Financial instruments with preferred rights**

Financial instruments with preferred rights issued by the Group are convertible into ordinary shares upon the closing of a qualified initial public offering ("QIPO") or at the option of the holders and redeemable upon occurrence of certain future events as detailed in Note 24.

Financial instruments with preferred rights are compound instruments with discretionary dividend right. The Company elected to designate the entire hybrid contracts that include a host contract and embedded derivatives as financial liabilities at fair value through profit or loss considering the fact that the instruments also have contingent settlement provisions. They are initially recognized at fair value. Any directly attributable transaction costs are expensed in the consolidated statements of loss.

Subsequent to initial recognition, the amount of change in the fair value of the financial instruments with preferred rights that is attributable to changes in the credit risk of that liability shall be presented in OCI with the remaining changes in fair value recognized in profit or loss.

As of December 31, 2018 and 2019, management believes that there are no triggering events resulting in redemption in 12 months from each end of the reporting period and so the financial instruments with preferred rights are classified as non-current liabilities unless the Group has an obligation to settle the liabilities within 12 months after the end of the reporting period.

Dividends on financial instruments with preferred rights classified as financial liabilities are normally included in financial costs.

**2.14 Current and deferred income tax**

The income tax expense or credit for the period is the tax payable on the taxable income of current period based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

**(a) Current income tax**

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.14 Current and deferred income tax (Continued)**

*(b) Deferred income tax*

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Group is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority.

*Investment allowances and similar tax incentives*

Companies within the Group may be entitled to claim special tax deductions for investments in qualifying assets or in relation to qualifying expenditure (e.g. the research and development tax incentive or other investment allowances). The Group accounts for such allowances as tax credits, which means that the allowance reduces income tax payable and current tax expense. A deferred tax asset is recognized for unclaimed tax credits that are carried forward as deferred tax assets.

**2.15 Employee Benefits**

*(a) Short-term obligations*

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in other payables and accruals in the balance sheet.

*(b) Defined benefit plans*

The liability or asset recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method.

The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms approximating to the terms of the related obligation. In countries where there is no deep market in such bonds, the market rates on government bonds are used.

The net interest cost is calculated by applying the discount rate to the net balance of the defined benefit obligation and the fair value of plan assets. This cost is included in employee benefit expense in the statement of profit or loss.

Remeasurement gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in the period in which they occur, directly in other comprehensive income. They are included in retained earnings in the statement of changes in equity and in the balance sheet.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.15 Employee Benefits (Continued)**

*(b) Defined benefit plans (Continued)*

Changes in the present value of the defined benefit obligation resulting from plan amendments or curtailments are recognized immediately in profit or loss as past service costs.

*(c) Defined contribution plans*

For defined contribution plans, including those under Section 401(k) of the U.S. Internal Revenue Code, the Group pays contributions to publicly administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available.

The members of the Group incorporated in the PRC contribute based on a certain percentage of the salaries of their employees to a defined contribution retirement benefit plan organized by relevant government authorities in the PRC on a monthly basis. The government authorities undertake to assume the retirement benefit obligations payable to all existing and further retired employees under these plans and the Group has no further obligation for post-retirement benefits beyond the contributions made. Contributions to these plans are expensed as incurred. Assets of the plans are held and managed by government authorities and are separate from those of the Group.

*(d) Housing funds and medical insurance*

The PRC employees of the Group are entitled to participate in various government-supervised housing funds and medical insurance. The Group contributes on a monthly basis to these funds based on a certain percentage of the salaries of the employees, subject to certain ceilings. The Group's liability in respect of these funds is limited to the contribution payable in each period and recognized as employee benefit expense when they are due.

**2.16 Share-based compensation**

The Group operates an equity-settled share-based compensation plan, under which the Group receives services from employees, directors and consultants. The consultants' work for the Group is under the Group's direction in the same way as employees and the services rendered by the consultants are similar to those rendered by the Group's employees.

The fair value of options granted under the share incentive plans is recognized as an employee benefits expense with a corresponding increase in equity. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including any market performance conditions (e.g. the entity's share price);
- excluding the impact of any service and non-market performance vesting conditions (e.g. profitability, sales growth targets and remaining an employee of the entity over a specified time period); and
- including the impact of any non-vesting conditions (e.g. the requirement for employees to save or hold shares for a specific period of time).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the entity revises its estimates of the number of options that are expected to vest based on the non-market vesting and service conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

The share incentive plans are administered by Connect Union which is consolidated in accordance with the principles outlined in Note 1.2. When options issued under this plan are exercised, Connect Union transfers the appropriate amount of shares to the employees. The proceeds received net of any directly attributable transaction costs are credited directly to equity.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.17 Research and development expenses**

The Group incurs costs and efforts on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditure is incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed service or product and all the following criteria are met:

- the technical feasibility to complete the development project so that it will be available for use or sale;
- the intention to complete the development project to use or sell the product;
- the ability to use or sell the product;
- the manner in which the development project will generate probable future economic benefits for the Group;
- the availability of adequate technical, financial and other resources to complete the development project and use or sell the product; and
- the expenditure attributable to the asset during its development can be reliably measured.

Elements of research and development expenses primarily include (1) expenses related to preclinical testing of the Group's technologies under development and clinical trials such as payments to contract research organization ("CRO"), investigators and clinical trial sites that conduct the clinical studies; (2) consultant service related to the design of clinical trials and data analysis, (3) payroll and other related expenses of personnel engaged in research and development activities, (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group's research and development services and have no alternative future uses.

**2.18 Administrative expenses**

Administrative expenses primarily include payroll and related expenses for employees involved in general corporate functions including finance, legal and human resources, rental and depreciation expenses related to facilities and equipment used by these functions, professional service expenses and other general corporate related expenses.

**2.19 Interest Income**

Interest income from financial assets at FVPL is included in the net fair value gains/(losses) on these assets, see Note 8 below. Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that subsequently become credit-impaired. For credit-impaired financial assets, the effective interest rate is applied to the net carrying amount of the financial asset (after deduction of the loss allowance). Interest income is presented as finance income where it is earned from financial assets that are held for cash management purposes.

**2.20 Government grants**

Grants from the government are recognized at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions. Government grants relating to costs are deferred and recognized in profit or loss over the period necessary to match them with the costs that they are intended to compensate.

**2.21 Leases**

The Group leases offices and the rental contracts are typically made for fixed periods of 4 years.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of real estate for which the Group is a lessee, it has elected not to separate lease and non-lease components and instead accounts for these as a single lease component.

Lease terms are negotiated on an individual basis. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.21 Leases (Continued)**

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable by the Group under residual value guarantees;
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option; and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability;
- any lease payments made at or before the commencement date less any lease incentives received;
- any initial direct costs; and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases and all leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less without a purchase option.

**2.22 Segment Information**

Identification of segments is based on internal reporting to the chief operating decision maker ("CODM"). The CODM for the Group are the Co-Founders of the Company. The Group does not divide its operations into different segments and the CODM operates and manages the Group's entire operations as one segment, which is consistent with the Group's internal organization and reporting system. The Group does not have any revenue and substantially all non-current assets outside of the country of domicile are in China, as disclosed in Note 14.

**2.23 Loss per share**

*(i) Basic loss per share*

Basic loss per share is calculated by dividing:

- the loss attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares;

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**2. Summary of Significant Accounting Policies (Continued)**

**2.23 Loss per share (Continued)**

*(i) Basic loss per share (Continued)*

- by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year and excluding treasury shares

*(ii) Diluted loss per share*

Diluted loss per share adjusts the figures used in the determination of basic loss per share to take into account:

- the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and
- the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

**3. Financial Instruments and Risk Management**

**3.1 Financial risk factors**

The Group's activities expose it to a variety of financial risks: market risk (including interest rate risk and exchange risk), credit risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Risk management is carried out by the senior management of the Group.

**(a) Market risk**

*(i) Interest rate risk*

The Group's interest rate risk primarily arises from wealth management products investments measured at fair value through profit or loss (Note 17) and cash and cash equivalents (Note 18). Those carried at variable rates expose the Group to cash flow interest rate risk whereas those at fixed rates expose the Group to fair value interest rate risk. The Group did not have significant interest rate risk during the periods presented.

*(ii) Exchange risk*

The Group operates internationally and is exposed to foreign exchange risk, primarily the USD. Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities denominated in a currency that is not the functional currency of the relevant group entity. The Group's exposure to foreign currency risk at the end of the reporting periods, expressed in RMB, was as follows:

	DECEMBER 31, 2018		DECEMBER 31, 2019	
	USD RMB'000	AUSTRALIAN DOLLAR RMB'000	USD RMB'000	AUSTRALIAN DOLLAR RMB'000
Cash and cash equivalents	12,805	—	32,028	—
Other receivables and prepayments	—	10	—	—

The aggregate net foreign exchange gains recognized in profit or loss were:

	YEAR ENDED DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
Net foreign exchange gains included in other gains—net	3,255	2,252

Most foreign exchange transactions were denominated in USD for the subsidiary that have functional currency in RMB. For the years ended December 31, 2018 and 2019, if the USD strengthened/weakened by 5% against the



**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**3. Financial Instruments and Risk Management (Continued)**

**3.1 Financial risk factors (Continued)**

**(a) Market risk (Continued)**

*(ii) Exchange risk (Continued)*

RMB with all other variables held constant, net loss for the years then ended would have been RMB598,000 lower/higher, RMB1,572,000 lower/higher, respectively.

**(b) Credit risk**

Credit risk primarily arises from cash and cash equivalents, financial assets at fair value through profit or loss, and other receivables. The maximum exposure to credit risk is represented by the carrying amount of each financial asset in the balance sheets.

The credit risk of cash and cash equivalents and financial assets at fair value through profit or loss is limited because the counterparties are mainly state-owned or reputable commercial institutions located in the PRC and other reputable financial institutions located in Australia and the U.S.

For other receivables, management makes periodic as well as individual assessments on the recoverability based on historical settlement records and past experience and adjusts for forward-looking information based on macroeconomic factors affecting the ability of the debtors to settle the receivables.

The Group applies the expected credit loss model to financial assets measured at amortized cost. Impairment on other receivables is measured as either 12-month expected credit losses or lifetime expected credit losses, depending on whether there has been a significant increase in credit risk since initial recognition. To assess whether there is a significant increase in credit risk, the Group compares the risk of default occurring on the asset as of the reporting date with the risk of default as of the date of initial recognition by considering available, reasonable and supportive forwarding-looking information.

In view of the history of cooperation with debtors, the sound collection history of other receivables as well as forward-looking factors, management believes that the credit risk inherent in these outstanding receivables is not significant.

**(c) Liquidity risk**

The Group aims to maintain sufficient cash to meet obligations coming due as well as operating and capital requirements.

The table below analyzes the Group's financial liabilities into relevant maturity groupings based on the remaining period at each year-end date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows except for financial instruments with preferred rights, which are presented on a fair value basis. The maturity dates are determined by the terms in financing agreements presented in Note 24(c) as management considers the other redemption terms are not probable to occur.

	AS OF DECEMBER 31, 2018				
	LESS THAN 1 YEAR RMB'000	BETWEEN 1 AND 2 YEARS RMB'000	BETWEEN 2 AND 5 YEARS RMB'000	MORE THAN 5 YEARS RMB'000	TOTAL RMB'000
Financial instruments with preferred rights	—	—	573,499	—	573,499
Trade payables	3,437	—	—	—	3,437
Other payables	238	—	—	—	238
Lease liabilities	445	445	482	—	1,372
<b>Total</b>	<b>4,120</b>	<b>445</b>	<b>573,981</b>	<b>—</b>	<b>578,546</b>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**3. Financial Instruments and Risk Management (Continued)**

**3.1 Financial risk factors (Continued)**

**(c) Liquidity risk (Continued)**

	AS OF DECEMBER 31, 2019				TOTAL RMB'000
	LESS THAN 1 YEAR RMB'000	BETWEEN 1 AND 2 YEARS RMB'000	BETWEEN 2 AND 5 YEARS RMB'000	MORE THAN 5 YEARS RMB'000	
	Financial instruments with preferred rights	—	—	643,008	
Trade payables	22,788	—	—	—	22,788
Other payables	664	—	—	—	664
Lease liabilities	445	445	37	—	927
<b>Total</b>	<b>23,897</b>	<b>445</b>	<b>643,045</b>	<b>—</b>	<b>667,387</b>

**3.2 Capital Management**

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group monitors capital by regularly reviewing the capital structure. The Group may adjust the amount of dividends paid to shareholders, provide returns for shareholders, issue new shares or sell assets to repay borrowings.

The Group monitors capital on the basis of the debt-to-adjusted capital ratio. This ratio is calculated as net debt divided by adjusted capital. Net debt is calculated as total borrowings less cash and cash equivalents. Adjusted capital comprises all components of equity as shown in the consolidated balance sheets and preferred shares on an as-if-converted basis. As of December 31, 2018 and 2019, the Group had no debt outstanding.

**3.3 Fair value estimation**

The table below analyzes the Group's financial instruments carried at fair value as of December 31, 2018 and 2019 by level of the inputs to valuation techniques used to measure fair value. Such inputs are categorized into three levels within a fair value hierarchy as follows:

- (i) Quoted prices (unadjusted) in active markets for identical assets or liabilities (level 1).
- (ii) Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (level 2).
- (iii) Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs) (level 3).

AS OF DECEMBER 31, 2018	LEVEL 1 RMB'000	LEVEL 2 RMB'000	LEVEL 3 RMB'000	TOTAL RMB'000
<b>Assets</b>				
Financial assets at fair value through profit or loss	—	—	27,565	27,565
<b>Total assets</b>	<b>—</b>	<b>—</b>	<b>27,565</b>	<b>27,565</b>
<b>Liabilities</b>				
Financial instruments with preferred rights	—	—	573,499	573,499
<b>Total liabilities</b>	<b>—</b>	<b>—</b>	<b>573,499</b>	<b>573,499</b>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**3. Financial Instruments and Risk Management (Continued)**

**3.3 Fair value estimation (Continued)**

AS OF DECEMBER 31, 2019	LEVEL 1 RMB'000	LEVEL 2 RMB'000	LEVEL 3 RMB'000	TOTAL RMB'000
<b>Assets</b>				
Financial assets at fair value through profit or loss	—	—	30,632	30,632
<b>Total assets</b>	—	—	30,632	30,632
<b>Liabilities</b>				
Financial instruments with preferred rights	—	—	643,008	643,008
<b>Total liabilities</b>	—	—	643,008	643,008

There were no transfers between levels 1, 2 and 3 during the years.

**Financial instruments in Level 3**

If one or more of the significant inputs are not based on observable market data, the instrument is included in level 3.

Specific valuation techniques used to value financial instruments include:

- Quoted market prices or dealer quotes for similar instruments;
- A combination of observable and unobservable inputs, including risk-free rate, expected volatility, discount rate for lack of marketability ("DLOM"), etc.

Level 3 instruments within the Group's assets and liabilities include short-term investment in wealth management products measured at fair value through profit or loss and financial instruments with preferred rights.

The following table presents the changes in level 3 instruments of short-term investment in wealth management products for the years ended December 31, 2018 and 2019.

	YEAR ENDED DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
<b>Financial assets at fair value through profit or loss</b>		
Opening balance	27,276	27,565
Additions	106,700	163,000
Settlements	(106,958)	(160,731)
Investment income credited to profit or loss (Note 8)*	547	798
Closing balance	27,565	30,632
* includes unrealised gains or (losses) recognized in profit or loss attributable to balances held at the end of the reporting period	65	132

The valuation of Level 3 instruments of wealth management products and financial instruments with preferred rights is set out in Note 17 and Note 24.

The changes in level 3 instruments of financial instruments with preferred rights for the years ended December 31, 2018 and 2019 are presented in Note 24.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**3. Financial Instruments and Risk Management (Continued)**

**3.3 Fair value estimation (Continued)**

The carrying amounts of the Group's other financial assets and liabilities, including cash and cash equivalents, other receivables, trade payable and other payables, approximate their fair values.

**4. Critical accounting estimates and judgements**

The preparation of financial statements requires the use of accounting estimates which, by definition, may not equal the actual results. Management also needs to exercise judgment in applying the Group's accounting policies.

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the Group and that are believed to be reasonable under the circumstances.

**a) Fair value of financial assets**

The fair value of financial assets that are not traded in an active market is determined using valuation techniques. The Group uses its judgement to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period.

**b) Fair value of financial instruments with preferred rights**

The fair value of financial instruments with preferred rights that are not traded in an active market is determined using valuation techniques. The Group first determined the equity value and then allocated the equity value to each element of the Group's capital structure using either an option pricing backsolve method ("OPM"), or a hybrid method, which employs the concepts of the OPM and the probability-weighted expected return method ("PWERM") that merged into a single framework.

Key assumptions such as risk-free interest rate, DLOM and expected volatility are disclosed in Note 24.

**c) Recognition of share-based compensation expenses**

As mentioned in Note 22, the equity-settled share-based compensation plan was granted to employees and consultants. The Group has used the Binomial option pricing model to determine the total fair value of the awarded options, which is to be expensed over the vesting period. Significant estimates on assumptions, such as the fair value of underlying shares, risk-free interest rate, expected volatility and dividend yield, are required to be made by the management.

**d) Current and deferred income taxes**

*(i) Deferred income tax*

The Group recognizes deferred tax assets based on estimates that it is probable to generate sufficient taxable profits in the foreseeable future against which the deductible losses and temporary differences will be utilized. The recognition of deferred tax assets mainly involves management's judgments and estimations about the timing and the amount of taxable profits of the companies which have tax losses.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**5. Expenses by nature**

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	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
CRO expenses	45,248	82,046
Consultancy fee	5,285	12,011
Employee benefit expenses (Note 6)	8,646	15,098
Office expenses	2,057	2,424
R&D materials and consumable supplies	980	988
Depreciations	631	790
Others	3,603	2,770
	<u>66,450</u>	<u>116,127</u>

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The Company exclusively licenses CBP-174 from Arena Pharmaceuticals, Inc. ("Arena"). Such license is worldwide and royalty-bearing. As of December 31, 2018 and 2019, CBP-174 has not yet been commercialized, the Company is only subject to a non-refundable, non-creditable license maintenance fee of USD20,000, which is paid to Arena on an annual basis and recorded within research and development expense.

**6. Employee Benefit Expenses**

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	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Wages, salaries and bonuses	6,315	8,628
Contributions to defined benefit plan (Note 26(d))	898	1,140
Share-based compensation expenses (Note 22)	584	3,875
Welfare expenses	518	964
Housing funds	331	491
	<u>8,646</u>	<u>15,098</u>

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Employee benefit expenses were charged in the following line items in the consolidated statements of loss:

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	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Research and development expenses	6,282	11,496
Administrative expenses	2,364	3,602
	<u>8,646</u>	<u>15,098</u>

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**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**7. Other income**

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Government grants	433	2,836

Government grants are cash incentives received related to specific operating expenses incurred.

**8. Other gains—net**

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Net foreign exchange gains	3,255	2,252
Investment income from wealth management products	547	798
	<u>3,802</u>	<u>3,050</u>

**9. Finance (cost)/ income—net**

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
<b>Finance income</b>		
Interest from bank deposits and term deposits	1,255	1,066
<b>Finance cost</b>		
Issuance cost of financial instruments with preferred rights	(9,859)	—
Interest for lease liabilities	(46)	(53)
	<u>(9,905)</u>	<u>(53)</u>
<b>Finance (cost)/ income—net</b>	<u>(8,650)</u>	<u>1,013</u>

**10. Income Taxes**

Income tax expense is recognized based on the income tax rates in the following main tax jurisdictions where the Group operates for the years ended December 31, 2018 and 2019.

**(a) Cayman Islands**

The Company is incorporated in the Cayman Islands as an exempted company with limited liabilities under the Companies Law of the Cayman Islands and accordingly, is exempted from Cayman Islands income tax.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**10. Income Taxes (Continued)**

**(b) Hong Kong**

Hong Kong profits tax rate is 16.5% as of April 1, 2018 when the two-tiered profits tax regime took effect, under which the tax rate is 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 during the years ended December 31, 2018 and 2019.

**(c) United States**

Connect US is incorporated in the U.S. and is a disregarded entity wholly owned by Connect SZ (before September 2018) and then Connect HK from tax perspective. Therefore, from a U.S. tax perspective, it is Connect SZ and Connect HK that are subject to US federal corporate income tax at a rate of 21% during the reporting periods. Connect SZ and Connect HK are also subject to state income tax in California at a rate of 8.84%, to the extent of the income attributable to Connect US. Connect US had no profit that is subject to income tax for all periods presented, therefore, no provision for income taxes has been provided.

**(d) Australia**

Connect AU is incorporated in Australia. Companies registered in Australia are 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%. Connect AU has no taxable income for all periods presented, therefore, no provision for income taxes has been provided.

**(e) PRC**

Provision for PRC corporate income tax is calculated based on the statutory income tax rate of 25% on the assessable income of respective PRC Group entities during the years ended December 31, 2018 and 2019 in accordance with relevant PRC enterprise income tax rules and regulations.

No provision for PRC corporate income tax has been made for the years ended December 31, 2018 and 2019 as the Group had no such assessable profit for the years then ended.

The reconciliation between the Group's actual tax charge and the amount that is calculated based on the statutory income tax rate of 25% in the PRC is as follows:

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Loss before income tax	(93,877)	(168,625)
Tax calculated at statutory tax rate of 25%	(23,469)	(42,156)
Effect of tax rate differences in other countries	650	16,930
Expenses not deductible for income tax purpose (a)	5,709	799
Super deduction of research and development expenses (b)	(7,715)	(9,529)
Tax losses and deductible temporary differences for which no deferred income tax assets were recognized	24,825	33,956
Income tax expense	—	—

(a) It is mainly comprised of share-based compensation expenses and fair value loss of financial instruments with preferred rights issued by Connect SZ which are permanent differences.

(b) According to policies promulgated by the State Tax Bureau of the PRC, certain of the Group's subsidiaries are entitled to tax incentives for research and development expenses at 175% of tax-deductible research and development expenses in 2018 and 2019.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**10. Income Taxes (Continued)****(e) PRC (Continued)**

The Group did not recognize deferred income tax assets for the tax losses and deductible temporary differences that amounted to approximately RMB 136 million and RMB 284 million as of December 31, 2018 and 2019, respectively that can be carried forward against future taxable income.

As of December 31, 2018 and 2019, the Group did not have any significant unrecognized uncertain tax positions.

**11. Loss Per Share**

The number of ordinary shares outstanding increased in 2018 as a result of the cancellation and reissuance of ordinary shares which gave the same effect as a share split, as set out in Note 19. To calculate loss per share, the new number of shares upon reissuance has been used retrospectively since January 1, 2018 for the calculation of the weighted average number of ordinary shares outstanding.

Basic and diluted losses per share reflecting the effect of the issuance of ordinary shares by the Company are presented as follows.

Basic loss per share is calculated by dividing the loss attributable to owners of the Company by the weighted average number of ordinary shares outstanding, excluding treasury shares which are detailed in Note 20.

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	YEAR ENDED DECEMBER 31,	
	2018	2019
Loss attributable to owners of the Company (RMB'000)	(76,965)	(168,625)
Weighted average number of ordinary shares outstanding (in thousands)	21,478	29,362
<b>Basic loss per share (RMB)</b>	<u>(3.58)</u>	<u>(5.74)</u>

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Share options and preferred shares are considered as potential dilutive shares throughout the reporting period. However, since the Group had incurred losses for the years ended December 31, 2018 and 2019, the potential dilutive shares have anti-dilutive effect on loss per share if they are converted to ordinary shares. Thus diluted loss per share is equivalent to the basic loss per share.

**12. Non-controlling interests****Transaction with NCI**

In 2018 the Group acquired the remaining 30% equity interest in Connect SZ by issuing ordinary shares of the Company at fair value of RMB 38,094,000. Immediately prior to the purchase, the carrying amount of the 30% NCI in Connect SZ was a deficit of RMB 6,852,000. After such transaction, Connect SZ became wholly owned subsidiary of the Company. The effect on the equity attributable to the owners of the Company during the year is summarized as follows:

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	YEAR ENDED DECEMBER 31, 2018	
	RMB'000	
Carrying amount of NCI acquired		(6,852)
Fair value of the consideration to NCI		38,094
Excess of consideration paid recognized in the transactions with NCI reserve within equity		<u>44,946</u>

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**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**13. Property, Plant and Equipment**

	<u>LABORATORY EQUIPMENT</u> RMB'000	<u>LEASEHOLD IMPROVEMENTS</u> RMB'000	<u>OFFICE EQUIPMENT AND FURNITURE</u> RMB'000	<u>TOTAL</u> RMB'000
<b>As of January 1, 2018</b>				
Cost	1,657	14	336	2,007
Accumulated depreciation	(708)	(2)	(278)	(988)
Net book value	<u>949</u>	<u>12</u>	<u>58</u>	<u>1,019</u>
<b>Year Ended December 31, 2018</b>				
Opening net book value	949	12	58	1,019
Additions	349	595	246	1,190
Depreciation	(199)	(105)	(55)	(359)
Closing net book value	<u>1,099</u>	<u>502</u>	<u>249</u>	<u>1,850</u>
<b>As of December 31, 2018</b>				
Cost	2,006	609	582	3,197
Accumulated depreciation	(907)	(107)	(333)	(1,347)
Net book value	<u>1,099</u>	<u>502</u>	<u>249</u>	<u>1,850</u>

	<u>LABORATORY EQUIPMENT</u> RMB'000	<u>LEASEHOLD IMPROVEMENTS</u> RMB'000	<u>OFFICE EQUIPMENT AND FURNITURE</u> RMB'000	<u>TOTAL</u> RMB'000
<b>Year Ended December 31, 2019</b>				
Opening net book value	1,099	502	249	1,850
Additions	1,053	19	—	1,072
Depreciation	(214)	(127)	(42)	(383)
Closing net book value	<u>1,938</u>	<u>394</u>	<u>207</u>	<u>2,539</u>
<b>As of December 31, 2019</b>				
Cost	3,059	628	582	4,269
Accumulated depreciation	(1,121)	(234)	(375)	(1,730)
Net book value	<u>1,938</u>	<u>394</u>	<u>207</u>	<u>2,539</u>

**14. Other non-current assets**

Other non-current assets include deductible value-added tax ("VAT") balances which can offset against future VAT payables.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**15. Financial instruments by category**

<b>FINANCIAL ASSETS</b>	<b>FINANCIAL ASSETS AT FVPL RMB'000</b>	<b>FINANCIAL ASSETS AT AMORTIZED COST RMB'000</b>	<b>TOTAL RMB'000</b>
<b>As of December 31, 2018</b>			
Other receivables	—	2,469	2,469
Financial assets at fair value through profit or loss	27,565	—	27,565
Cash and cash equivalents	—	401,597	401,597
	<u>27,565</u>	<u>404,066</u>	<u>431,631</u>

<b>FINANCIAL ASSETS</b>	<b>FINANCIAL ASSETS AT FVPL RMB'000</b>	<b>FINANCIAL ASSETS AT AMORTIZED COST RMB'000</b>	<b>TOTAL RMB'000</b>
<b>As of December 31, 2019</b>			
Other receivables	—	5,180	5,180
Financial assets at fair value through profit or loss	30,632	—	30,632
Cash and cash equivalents	—	308,972	308,972
	<u>30,632</u>	<u>314,152</u>	<u>344,784</u>

<b>FINANCIAL LIABILITIES</b>	<b>FINANCIAL LIABILITIES AT FVPL RMB'000</b>	<b>FINANCIAL LIABILITIES AT AMORTIZED COST RMB'000</b>	<b>TOTAL RMB'000</b>
<b>As of December 31, 2018</b>			
Financial instruments with preferred rights	573,499	—	573,499
Other payables	—	238	238
Trade payables	—	3,437	3,437
Lease liabilities	—	1,274	1,274
	<u>573,499</u>	<u>4,949</u>	<u>578,448</u>

<b>FINANCIAL LIABILITIES</b>	<b>FINANCIAL LIABILITIES AT FVPL RMB'000</b>	<b>FINANCIAL LIABILITIES AT AMORTIZED COST RMB'000</b>	<b>TOTAL RMB'000</b>
<b>As of December 31, 2019</b>			
Financial instruments with preferred rights	643,008	—	643,008
Other payables	—	664	664
Trade payables	—	22,788	22,788
Lease liabilities	—	882	882
	<u>643,008</u>	<u>24,334</u>	<u>667,342</u>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**16. Other receivables and prepayments**

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	AS OF DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
Prepayment for CRO services	13,724	17,557
Deposits	2,429	4,440
Good and Service Tax Recoverable	370	471
Others	40	740
	<u>16,563</u>	<u>23,208</u>

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**17. Financial assets at fair value through profit or loss**

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	AS OF DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
Wealth management products	<u>27,565</u>	<u>30,632</u>

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The returns on these wealth management products were not guaranteed, hence their contractual cash flows did not qualify solely as payments of principal and interest. Therefore, they were measured at fair value through profit or loss. Wealth management products held by the Group with various maturities bear floating interest rates of 1.70%-4.99% and 2.6%-4.5% per annum for the years ended December 31, 2018 and 2019, respectively.

The fair value of wealth management products is based on discounted cash flows using their expected returns. Changes in fair value of these financial assets are recorded in other gains – net in the consolidated statements of loss.

**18. Cash and Cash Equivalents**

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	AS OF DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
Cash at bank		
—USD deposits	394,731	303,108
—RMB deposits	6,607	4,811
—Australian Dollar deposits	259	1,053
	<u>401,597</u>	<u>308,972</u>

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Cash at bank earns interest at floating rates based on daily bank deposit rates.

Cash at banks denominated in RMB are deposited with banks in the PRC. The conversion of these RMB-denominated balances into foreign currencies and the remittance of funds out of China are subject to the rules and regulations of foreign exchange control promulgated by the Government of the PRC.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**19. Share Capital**

The authorized share capital of the Company as of December 31, 2019 is USD50,000 divided into 500,000,000 Shares of par value of USD0.0001 each, including 478,292,221 ordinary shares, 3,109,000 Series Pre-A preferred shares, 8,471,200 Series A preferred shares and 10,127,579 Series B preferred shares. Refer to Note 24 for significant terms of preferred shares.

ISSUED	NUMBER OF ORDINARY SHARES '000	SHARE CAPITAL USD'000	SHARE CAPITAL RMB'000	SHARE PREMIUM* USD'000	SHARE PREMIUM* RMB'000	TOTAL USD'000	TOTAL RMB'000
<b>As of January 1, 2018</b>	10	10	64	(10)	(64)	—	—
Issuance of ordinary shares	10	10	70	(10)	(70)	—	—
Cancellation of ordinary shares	(20)	(20)	(134)	20	134	—	—
Issuance of treasury shares	1,539	—	1	—	—	—	1
Reissuance of ordinary shares	20,000	2	14	(2)	(14)	—	—
Transaction with non-controlling interests	9,233	1	6	5,538	38,088	5,539	38,094
<b>As of December 31, 2018</b>	30,772	3	21	5,536	38,074	5,539	38,095
<b>As of January 1, 2019</b>	30,772	3	21	5,536	38,074	5,539	38,095
Exercise of share options	—	—	—	7	49	7	49
<b>As of December 31, 2019</b>	30,772	3	21	5,543	38,123	5,546	38,144

\* Share premium mainly included historical cash contribution to the Company by its ordinary shareholders. The negative share premium represents issued ordinary shares issued but not fully paid.

As of December 20, 2018, previously issued ordinary shares were cancelled and 20,000,000 ordinary shares were reissued to the Co-Founders at par value of USD0.0001.

Pursuant to the Company's shareholder agreement in effect as of the completion of the Series B financing, each of the Company's founders is entitled to two or more votes to ensure the Co-Founders control the majority of the votes under certain circumstances.

**20. Treasury shares**

Treasury shares held by Connect Union are shares for the purpose of issuing shares under the share incentive plans. As of December 31, 2018 and 2019, 1,538,800 and 1,526,095 ordinary shares of the Company were held by Connect Union and considered as treasury shares, respectively.

**21. Reserves**

**(a) Share-based compensation reserves**

The share-based compensation reserves represent the fair value of unexercised options granted to employees recognized in accordance with the accounting policy adopted for equity-settled share-based payments described in Note 2.16 to the financial statements.

**(b) Other reserves**

Other reserves represent the reserve transferred from share-based compensation reserve upon exercise of share options, transaction with non-controlling interests reserve described in Note 12 and foreign currency translation reserve described in Note 2.5(c).

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**21. Reserves (Continued)**

**(c) Statutory reserves**

In accordance with the PRC regulations and the articles of association of the PRC companies now included in the Group, before annual profit distribution companies registered in the PRC are required to set aside 10% of their net profit for the year after offsetting any prior year losses as determined under relevant PRC accounting standards to the statutory surplus reserve fund. When the balance of such reserve reaches 50% of the entity's registered capital, any further appropriation is optional. No profit appropriation to the reserve fund was made for those Group entities for the reporting periods as they were in accumulated loss positions.

Under PRC laws and regulations, there are restrictions on the Company's PRC subsidiaries with respect to transferring certain of their net assets to the Company either in the form of dividends, loans, or advances. Restricted net assets including paid-in capital and statutory reserve funds of the Company's PRC subsidiaries was nil as of December 31, 2018 and amounted to RMB37 million as of December 31, 2019.

**22. Share-Based Compensation**

**2019 Stock Incentive Plan**

The Group adopted the 2019 stock incentive plan and obtained Board's approval on November 1, 2019, under which the Group may grant various awards such as options, restricted shares or restricted share units to employees, directors, and consultants for services rendered. The Group has reserved 1,538,800 ordinary shares which are held by Connect Union for the issuance of options that are considered as treasury shares.

Pursuant to the plan, a grantee has the right to subscribe for the ordinary shares at a price determined by the Board. The options granted can only vest if the service conditions are met. Options granted under the plan are valid and effective for 10 years from the date of grant and vest over a service period which is generally four years; 25% of the granted options vest on the first anniversary of the grant date and the remaining options vest in equal monthly installments over next 36 months. Some options are vested in equal monthly installments over the entire service period or vested immediately upon the grant date in instances where services had already been performed in their entirety.

The Chinese grantees are entitled to subscribe for underlying shares only if an IPO is achieved, provided that the service condition is also met. As of each grant date during the year ended December 31, 2019, management believed achievement of the IPO was probable.

The grant date of certain grantees occurred after the date they had begun rendering services to satisfy the condition attached to the share option award, the management estimated the grant date fair value in each reporting period for the purpose of recognizing the expense during the period between the service commencement date and the grant date. Once the grant date has been established, the recognized expense is based on the actual grant date fair value of the share option in the period of change.

Grantees who leave the Group other than for certain causes will lose their entitlement to the vested options if not exercised within three months of their termination date (or within three months after the IPO kick-off date for certain option holders).

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**22. Share-Based Compensation (Continued)**

The activities of the options outstanding at December 31, 2019 were as follows:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE OPTION
Options outstanding at December 31, 2018	—	
Granted during the year	344,631	USD 0.55
Exercised during the year	(12,705)	USD 0.55
Options outstanding at December 31, 2019	<u>331,926</u>	
Options exercisable at December 31, 2019	<u>208,580</u>	

The weighted average remaining contractual life of options outstanding as of December 31, 2019 is 7.63 years.

**Fair value of options granted**

The Group determined its equity value which was estimated using the hybrid method and adopted the allocation model to determine the fair value of its underlying ordinary shares.

Based on the fair value of underlying ordinary shares, the Group used the Binomial option-pricing model to determine the fair value of options as of the grant date. Key assumptions for the options granted are set forth below:

	YEAR ENDED DECEMBER 31, 2019
Exercise price	USD 0.55
Grant date share price	USD 1.103~USD 1.180
Risk-free interest rate	1.7%~2.1%
Expected volatility	56.6%~77.4%
Option life	10 years
Expected early exercise multiple	2.20
Dividend yield	Nil
Forfeiture rate	9.55%
Weighted average fair value of options granted during the year	USD 0.707

The Company adopted the average volatility of the comparable companies as the proxy of the expected volatility of the underlying share. The volatility of each comparable company was based on the historical daily stock prices for a period with length commensurate to the remaining maturity life of the share options.

**Share-based compensation to Co-Founders**

On December 20, 2018, pursuant to the shareholders agreement entered into among the Company and all its shareholders in connection with its Series B financing, up to 702,278 and 1,140,474 ordinary shares will be issued to the Co-Founders and Connect Union, respectively, for no consideration, contingent on achieving of various R&D milestones as non-market performance conditions. Under such agreement, the ordinary shares may also be issued in a lump sum immediately after the closing of new financing that meets several requirements including, among others, the pre-money valuation of the Group exceeding USD600,000,000 (the "2018 Incentive Plan"). Such shares to be issued to Connect Union were reserved for future issuance of options. Upon achievement of certain R&D milestones, 351,140 ordinary shares were vested and yet to be issued to the Co-Founders as of December 31, 2019. The Company recognized the related share-based compensation expenses in the amounts of RMB 0.6 million and RMB 2.7 million for the years ended December 31, 2018 and 2019, respectively.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**22. Share-Based Compensation (Continued)**

The Group determined its equity value which was estimated using the hybrid method and adopted the allocation model to determine the fair value of this share-based payment as USD0.9870 per share on the grant date. Key assumptions included risk-free interest rate of 2.54%, expected volatility of 60%, dividend yield of nil based on the management's best estimates.

Share-based compensation expenses included in the consolidated statements of loss for the years ended December 31, 2018 and 2019 is as follows:

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Research and development expenses	584	3,635
Administrative expenses	—	240
	<u>584</u>	<u>3,875</u>

**23. Other Payables and Accruals**

	AS OF DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Payroll, welfare and bonus payables	2,223	3,488
Accrued professional service fee	193	527
Accrued taxes other than income tax	38	45
Others	45	137
	<u>2,499</u>	<u>4,197</u>

**24. Financial Instruments with Preferred Rights**

The Group has completed a series of financings by issuing preferred shares with the following details:

DATE OF SUBSCRIPTION	ROUND	NUMBER OF PREFERRED SHARES	SUBSCRIPTION CONSIDERATION (RMB'000)
March 3, 2016	Series Pre-A	3,109,000	33,110
January 3, 2017	Series A	8,471,200	137,868
December 20, 2018	Series B	10,127,579	379,148
		<u>21,707,779</u>	<u>550,126</u>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**24. Financial Instruments with Preferred Rights (Continued)**

The key preferred rights of the above preferred shares are summarized as follows:

**(a) Conversion Feature**

*i) Optional conversion*

Each holder of preferred share shall be entitled to exercise its right to convert any of its preferred shares, at any time after the date of issuance of such shares, and each preferred share may be convertible into a certain number of fully paid and non-assessable ordinary shares at a ratio calculated by dividing the Series Pre-A issue price, the Series A issue price, or the Series B issue price, as applicable, by the then applicable conversion price (the "Conversion Price"). The Conversion Price is initially equal to the Series Pre-A issue price, the Series A issue price, or the Series B issue price, as applicable, and is subject to adjustment from time to time to reflect stock dividends, stock splits and other events. For the avoidance of doubt, no payment shall be made by the holders of preferred shares to the Company upon or in connection with the conversion of the preferred shares into ordinary shares.

*ii) Automatic conversion*

The preferred shares held by each holder shall be, at the applicable Conversion Price in effect at the time of conversion, without the payment of any additional consideration, converted into fully-paid and non-assessable ordinary shares upon the closing of a QIPO.

**(b) Liquidation preferences**

In the event of (i) any liquidation, dissolution or termination event, whether voluntary or involuntary, or (ii) unless waived by the holders of at least a majority of ordinary shares and the holders of at least two thirds of the preferred shares (calculated on a fully-diluted and as-converted basis), any deemed liquidation event as defined in the Company's shareholders agreement, such as a merger, consolidation, sale, transfer, lease, exclusive license or other disposal of all or substantially all of the assets or intellectual property of the Company or of all of its subsidiaries as a whole ("Deemed Liquidation Event"), all assets and funds legally available for distribution shall be distributed to the holders of preferred shares in preference to the holders of ordinary shares, in an amount per share equal to the applicable series issue price plus any declared but unpaid dividends (the "Preference Amount").

The full preferential amount is first paid to the holders of the series of preferred shares that was most recently issued then to the holders of the next level of preference in order (Series B preferred shares, Series A preferred shares, and Series Pre-A preferred shares (ranked pari passu), which are listed in order of highest liquidation preference to lowest).

If there are any assets or funds remaining after the aggregate Series Pre-A Preference Amount, Series A Preference Amount, and Series B Preference Amount have been distributed or paid in full to the applicable holders of the preferred shares, the remaining assets and funds of the Company available for distribution shall be distributed ratably among all shareholders (including the preferred shareholders) according to the relative number of ordinary shares of the Company held by such shareholder (on an as-converted basis).

If the available funds and assets become insufficient to satisfy the full preferential payment to the holders of a particular series of preferred shares, then such assets shall be distributed among the holders of that particular series of preferred shares, ratably in proportion to the full amounts to which they would otherwise be respectively entitled thereon.

**(c) Redemption rights**

Upon the occurrence of any of the following events, any holder of any other series of preferred shares is entitled to request a redemption of any of its shares.

- (i) the Company fails to consummate a QIPO on or before December 31, 2024 (the "Target QIPO Date"), such Target QIPO Date shall be postponed reasonably if any force majeure event adversely affects the process of the QIPO of the Company and the postponement arising therefrom is agreed by all the parties (including the preferred shareholders);



**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**24. Financial Instruments with Preferred Rights (Continued)****(c) Redemption rights (Continued)**

- (ii) the Company or any of the Co-Founders or the other group companies materially breaches its or his representations, warranties, covenants or obligations under any transaction document.

With the written consent of the holder(s) of more than fifty percent (50%) of the voting power of the aggregate number of a particular series of issued and outstanding preferred shares, the Company shall redeem such particular series of preferred shares, out of funds legally available therefor including the capital.

The redemption price for each issued and outstanding Series B preferred share (the "Series B Redemption Price") shall be the amount equal to the sum of (i) an amount that would give an internal rate of return that equals to eight percent (8%) per annum on such Series B preferred share in respect of the Series B issue price, calculated for a period of time commencing from the Series B issue date and ending on the date that the Series B Redemption Price is paid in full by the Company, and (ii) any declared but unpaid dividends thereupon.

Series A Redemption Price is the amount equal to 150% of the Series A issue Price and any declared but unpaid dividends thereupon.

Pre-A shareholders do not have redemption rights, although they have a liquidation preference upon occurrence of any Deemed Liquidation Events.

**(d) Dividends**

Dividends are payable when and if declared by the Board out of funds legally available, and such dividends are not cumulative. Holders of the shares shall be entitled to receive out of any funds legally available therefor, when, as and if declared by the Board, non-cumulative dividends, as well as any non-cash dividends when, as and if declared by the Board. In the event the Company shall declare a distribution other than in cash, the holders of shares shall be entitled to a proportionate share of any such distribution when, as and if declared by the Board.

No dividends have been declared as of December 31, 2019.

The Group designates the entire instruments as financial liabilities at fair value through profit or loss with the changes in the fair value recorded in the consolidated statements of loss, except for the changes in the fair value due to own credit risk, which are recorded in other comprehensive income/(loss).

Movements of financial instruments with preferred rights during the years ended December 31, 2018 and 2019 were as follow:

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	<u>FAIR VALUE</u> <u>RMB'000</u>
<b>Year ended December 31, 2018</b>	
<b>As of January 1, 2018</b>	175,693
Issuance of Series B Preferred Shares	379,148
Change in fair value recognized in profit or loss	23,012
Change in fair value due to foreign currency translation recognized in OCI	<u>(4,354)</u>
<b>As of December 31, 2018</b>	<u>573,499</u>
<b>Year ended December 31, 2019</b>	
<b>As of January 1, 2019</b>	573,499
Change in fair value recognized in profit or loss	59,397
Change in fair value due to foreign currency translation recognized in OCI	<u>10,112</u>
<b>As of December 31, 2019</b>	<u>643,008</u>

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**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**24. Financial Instruments with Preferred Rights (Continued)**

The Group first determined the equity value and then allocated the equity value to each element of the Group's capital structure using either OPM or a hybrid method.

Key valuation assumptions used to determine the fair value of the financial instruments with preferred rights are as follows:

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	YEAR ENDED DECEMBER 31,	
	2018	2019
DLOM	28% ~ 32%	25.85% ~ 30.70%
Expected volatility	55% ~ 60%	55% ~ 55.99%
Risk-Free interest rate	2.54% ~ 3.48%	1.68% ~ 2.33%

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DLOM was estimated based on OPM. Under OPM, the cost of put option, which can hedge price changes before the privately held shares are sold, was considered as a basis to determine the DLOM.

Expected volatility was estimated based on the annualized standard deviation of daily stock price return of comparable companies for periods from respective valuation dates and with similar span as time to exit.

Risk-free interest rates were estimated based on the yield of U.S. Treasury strips as of each valuation date.

*Sensitivity to changes in fair value*

The Company performed sensitivity test to changes in unobservable inputs in determining the fair value of preferred shares issued by the Company. The changes in unobservable inputs risk-free interest rate and expected volatility will result in a higher or lower fair value measurement. The increase in the fair value of financial instruments with preferred rights would increase the fair value loss in the consolidated statements of loss. When performing the sensitivity test, management applied an increase or decrease to each unobservable input, which represents management's assessment of reasonably possible change to these unobservable inputs, and effect of those changes to the fair value of financial instruments with preferred rights is as set forth below:

If the volatility had increased/decreased 5%, the loss before income tax for the year ended December 31, 2019 would have been approximately RMB4,342,000 lower/RMB3,970,000 higher.

If the Risk-Free interest rate had increased/decreased 1%, the loss before income tax for the year ended December 31, 2019 would have been approximately RMB2,187,000 lower/RMB2,194,000 higher.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**25. Cash flow information**

**(a) Cash used in operations**

	NOTES	YEAR ENDED DECEMBER 31,	
		2018	2019
		RMB'000	RMB'000
Loss before income tax		(93,877)	(168,625)
Adjustments for:			
—Finance cost	9	9,905	53
—Investment income from wealth management products	8	(547)	(798)
—Depreciation of property, plant and equipment	13	359	383
—Depreciation of rights-of-use assets		272	407
—Share-based compensation expenses	22	584	3,875
—Net exchange differences		(2,666)	(1,368)
—Fair value changes of financial instruments with preferred rights	24	23,012	59,397
Changes in working capital			
—Other receivables and prepayments		(7,011)	(3,026)
—Other non-current assets		(2,875)	(1,603)
—Other payables and accruals		1,290	1,698
—Trade payables		2,522	19,351
<b>Net cash used in operations</b>		<b>(69,032)</b>	<b>(90,256)</b>

**(b) Non-cash financing activities**

	YEAR ENDED DECEMBER 31,	
	2018	2019
	RMB'000	RMB'000
Fair value changes of financial instruments with preferred rights	23,012	59,397

**(c) Reconciliation of liabilities arising from financing activities**

	FINANCIAL INSTRUMENTS WITH PREFERRED RIGHTS	LEASE LIABILITY
	RMB'000	RMB'000
<b>At January 1, 2018</b>	<b>175,693</b>	<b>—</b>
Cash flows	379,148	(334)
New leases	—	1,562
Interest expenses	—	46
Differences of foreign currency translation	(4,354)	—
Changes in fair value	23,012	—
<b>At December 31, 2018</b>	<b>573,499</b>	<b>1,274</b>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**25. Cash flow information (Continued)**

**(c) Reconciliation of liabilities arising from financing activities (Continued)**

	FINANCIAL INSTRUMENTS WITH PREFERRED RIGHTS RMB'000	LEASE LIABILITY RMB'000
<b>At January 1, 2019</b>	<b>573,499</b>	<b>1,274</b>
Cash flows	—	(445)
Interest expenses	—	53
Differences of foreign currency translation	10,112	—
Changes in fair value	59,397	—
<b>At December 31, 2019</b>	<b>643,008</b>	<b>882</b>

**26. Related party transactions**

Parties are considered to be related if one party has the ability, directly or indirectly, to control or exercise significant influence over the other party. Parties are also considered to be related if they are subject to common control. Members of key management of the Group and their close family members are also considered as related parties.

NAMES OF RELATED PARTIES	NATURE OF RELATIONSHIP
Hangzhou Simo Company Limited	Entity controlled by a director of the Company
Frontage Laboratories (Suzhou) Company Limited	Entity controlled by a director of the Company
Shanghai Tigermed Consulting Company Limited	Entity controlled by a director of the Company
Hangzhou Tigermed Consulting Company Limited	Entity controlled by a director of the Company
Beijing Medical Development (Suzhou) Company Limited	Entity controlled by a director of the Company

In addition to other related party transactions and balances disclosed elsewhere in this financial information, the following is a summary of significant transactions and balances with related parties during the years ended December 31, 2018 and 2019 and at each year-end.

**(a) Interests in subsidiaries of the Company are set out in Note 1.2.**

**(b) Significant transactions with related parties**

	YEAR ENDED DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
<b>Purchase of CRO Services</b>		
Hangzhou Simo Company Limited	—	5,601
Frontage Laboratories (Suzhou) Company Limited (Note)	—	2,346
Shanghai Tigermed Consulting Company Limited	1,155	891
Hangzhou Tigermed Consulting Company Limited	158	810
Beijing Medical Development (Suzhou) Company Limited	—	186

Note: Frontage Laboratories (Suzhou) Company Limited became a related party of the Group on October 25, 2019.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**26. Related party transactions (Continued)****(c) Balances with related parties**

	AS OF DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
<b>(i) Prepayments</b>		
Hangzhou Tigermed Consulting Company Limited	—	640
Hangzhou Simo Company Limited	3,486	—
Shanghai Tigermed Consulting Company Limited	182	—
<b>(ii) Trade Payables</b>		
Hangzhou Simo Company Limited	—	8
Beijing Medical Development (Suzhou) Company Limited	—	31

All the above balances with related parties were unsecured, interest-free and had no fixed repayment terms.

**(d) Key management personnel compensation**

	YEAR ENDED DECEMBER 31,	
	2018 RMB'000	2019 RMB'000
Wages, salaries and bonuses	2,530	3,358
Contributions to defined benefit plan	898	1,140
Share-based compensation expenses	584	2,749
Welfare, housing funds and other	207	216
	<u>4,219</u>	<u>7,463</u>

The defined benefit plan was established in 2018 for one founder and subsequently terminated in 2020. The aggregate value of the benefits under this plan was fully funded and rolled over into an individual retirement account for the benefit of the founder following termination. The Company will have no further obligations with respect to such plan and is no longer subject to actuarial risk and investment risk. The benefit obligation was determined using certain assumptions, including life annuity factor and specified interest rate, which were published by the U.S. Internal Revenue Service.

**27. Events After the Reporting Period**

In addition to those disclosed elsewhere in these financial statements, the following events occurring after the reporting periods are noted.

**Financing Activities**

Through December 1, 2020, the Group issued 21,349,537 shares of Series C preferred shares to investors for a cash consideration of USD135 million which has been received.

The key terms and conditions of the Series C preferred shares are similar to the Series B preferred shares, as such, the Company has designated the entire new issued instrument with preferred rights as financial liabilities at fair value through profit or loss.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**27. Events After the Reporting Period (Continued)**

***Share-based compensation***

In April 2020, the Company issued 491,596 ordinary shares to the Co-Founders and 798,330 ordinary shares to Connect Union for no consideration, respectively, as a result of the achievement of certain non-market performance condition under the 2018 Incentive Plan as set out in Note 22.

Pursuant to the shareholders agreement entered into in connection with the Company's Series C financing, upon the issuance of the remaining ordinary shares under the 2018 Incentive Plan (i.e. 342,144 ordinary shares to be issued to Connect Union and 210,682 ordinary shares to be issued to the Co-Founders), the Company shall issue additional Series C preferred shares at par value to each of the Series C shareholders so that the shareholdings of the Series C preferred shares obtained by such Series C shareholder will not be diluted.

On December 14, 2020, upon the Board's approval, 1,977,488 options were granted to certain employees and directors.

***COVID 19***

The COVID-19 situation is very fluid across the world where each country or the sites within a country could be impacted differently. The Group is in the process of assessing the situation case by case as the pandemic evolves. In China, clinical studies slowed down due to clinical sites priority shifting to COVID-19 related work and local policy of quarantine after Chinese New Year. The situation has been improving gradually and the majority of the Group's clinical studies work has resumed since March 2020. Patient treatment has continued unabated, however the Group is experiencing lower enrollment rates in certain clinical trials, resulting in the delay of CRO work. Enrollment of the Company's Phase 2 clinical trial of CBP-307 in patients with Crohn's disease in China was prematurely terminated due to challenges in recruitment caused by the ongoing COVID-19 pandemic. Further, conducting clinical trials in foreign countries, which the Company is doing for its product candidates, presents additional risks that may delay completion of initially planned clinical trials.

The Group will continue to monitor and assess the impact of the ongoing development of the pandemic on the financial position and operating results of the Group and respond accordingly.

**28. Restricted net assets and parent company only condensed financial information**

The Company's ability to pay dividends is primarily dependent on the Company receiving distributions of funds from its subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Company's subsidiaries in the PRC only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations.

In accordance with the PRC laws and regulations, statutory reserve funds shall be made and can only be used for specific purposes and are not distributable as cash dividends. As a result of these PRC laws and regulations that require annual appropriation of 10% of net after-tax profits to be set aside prior to payment of dividends as statutory surplus fund, unless such reserve fund reaches 50% of the entity's registered capital, the Group's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

The Company performs a test on the restricted net assets of its consolidated subsidiaries (the "Restricted Net Assets") in accordance with Securities and Exchange Commission Regulation S-X Section 4-08 (e) (3) "General Notes to Financial Statements" and concluded that the condensed financial information for the parent company is required to be presented as of and for the years ended December 31, 2019 and 2018.

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**28. Restricted net assets and parent company only condensed financial information (Continued)**

**(a) Condensed Balance Sheets**

	AS OF DECEMBER 31,		
	2018 RMB'000	2019 RMB'000	2019 USD'000 Note 2.5(d)
<b>ASSETS</b>			
<b>Non-current assets</b>			
Interest in a subsidiary	128,354	293,443	42,064
<b>Total non-current assets</b>	<b>128,354</b>	<b>293,443</b>	<b>42,064</b>
<b>Current assets</b>			
Cash and cash equivalents	267,665	213,253	30,569
Other receivables	186,952	90,107	12,916
<b>Total current assets</b>	<b>454,617</b>	<b>303,360</b>	<b>43,485</b>
<b>Total assets</b>	<b>582,971</b>	<b>596,803</b>	<b>85,549</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Financial instruments with preferred rights	573,499	643,008	92,171
<b>Total non-current liabilities</b>	<b>573,499</b>	<b>643,008</b>	<b>92,171</b>
<b>Total liabilities</b>	<b>573,499</b>	<b>643,008</b>	<b>92,171</b>
<b>Net liabilities</b>	<b>9,472</b>	<b>(46,205)</b>	<b>(6,622)</b>
<b>SHAREHOLDERS' DEFICIT</b>			
Share capital	21	21	3
Share premium	38,074	38,123	5,465
Treasury shares	(1)	(1)	—
Other reserves	(28,423)	(25,063)	(3,592)
Accumulated losses	(199)	(59,285)	(8,498)
<b>Total shareholders' deficit</b>	<b>9,472</b>	<b>(46,205)</b>	<b>(6,622)</b>

**(b) Condensed statements of loss**

	YEAR ENDED DECEMBER 31,		
	2018 RMB'000	2019 RMB'000	2019 USD'000 Note 2.5(d)
Administrative expenses	—	(23)	(4)
<b>Operating loss</b>	<b>—</b>	<b>(23)</b>	<b>(4)</b>
Finance income—net	—	335	48
Fair value loss of financial instruments with preferred rights	(199)	(59,397)	(8,514)
<b>Loss before income tax</b>	<b>(199)</b>	<b>(59,085)</b>	<b>(8,470)</b>
Income tax expense	—	—	—
<b>Loss for the year</b>	<b>(199)</b>	<b>(59,085)</b>	<b>(8,470)</b>

**CONNECT BIOPHARMA HOLDINGS LIMITED**  
**Notes to the Consolidated Financial Statements**

**28. Restricted net assets and parent company only condensed financial information (Continued)**

*(c) Condensed statements of cash flows*

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	YEAR ENDED DECEMBER 31,		
	2018	2019	2019
	RMB'000	RMB'000	USD'000 Note 2.5(d)
<b>Net cash generated from operating activities</b>	—	249	36
<b>Net cash used in investing activities</b>	(109,811)	(159,057)	(22,800)
<b>Net cash generated from financing activities</b>	377,476	99,990	14,333
<b>Net increase in cash and cash equivalents</b>	267,665	(58,818)	(8,431)
Cash and cash equivalents at the beginning of year	—	267,665	38,368
Effects of exchange rate changes on cash and cash equivalents	—	4,406	632
<b>Cash and cash equivalents at end of year</b>	<b>267,665</b>	<b>213,253</b>	<b>30,569</b>

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## American Depositary Shares



Representing

Ordinary Shares

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PRELIMINARY PROSPECTUS

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Jefferies

SVB Leerink

Piper Sandler

CICC

, 2021

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## PART II—INFORMATION NOT REQUIRED IN THE PROSPECTUS

### Item 6. Indemnification of directors and officers

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The post-offering amended and restated articles of association that we expect to adopt to become effective immediately prior to the completion of this offering provide that we shall indemnify our directors and officers (each an indemnified person) against all actions, costs, charges, expenses, losses, and damages incurred or sustained by such indemnified person, other than by reason of such person's own 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 as a director or officer of our company, which is to include without prejudice to the generality of the foregoing, any costs, expenses, losses or damages incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

Pursuant to the indemnification agreements, the form of which is filed as Exhibit 10.2 to this registration statement, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer.

The underwriting agreement, the form of which is filed as Exhibit 1.1 to this registration statement, will also provide for indemnification of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, but only to the extent that such liabilities are caused by information furnished to us in writing by the underwriters expressly for use in this registration statement and certain other disclosure documents.

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

### Item 7. Recent sales of unregistered securities

#### *Issuance of Capital Stock*

The following sets forth information regarding all unregistered securities sold since January 1, 2018.

- On December 20, 2018, we issued 3,109,000 Series Pre-A Preferred Shares to certain preferred shareholders of Suzhou Connect Biopharma Co., Ltd., or Connect SZ, as consideration in exchange for the same equity interests they held in Connect SZ.
- On December 20, 2018, we issued 8,471,200 Series A Preferred Shares to certain preferred shareholders of Suzhou Connect Biopharma Co., Ltd., or Connect SZ, as consideration in exchange for the same equity interests they held in Connect SZ.
- On December 20, 2018, we issued and sold to investors in private placements an aggregate of 10,127,579 Series B Preferred Shares at a subscription price of \$5.4307 per share, for aggregate consideration of approximately \$55 million.
- On April 14, 2020, we issued 245,798 ordinary shares to each of BioFortune Inc. and Zheng Wei, Ph.D.
- On August 21, 2020, we issued and sold to investors in private placements an aggregate of 16,605,196 Series C Preferred Shares at a subscription price of \$6.3233 per share, for aggregate consideration of approximately \$105 million.
- On December 1, 2020, we issued and sold to investors in private placements an aggregate of 4,744,341 Series C Preferred Shares at a subscription price of \$6.3233 per share, for aggregate consideration of approximately \$30 million.

## Table of Contents

- From December 2018 through December 2020, we issued 4,473,305 ordinary shares to Connect Union as nominee for purposes of the implementation of awards issue or to be issue to employees, directors and consultants of our company pursuant to the 2019 Plan.
- From December 2018 through December 2020, pursuant to the 2019 Plan, we granted share options to purchase an aggregate of 2,812,342 ordinary shares at a weighted-average exercise price of \$3.46 to certain of our employees, directors and consultants in connection with services provided to us by such persons. Of those, 12,705 have been exercised.

### **Item 8. Exhibits and financial statements**

- (a) **Exhibits.** The exhibits to this registration statement are listed in the Exhibit Index to this registration statement and incorporated herein by reference.
- (b) **Financial Statement Schedules.** Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in our combined financial statements or the notes thereto.

### **Item 9. Undertakings**

- (a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
  - (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**EXHIBIT INDEX**

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<b>EXHIBIT NUMBER</b>	<b>EXHIBIT DESCRIPTION</b>
1.1*	Form of Underwriting Agreement
3.1**	Fourth Amended and Restated Memorandum and Articles of Association, as currently in effect
3.2*	Form of Amended and Restated Memorandum and Articles of Association, effective immediately prior to the completion of this offering
4.1*	Specimen Certificate for Ordinary Shares
4.2*	Form of Deposit Agreement, among the Registrant, the depository, and the holders and beneficial owners of American Depositary Shares issued thereunder
4.3*	Specimen American Depositary Receipt
4.4**	Second Amended and Restated Shareholders Agreement, dated as of December 1, 2020, between the Registrant, its subsidiaries and certain of its shareholders
5.1*	Opinion of Maples and Calder (Hong Kong) LLP regarding the validity of the ordinary shares being registered and certain Cayman Islands tax matters
8.1*	Opinion of Maples and Calder (Hong Kong) LLP regarding certain Cayman Islands tax matters (included in Exhibit 5.1)
8.2*	Opinion of Han Kun Law Offices regarding certain PRC tax matters (included in Exhibit 99.2)
10.1#**	Connect Biopharma Holdings Limited 2019 Stock Incentive Plan
10.2*#	Form of Indemnification Agreement, between the Registrant and its directors and executive officers
10.3*#	Form of Employment Agreement, between the Registrant and its executive officers
10.4*#	Form of 2021 Incentive Award Plan
10.5*#	Form of 2021 Employee Share Purchase Plan
10.5†**	Exclusive License Agreement, dated June 19, 2012, between Arena Pharmaceuticals, Inc. and Connect Biopharm LLC
10.6†**	Amendment #1 to Exclusive License Agreement, dated October 15, 2015, between Arena Pharmaceuticals, Inc. and Connect Biopharm LLC
10.7†**	Amendment #2 to Exclusive License Agreement, dated as of February 23, 2018, between Arena Pharmaceuticals, Inc. and Connect Biopharm LLC
10.8†**	Amendment #3 to Exclusive License Agreement, dated as of November 19, 2020, between Arena Pharmaceuticals, Inc. and Connect Biopharm LLC
10.9**	English translation of House Lease Contract, dated February 1, 2019, between Suzhou Connect Biopharma Co., Ltd. and Taicang Science and Technology Venture Park Co., Ltd.
10.10**	English translation of House Lease Contract, dated August 1, 2020, between Suzhou Connect Biopharma Co., Ltd. and Taicang Science and Technology Venture Park Co., Ltd.
10.11*#	English translation of Labor Contract, dated as of January 15, 2015, between the Registrant and Zheng Wei, Ph.D.
10.12*#	English translation of Labor Contract, dated as of January 15, 2015, between the Registrant and Wubin (Bill) Pan, Ph.D.
10.13*#	English translation of the Labor Contract, dated as of January 2, 2020, between the Registrant and Lei Sun, Ph.D.
10.14*#	English translation of the Labor Contract, dated as of October 9, 2020, between the Registrant and Lan Xie
10.15*#	Employment Letter Agreement, dated January 19, 2021, by and between Connect Biopharm LLC and Selwyn Ho, MB BS
21.1*	List of Subsidiaries
23.1*	Consent of PricewaterhouseCoopers Zhong Tian LLP
23.2*	Consent of Maples and Calder (Hong Kong) LLP (included in Exhibit 5.1)
23.3*	Consent of Han Kun Law Offices (included in Exhibit 99.2)
24.1*	Powers of Attorney (included on signature page to the registration statement)
99.1*	Code of Business Conduct and Ethics of the Registrant
99.2*	Opinion of Han Kun Law Offices regarding certain PRC law matters

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\* To be filed by amendment.

\*\* Previously submitted.

† Portions of this exhibit (indicated by asterisks) have been omitted because the registrant has determined they are not material and would likely cause competitive harm to the registrant if publicly disclosed.

# Indicates senior management contract or compensatory plan.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Taicang, China on \_\_\_\_\_, 2021.

CONNECT BIOPHARMA HOLDINGS LIMITED

By: \_\_\_\_\_  
Name: Zheng Wei, Ph.D.  
Title: Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Zheng Wei, Ph.D. and Eric Hall and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on \_\_\_\_\_, 2021 in the capacities indicated:

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<u>NAME</u>	<u>TITLE</u>
_____ Zheng Wei, Ph.D.	Chief Executive Officer and Member of the Board (Principal Executive Officer)
_____ Eric Hall	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
_____ Wubin (Bill) Pan, Ph.D.	President and Chairman of the Board
_____ Derek DiRocco, Ph.D.	Member of the Board
_____ Kan Chen, Ph.D.	Member of the Board
_____ Jinghua (Jennifer) Jin	Member of the Board
_____ Karen J. Wilson	Member of the Board
_____ Kleanthis G. Xanthopoulos, Ph.D.	Member of the Board

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**SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT**

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Connect Biopharma Holdings Limited has signed this registration statement on \_\_\_\_\_, 2021.

By: \_\_\_\_\_  
Name:  
Title: